XpanDH

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

D5.3 – X-bundle open-source community of the doers

WP5 – Growing Digital Health ecosystems

31.12.2024

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What did this document aim to achieve?	[In NO MORE than 5-7 lines]
Present the main methodological approaches in bullet point format	The scope of this task is to bring together implementers and end-users of new and existing solutions: IT developers and vendors/suppliers on one hand; patients and healthcare professionals on the other, under the concept of the 3C-3P community (Co-creation Community of Patients, Professionals and Programmers).
What were the main findings or take-away messages? What implications does it have for the XpanDH project?	See section 6 about the recommendations and results
Which project stakeholder group would benefit the most from the document and why?	

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List any relevant organizations or social media accounts for wider visibility	https://xpandh-project.iscte-iul.pt/shape-the-future-of-healthcare-join-xpandhs-community-of-doers-and-co-creators/

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List of abbreviations

Acronym	Description
3C-3P	Co-creation Community of Patients, Professionals and Programmers
COD	Community of Doers
EEHRxF	European Electronic Health Record Exchange Format
EHDS	European Health Data Space
WG	Working group

Executive summary

This deliverable provides a comprehensive overview of the philosophy, structure, and key outcomes of the X-Bundle open-source community initiative, known as the 3C-3P Community (Co-Creation Community of Patients, Professionals, and Programmers), as developed within the XpanDH project. The deliverable explores how this collaborative framework was designed and operationalised to support the adoption of the European Electronic Health Record Exchange Format (EEHRxF) and advance the European Health Data Space (EHDS).

The document begins by introducing the background, scope, and objectives of the X-Bundle initiative, which aims to engage diverse stakeholders—IT developers, healthcare professionals, and patients—in a transparent and sustainable co-creation environment. The community's structure is defined in terms of its core objectives, governance, and operational methodologies, which draw on successful models such as openNCP and openHIE.

The rationale and methodological approach outline the guiding principles and strategies for community formation, focusing on inclusivity, collaboration, and the reuse of assets developed in previous work packages. Particular emphasis is placed on the establishment of a Plenary Community of Doers and several specialised working groups.

Four working groups were established during the course of the project:

1. Multidisciplinary tumour boards for cancer patients (3C-3P-MDT)
2. Electronic prescription, electronic dispensation and electronic product information (3C-3P-EPD)
3. Multi-Country working group on imaging – CoD (3C-3P-MIM)
4. Telehealth— Teleconsultation Encounter Report (3C-3P-TER)

These groups facilitated targeted discussions and workshops, including a highly attended on-site meeting of the 3C-3P-MDT group during the 1st Greek Forum on Cancer: Policy, Research & Funding Strategies on July 2nd, 2024, and a notable series of 3 intense plenary sessions from the 3C-3P-EPD group held in the last trimester of 2024. Such workshops served as platforms for knowledge-sharing, co-creation, and refining tools to support EEHRxF adoption.

Key lessons learned and recommendations highlight the challenges and enablers encountered during the process, providing actionable insights for sustaining and scaling the community. Finally, the deliverable outlines the continuation and next steps, ensuring the momentum of the X-Bundle initiative is maintained and its contributions to the EHDS are expanded.

This deliverable not only captures the foundational efforts behind the 3C-3P Community but also serves as a roadmap for fostering collaborative innovation and sustainable governance in digital health interoperability initiatives.

Following the plenary Community of Doers workshop during the European Digital Health Interoperability Days held at Iscte in Lisbon, Portugal in December 2024, a set of other possible WGs have been identified, and while the synergies between this bottom-up participated and co-created manner and the top-down "format Implementing Acts" approach will be difficult at times, it seems essential to ROOT the format in concrete value-adding processes of care.

1 Introduction

1.1 Background

The scope of this deliverable is to document the methodology, governance, and operational strategies employed by XpanDH to establish and support the 3C-3P Community of Doers. It captures the collaborative efforts undertaken to co-create tools, refine workflows, and align practices with the requirements of the EEHRxF and EHDS. The deliverable also synthesises key lessons learned and provides actionable recommendations for fostering a sustainable and scalable community of stakeholders.

The objectives of Deliverable 5.3 include:

1. Describing the foundational principles and governance structure of the X-Bundle open-source community.
2. Highlighting the participatory methods and stakeholder engagement strategies employed in the co-creation of digital health tools and services.
3. Reporting on the key outcomes and insights from working groups and community activities, such as workshops and plenary sessions.
4. Proposing recommendations for the continuation and scalability of the X-Bundle community, ensuring its alignment with the evolving digital health landscape in Europe.

By addressing these objectives, this deliverable aims to provide a comprehensive resource for stakeholders interested in fostering co-creation and interoperability within the European health data ecosystem.

1.2 Scope and objectives

Deliverable 5.3 focuses on describing the philosophy and structure of the approach taken to establish the X-Bundle open-source community, known as the 3C-3P Community, within the XpanDH project. It provides an account of the collaborative framework designed to engage IT developers, healthcare professionals, and patients in co-creating tools aligned with the EEHRxF and the EHDS. This deliverable reports on the governance model, community dynamics, operational processes and results of the Community of Doers and its working groups.

Additionally, it captures key insights and outcomes from the various working groups formed as part of the initiative, showcasing their contributions to the co-creation process. By documenting these activities, along with annexed materials from working

groups, Deliverable 5.3 offers a detailed account of the approach, structure, and lessons learned in fostering a vibrant and sustainable X-Bundle community.

2 Definition of the Community of Doers

As an aspect of its collaborative approach, XpanDH operates through the Community of Doers, which comprises the Co-Creation Community of Patients, Professionals, and Programmers (or other Internet Service Providers and developers), acronym 3C-3P. This community seeks to bridge the long-standing divide between these three categories of digital health players, which has posed serious challenges to the development of useful tools and services for patients and providers alike. The CoD fosters a participatory, bottom-up approach to the co-creation of digital health tools and services, ensuring that the needs and values of end users are central to the development process.

3 Rationale and methodological approach

XpanDH's proposal is that key stakeholders should have full access to health data and be called to co-create the AEIOU (Accessible, Engaging, Interoperable, Operational and Useful) digital health tools of the future. This participatory design approach has two main implications: 1) all key stakeholders are actively involved in the co-creation of the EEHRxF ecosystem in all project phases; and 2) the consortium ensures the necessary flexibility and openness to manage potential changes and needs that arise from the co-creation process, to ensure real acceptance (Bowen et al., 2013; Boyd et al., 2012; Thabrew et al., 2018).

Co-creation, initially introduced for marketing purposes in the collaborative design of products and services, has since evolved into a fundamental methodology across various fields. Several researchers have developed methodological approaches and models to support co-creation processes (De Koning et al., 2016). It is inherently collaborative, engaging multiple stakeholders in the design and delivery of products or services, and enhancing value within ecosystems (Eckhardt et al., 2021). Beyond its applications in science, co-creation has been embraced across sectors to promote community engagement and innovation. In platform ecosystems, co-creation has been shown to drive increased sales and improved business performance for smaller vendors, underscoring the economic advantages of such collaborative partnerships (Ceccagnoli et al., 2012). This methodology is particularly effective in complex environments such as healthcare, where it fosters innovation and responsiveness to user needs (Indurti et al., 2023). Moreover, co-creation

contributes to EU competitiveness in healthcare delivery and the deployment of digital tools, strengthening its position relative to competing regions.

The process of co-creation is underpinned by active stakeholder engagement, which integrates behavioural, cognitive, and emotional dimensions. Such engagement fosters cooperation and collaboration, ultimately enabling co-creation, which is indispensable for ecosystem activation (Viglia et al., 2023). Within healthcare, involving diverse stakeholders—patients, providers, and policymakers—ensures that services are tailored to actual needs, thereby enhancing overall effectiveness (Adlakha et al., 2020). While co-creation offers substantial benefits, challenges such as balancing diverse stakeholder interests and ensuring effective communication must be addressed. Successfully managing these dynamics is critical for achieving sustainable ecosystem activation. The XpanDH method, through its democratic participatory strategy, exemplifies how co-creation can support the growth of the EEHRxF and the broader pan-European digital health ecosystem.

XpanDH has prioritised the creation, maintenance, and stimulation of a pan-European digital health ecosystem centred on the EEHRxF. By fostering co-creation and collaboration through the Community of Doers (CoD) in Work Package (WP) 5, led by empirica, and Task 5.3, led by Gnomon, XpanDH has employed a participatory, multi-stakeholder approach to address the diverse needs of healthcare systems across Europe. This strategy ensures that relevant actors—from policymakers and healthcare professionals to patients and developers—contribute to the adoption and refinement of the EEHRxF, a priority highlighted by speakers at events such as the 2nd EEHRxF Expert Summit in Brussels on 13 November 2024. The active engagement of these stakeholders is critical to establish a scalable and sustainable ecosystem that can evolve to meet the ongoing challenges and opportunities in digital health.

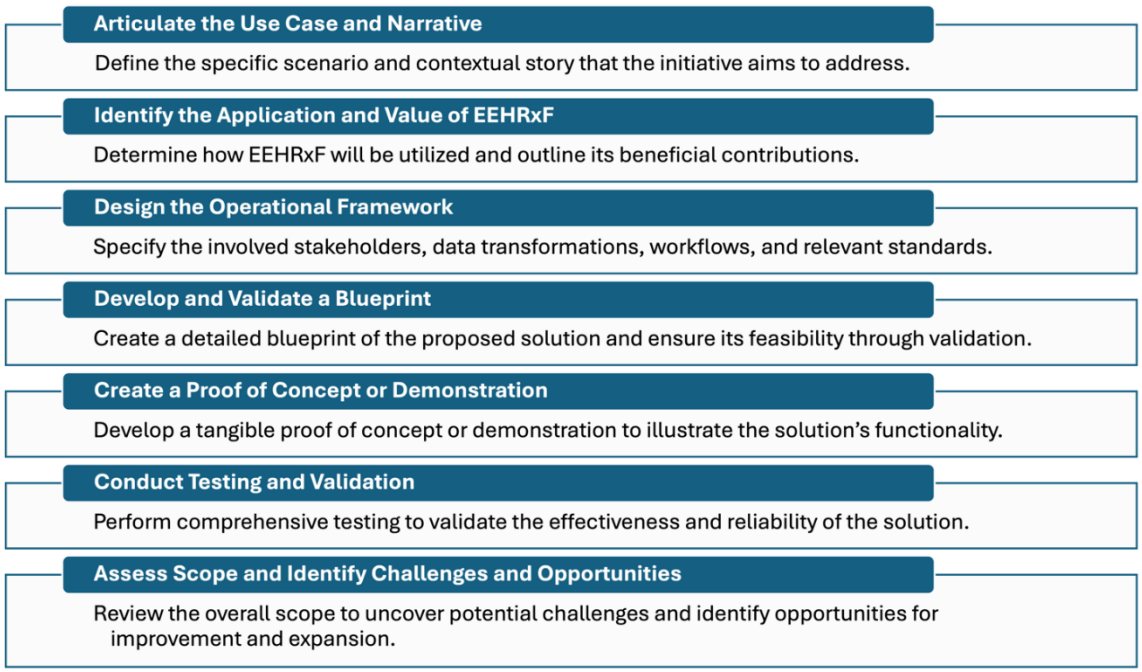


Figure 1 Community of Doers methodology (authors' own elaboration)

In the context of XpanDH, the CoD focuses on bottom-up research and definition of new or revisited use cases with the active participation of end users, looking at new concepts and innovative use of the EEHRxF. The approach is to define real life needs where the adoption of the EEHRxF would provide added value to all stakeholders, with the notion of jointly developing an end-to-end service that adheres to the principles of the recently adopted European Health Data Space law "by design."

Co-creation brings together those that need a service, solution or a process with those that can realise it. In our case, we start by bringing together patients' associations, healthcare providers and implementers (vendors, academia) to investigate future use of the EEHRxF in business use cases that reflect real needs. The result is that co-created solutions have a better chance of being adopted and operated by the end users. During the process we also Iterated with other XpanDH stakeholders to provide feedback on the X-Bundles, expand X-Bubbles, test EEHRxF specifications, build proof of concepts, and review the proposed readiness model. During the CoD working group meetings we managed to define risks, issues, problems but also opportunities, needs, and foresee the future, trying to mature new ideas and investigating new domains.

The methodological approach used is a 7-step process into the issues and challenges of progressing a new use case as depicted in Figure 1.

The CoD is organised into a plenary group and Working Groups (WGs) that seek to form teams of eHealth actors, each with a single main objective: investigating and delivering concrete recommendations for formalising an evolution of the current

services in the context of EHDS into new adoption domains or new approaches to the specification of existing data categories.

4 Plenary Community of Doers

The Plenary Community of Doers was formally established during the **XpanDH Workshop on the Community of Doers** held on 18 January 2024 in Athens, Greece, during the Athens Digital Health Week, with 18 participants. This foundational event united implementers and end-users, such as IT developers, vendors, and suppliers, alongside patients and healthcare professionals. Organised under the 3C-3P concept (Co-creation Community of Patients, Professionals, and Programmers), the workshop aimed to foster a collaborative environment for integrating the EEHRxF into healthcare solutions.

The workshop provided an interactive forum for diverse stakeholders, including decision-makers, experts, healthcare providers, academia, the IT and pharmaceutical industries, healthcare payer associations, and patient and professional organisations, to share ideas and insights. The primary focus was on aligning business needs with the EEHRxF through specific use cases, aiming to energise a community of active contributors. It also set the groundwork for ongoing collaboration, with plans to refine these use cases at the XpanDH format@thon in Trieste in June 2024 and showcase the outcomes at the XpanDH last events in Lisbon in December 2024.

Figure 1 Photos of the first gathering of the Community of Doers in Athens

Following this, a **webinar on 22 April 2024** brought together 48 participants online to further expand the Community of Doers and Co-Creators. Moderated by experts including Alexander Berler (Gnomon) and Sofia Franconi (IHE Europe), the session explored key challenges in healthcare interoperability, such as inconsistencies in discharge letters, delays in report preparation, and the complexities of digital exchange, particularly regarding DICOM medical images. The webinar highlighted the importance of standardisation, technology integration, and education in improving healthcare processes and patient outcomes.

Four compelling use cases were presented to illustrate practical challenges and innovations: "Medical Imaging – the French Case" by Sofia Franconi (IHE-Europe), "Tumour Boards in Cancer" by Thanos Kosmidis (CareAcross), "Working with Discharge Letters" by Konstantinos Chalkias (KETEKNY), and "MedimHub" by Ghazaleh Yazdi (Minnovaa). These examples underscored the collective potential of the Community of Doers to drive impactful, co-created solutions for advancing healthcare interoperability and patient care.

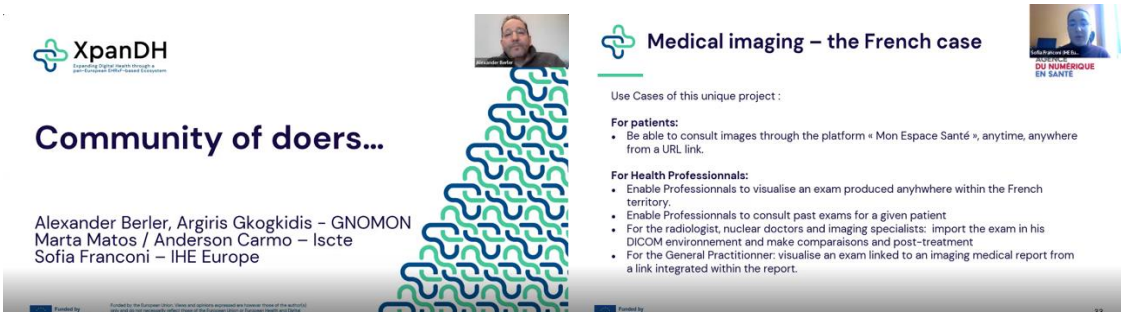


Figure 2 Screenshots from the first online webinar of the Community of Doers.

Following these first in-person and online events, the plenary Community of Doers was prompted to rejoin when needed to review and contribute to the Working Groups' ongoing work and respective focuses. With time, the plenary community has grown to include over 100 individuals who can be reached out to by the different working groups for consultation.

5 Working groups

Specifically, there are four working groups, focused respectively on the following use cases:

(a) Multidisciplinary tumour boards for cancer patients (facilitated by Gnomon).
(b) Electronic prescription, electronic dispensation and electronic product information (facilitated by UiO).
(c) Multi-Country working group on Imaging – CoD (facilitated by IHE-Europe)
(d) Telehealth—Teleconsultation Encounter Report (facilitated by Iscte)

A short description on each working group describing their ideation, functioning and aims can be found in Table 1.

Table 1 Community of Doers Working Groups with short description[1]

Acronym	Title	Short Description

[1] Source: Lewerenz S, Berler A, Martins H, et al. (2024) Building the European Digital Health Ecosystem for the Format and the EHDS. Healthmanagement.org The Journal. 24(5):377-386. Available at healthmanagement.org

3C-3P-MDT	Multidisciplinary Tumour Boards for Cancer Patient	The working group was initiated as a real-life need in Greece as a support working group in the process of adopting the EEHRxF in the workflow of the tumour board operations. The working group is sponsored by ELLOK the Greek cancer patient association, the industry and IT services providers in oncology (Gnomon, Care Across), the Academia (Aristotle University of Thessaloniki, University of Thessaly), Providers associations and hospitals (EOPE, Agios Savvas Hospital) and the Greek Government (Ministry of Health, IDIKA, KETEKNY). The working group has already made several online and f2f meetings discussing workflows, legal requirements, patient consent, inputs and outputs, etc, with an active participation of more than 47 stakeholders for the 3Ps.
3C-3P- EPD	eP/eD and Patient Information	The working group was initiated during the Madeira Digital Transformation Week in Portugal with the participation of more than 30 delegates representing all stakeholders. The working group investigates innovative ways of patient mediated ePrescription, eDispensation and Personal information sharing based on the EEHRxF, taking inspiration of the innovative cross border services in Europe (MyHealth@EU) and large scale projects such as Unicom and Gravitate-Health.
3C-3P - MIV	Enabling Patient mediated access and view of medical imaging reports	This working group was identified as a need during the IHE Europe Connectathon event in Rennes in 2023. Medical imaging is currently being redesigned at the global scale by incorporating new standards and technologies providing new ways of managing images for primary use, for secondary use and with the active participation of the patients. This group is inspired by the work performed in France (Segur), by the recommendation provided by IHE Europe under the multi-country working group and the new developments adopted by the eHealth Network, X-eHealth and XpanDH.

5.1 Working group on Multidisciplinary tumour boards for cancer patients (3C-3P-MDT)

The XpanDH Community of Doers' working group on Multidisciplinary Tumour Boards for cancer patients was ideated during the inaugural Greek Cancer Forum, held on 1–2 July 2024 in Athens and hosted by the Hellenic Cancer Federation (ELLOK). This landmark event convened over 30 participants, including prominent stakeholders such as the Greek Minister of Health, Mr Adonis Georgiadis and the European Commissioner for Health and Food Safety, Mrs Stella Kyriakides. The forum

underscored the importance of prevention, early detection, vaccination access, and the provision of high-quality healthcare services in enhancing patient outcomes and saving lives. With leadership from WHO Europe's Regional Director Dr. Hans Kluge, discussions fostered collective strategies to enhance cancer care, paving the way for multidisciplinary collaboration. The forum's emphasis on innovative, patient-centred care, models inspired the XpanDH working group's commitment to advancing the role of digital tools and interdisciplinary cooperation in optimising tumour board practices for cancer management.

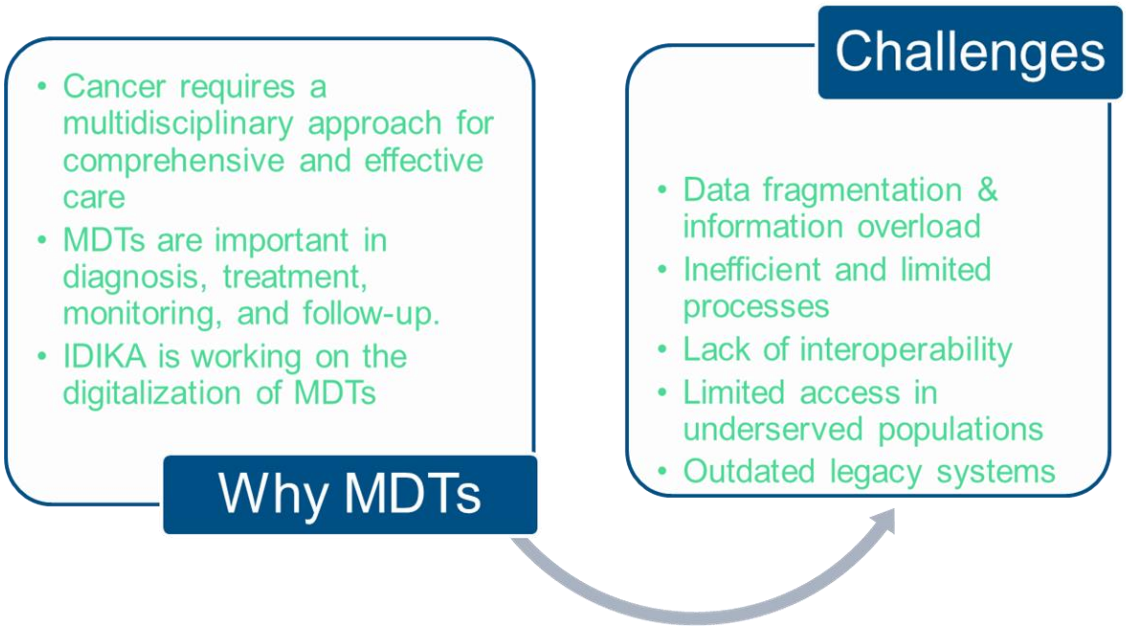
Figure 3 Photo of first meeting of working group on tumour boards at Greek Cancer Forum in Athens, Greece[2]

This first in-person gathering was used as a platform to launch the working group. Following this, the group convened for seven meetings, alternating between in-person and online formats. These sessions focused on co-creating solutions to enhance the operation of multidisciplinary tumour boards.

Key activities included reviewing interoperability gaps in patient data sharing, exploring the integration of digital tools to support decision-making, and addressing challenges in aligning multidisciplinary collaboration with EHDS regulations. Stakeholder engagement was central, involving oncologists, IT professionals, patient representatives, and policymakers to ensure a well-rounded approach.

[2] Source: LinkedIn of the Hellenic Cancer Federation - ELLOK

MDT was defined as a key use case for the adoption of the EEHRxF as depicted in the picture below



The outcomes of these discussions are consolidated in a comprehensive report (see Annex 2), which outlines actionable recommendations for improving tumour board processes through innovative digital solutions and multidisciplinary cooperation.

5.2 Working group on electronic prescription, electronic dispensation and electronic product information (3C-3P-EPD)

The ideation of the XpanDH Community of Doers' working group on electronic prescription (eP), electronic dispensation (eD), and electronic product information (ePI) emerged during a dedicated workshop held on 27 June 2024 at Madeira Digital Transformation Week in Funchal, Portugal. This event, moderated by experts including Henrique Martins (ISCTE), Alexander Berler (Gnomon), and Anne Moen (University of Oslo), engaged over 20 participants from academia, industry, and research communities. The discussions highlighted the integration of user perspectives to design interoperable solutions that align with the practical needs of patients and healthcare professionals, bridging the digital divide. Breakout sessions explored added value, service domain scope, and technical assets to enhance eP/eD/ePI services. Contributions from related projects like UNICOM and Gravitate-Health enriched the discourse, focusing on cross-border digital health innovation and value-adding patient-centric information systems.

Figure 4 Photos of the working group on eP/eD/ePI workshop 27 June at Madeira Digital Transformation Week in Funchal, Portugal

After this first on-site meeting, the working group created a core team of 7 individuals to meet weekly and focus on producing the report annexed in this deliverable (See Annex 3). Three online meetings with the plenary CoD were held to review and integrate broader contributions into the discussion and to directly inform the final report.

5.3 Multi-Country working group on imaging – CoD (3C-3P-MIM)

The Multi-Country Working Group on Imaging – CoD (hosted by IHE-Europe[3]) was conceived during the IHE Europe Connectathon event held in Rennes in September 2023. This group focuses on advancing imaging practices by integrating new standards and technologies for managing images in both primary and secondary use cases. The initiative builds on prior work carried out in France under the Segur programme and incorporates recommendations from IHE Europe's multi-country working group. With active patient involvement, this working group is also aligned

[3] See: https://www.ihe-europe.net/multi-country-working-group-Imaging-Information-Sharing

with the eHealth Network, X-eHealth, and XpanDH projects. It aims to harmonise imaging practices across borders, ensuring interoperability and innovation in the use and exchange of medical imaging data under the European Health Data Space framework.

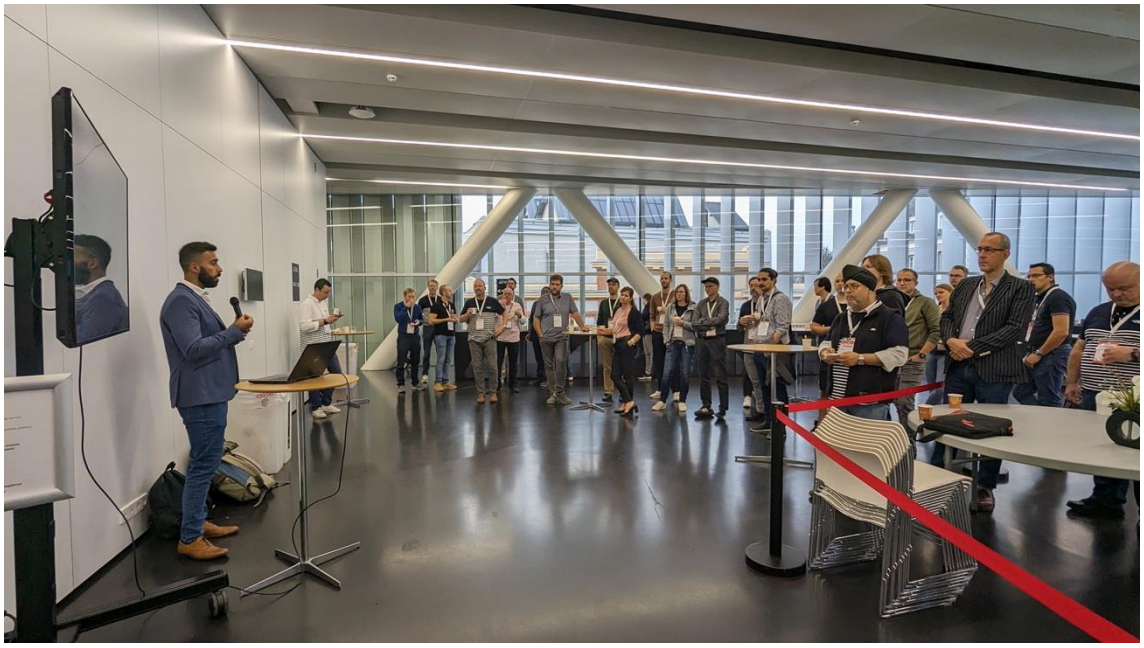


Figure 5 Photo of XpanDH at the IHE-Europe Connectathon in Rennes, France

The MCWG on Imaging brings together a diverse network of stakeholders, such as national eHealth agencies, ministries, competence centres, and representatives from XpanDH's other Communities of Doers. By aligning imaging practices and standards, the group fosters interoperability and leverages feedback from its participants to develop actionable recommendations. The initiative is supported by a co-creation framework, integrating patients, professionals, and programmers to ensure that end-user needs remain central. This working group plays a pivotal role in shaping European healthcare policies and standards, further reinforcing the EHDS goals. See Annex 4 for a full review of the recommendations of this working group.

5.4 Working group on Telehealth—Teleconsultation Encounter Report (3C-3P-TER)

The Telehealth—Teleconsultation Encounter Report working group was established through a series of online workshops and research activities carried out under WP6, particularly Task 6.2. Initially drawing heavily on the Nordic experience, especially Denmark, the group is now expanding its scope to incorporate insights from other pioneering countries like Portugal, an early developer of telehealth services.

The primary objective of the group is to design services that support teleconsultations within the framework of the EEHRxF. Its inspirations and focuses include advancing data collection methodologies from telemonitoring, particularly

ensuring the automatic storage of collected measurement data in national repositories. Furthermore, key technical challenges include exploring the use of AI to support data collection and the preparation of encounter reports, addressing access rights for sharing, viewing, and forwarding patient health data, and determining optimal methods for data storage—all while ensuring full alignment with the EEHRxF. See annex 5 for the full recommendations of this working group.

Figure 6 Photo of the 3C-3P-TER working group's presentation at the European Digital Health Interoperability Days @Iscte in Lisbon, Portugal

6 Lessons learned and Key Recommendations

Lessons learned from ideating, igniting and propelling the Community of Doers and its different working groups are shared, before dwelling into the key recommendations from each working group. The recommendations are more or less detailed depending on the groups' level of maturity.

The full recommendations can be found in the annexed reports from the respective working groups. They encompass legal, regulatory, policy, care process, information, applications and IT infrastructure layers of interoperability for each focus.

6.1 Lessons Learned

This process of involving experts and volunteers from the three main communities proved that bottom-up approach engaging the real end users can properly define specific use cases taking into account all the problems and challenges that end users face in real life. The introduction of the EEHRxF in their daily processes need to be beneficial for all namely.

1. For the programmers community (software engineers, information architects, etc) this process was enlightening as technical people had access to the end users they are building information systems.
2. For the provider's community, the process allowed them to freely describe their daily challenges, focus on the parts that could be improved and reduce their workload. They understood better why the use of structured documents such as those proposed by the EEHRxF could facilitate their work. In some cases, they had the opportunity to propose out of the box ideas and new clinical documents for new health information domains to be considered for the EEHRxF and the EHDS regulation in the future.
3. For the patient's community, a great part of their work focused on ensuring that patients can be included as an important stakeholder, ensuring digital literacy for patients as well as securing their rights and access to their data.

We summarize the lessons learned from our XpanDH Community of Doers, below:

The Power of Multistakeholder Engagement

The inclusion of diverse stakeholders—healthcare professionals, IT experts, legal authorities, governmental bodies, patient associations —proved essential for understanding the complexities of data exchange in specific use cases. Their varied perspectives enriched the discussions and highlighted the need for a collaborative approach in addressing shared challenges.

Furthermore, this process was proven beneficial for all stakeholders engaged as they had the possibility to clearly state their needs and challenges.

The 7-layer methodological approach proposed by XpanDH COD guided the stakeholders into diving step by step in the description of a use case where EEHRxF use could be beneficial. The process enabled open discussions and consensus building allowing all voices to be heard.

Patient-Centric Approaches Are Key

A recurring theme was the need to empower patients with greater involvement in health care processes. Ensuring that patients are well-informed about their condition and treatment options fosters trust and improves decision-making. The consent process also emerged as a critical area for enhancement, emphasizing transparency and simplicity. From the process and discussions during the WG meetings it was clear that not all stakeholders had the same view about important issues related to patient rights, such as access to data, right to object in the use of their data, data portability, secondary use of their data and many more.

During the meetings patients and providers managed to find the right way to define the processes and workflow so that healthcare professionals can do their work properly with no delay and impediments but taking into account the need to keep

their patients informed during their treatment. This involves understanding how to use medication documentation, be informed about critical challenges and decisions that need to be made during the therapeutic treatment. This was especially true during the discussions of for the Tumour Board processes.

Dealing with barriers and challenges together

For example, in the Multidisciplinary tumour board WG, while the focus was on cancer, several challenges—such as the need for better communication between doctors and patients, smoother workflows, and the adoption of digital technologies like remote monitoring—were identified as systemic issues across healthcare domains. Addressing these could yield broader benefits beyond the scope of cancer care.

Each working group focused on defining the challenges and barriers currently existing and tried to focus on how the EHDS regulation and the application of EEHRxF could remove barriers and facilitate the process of care. Discussing challenges and open issues at the level of the working groups enabled to simplify the discussions and find ways to propose possible solutions for the future. It was noted in many cases that most of the barriers were not technical, but mostly legal or procedural. EHDS regulation will potentially enable discussions in member states to alter the current legal framework and enhance the use of digital tools for both patient and healthcare providers.

Interoperability and Integration Are Non-Negotiable

Seamless information exchange between systems remains a cornerstone for achieving better outcomes. Technical barriers, such as system incompatibilities, and the lack of standardized formats for data sharing, need urgent resolution to support the goals of the upcoming European Health Data Space (EHDS). The use of EEHRxF compliant clinical document will enable to reduce this problem in most cases. It is important though to ensure the implementation of an interoperability framework governance in all EU member states to enable bottom-up discussions for each interoperability use case separately. Countries such as France and Greece have benefited of this process and enabled the possibility to co-create the design and technical specifications to solve specific interoperability use cases taking into account the opinion and expertise of all stakeholders. Interoperability Frameworks are a key element of success for the future adoption of the EEHRxF specifications at the MS level. The existing Refined eHealth Interoperability Framework is a good example at the European level.

Administrative and Workload Challenges for Healthcare Professionals

Bureaucratic hurdles and heavy workloads were identified as significant barriers for healthcare professionals. These issues not only hinder efficient care delivery but also affect the adoption of new digital solutions. Streamlined processes and targeted support could alleviate these challenges. The creation of WG reusing the approach of the 3C-3P methodology proposed by XpanDH has proven that this co-creation process managed to identify at the early stages such issues, trying to find technological proposal, new innovative business services that could reduce those challenges and empower the role of the healthcare professionals.

Value of a Structured "As-Is" to "To-Be" Approach

Mapping the current state (“as-is”) and envisioning the future state (“to-be”) provided a structured way to analyse gaps and propose actionable solutions. This framework was instrumental in formulating practical recommendations tailored to care processes, IT infrastructure, and regulatory environments. Some working groups used collaboration tools to analyse step by step how to move from the current status quo to a future better designed, technology enabled use case. In several cases the to-be approach proposed new clinical documents or proposed to use clinical modelling to create new clinical documents that can be reused for the continuity of care process as well as for secondary use of data.

The Importance of Legal and Regulatory Alignment

Regulatory frameworks often lag technological advancements, creating friction in adoption. Discussions highlighted the importance of aligning legal requirements with the EHDS regulation to ensure secure, ethical, and efficient data use across Europe. The work of the 3C-3P WG defined in most cases recommendations to alter, review and adapt the current legal framework to allow the use of structured data, find ways to allow the use of digital healthcare tools especially in the collaboration of patients and healthcare professionals for both the treatment and preventions cycles.

Recommendations Need to Be Holistic and Actionable

Dividing recommendations into clear categories—care processes, IT infrastructure, applications, and legal frameworks—helped in providing targeted and actionable insights for stakeholders. This approach ensures that proposed solutions address the specific needs of each domain while aligning with the overall project goals.

Digital Transformation Must Be Comprehensive

Digital technology’s role in health care, including remote monitoring and advanced data management, was recognized as crucial. However, its successful

implementation depends on both technical readiness and cultural acceptance within healthcare systems.

Communication Is the Glue

Effective communication and collaboration between patients, caregivers, and healthcare providers emerged as an overarching theme. Without strong communication channels, even the most advanced systems and processes risk failing to deliver optimal care.

6.2 Key Recommendations from WGs

Below are listed the key recommendations stemming from the four working groups: Multidisciplinary tumour boards for cancer patients (3C-3P-MDT), Electronic prescription, electronic dispensation and electronic product information (3C-3P-EPD), Multi-Country working group on Imaging (3C-3P-MIM), Telehealth—Teleconsultation Encounter Report (3C-3P-TER). More details for each respective focus can be found in the annexed reports.

6.2.1 Key Recommendations from 3C-3P-MDT

The following recommendations were identified in the process of the working group on Multidisciplinary tumour boards for cancer patients (3C-3P-MDT):

1. **Legal and Procedural Frameworks**:
    - Develop comprehensive legal frameworks to ensure GDPR compliance and alignment with the European Health Data Space (EHDS).
    - Address challenges such as consent revocation, patient privacy, and shared liability within Multidisciplinary Teams (MDTs).
    - Implement protocols for anonymisation and structured communication to enhance transparency and mitigate risks in decision-making.
2. **Stakeholder Collaboration**:
    - Foster collaboration among healthcare providers, research institutions, technology firms, and patient advocacy groups.
    - Establish clear governance structures, roles, and communication channels to ensure alignment with patient-centred care principles.
    - Promote innovation and evidence-based practices by integrating standardised workflows and best practices.
3. **Care Process Optimisation**:

- Implement Integrated Care Pathways (ICPs) to align care processes and standardise milestones.
- Use Shared Workflows to assign roles, streamline operations, and incorporate best practices, thereby enhancing accountability and efficiency.
- Leverage structured data formats and real-time communication tools to reduce delays and improve coordination.

4. **IT Infrastructure Standards**:
   - Build scalable, secure, and interoperable systems adhering to HL7 FHIR, other HL7 standards, and IHE profiles.
   - Ensure compliance with international terminology standards like SNOMED CT, ICD-10/11, and ICD-O-3.
   - Incorporate robust encryption, modular architectures, attribute-based access controls, and audit logs for secure data management.
5. **Integration of Advanced Tools**:
   - Enable the use of wearables and IoT devices for enriched data collection and real-time health monitoring.
   - Invest in storage, backup solutions, and redundancy to ensure system resilience and minimise disruptions.
6. **User-Centric Applications**:
   - Develop applications with intuitive interfaces, data visualisation capabilities, and integration with existing systems such as EHRs.
   - Ensure patient empowerment by providing transparent, real-time access to personal health data while adhering to emerging standards.
7. **Cross-Enterprise Data Sharing**:
   - Leverage the European Electronic Health Record Exchange Format (EEHRxF) to collect and present disparate data to MDT tumour boards.
   - Utilise cross-enterprise document sharing architectures to facilitate effective MDT operations, supporting precision medicine and innovative treatments.

6.2.2 Key Recommendations from 3C-3P-EPD

The following recommendations were identified in the process of the working group on electronic prescription, electronic dispensation and electronic product information (3C-3P-EPD):

Recommendation 1: Add ePI in language of choice to [eP-eD] as "[ePI-eD] + ePI"

Align with regulators (EMA and NCAs), compendia and other relevant dissemination parties at EU and national level to make regulator-approved ePI available in a chosen language (patient – pharmacist) at dispensation to complement current arrangements with paper inserts (PIL) in language(s) of the jurisdiction where a medicinal product is dispensed.

Recommendation 2: Explore feasibility of standardisation – translation of person specific instructions by prescriber and recommendations by dispenser

Viability of efforts to standardise the person-specific instructions – printed on label and added when dispensation of a medicinal product – to allow for selection and presentations in a chosen language (patient – pharmacist) to promote intended use of a product, also in cross-border [eP –eD] scenarios, and overall safe use of medicines across Europe.

6.2.3 Key Recommendations from 3C-3P-MIM

The following recommendations were identified in the process of the Multi-Country working group on imaging – CoD (3C-3P-MIM):

Legal and regulatory

- Harmonize legal frameworks, including compliance with GDPR and patient consent across borders.
- Address data sovereignty issues to ensure consistent cross-border exchange of medical data, particularly for imaging.

Policy

- Formalize collaboration agreements between healthcare organizations, focusing on data sharing in imaging.
- Define mutual responsibilities and the trust-building processes between countries or organizations for cross-border data exchange.

Care Processes

- Align clinical workflows for the exchange of imaging data across borders.
- Standardize care pathways for cross-border interoperability, ensuring seamless integration of medical imaging data in the clinical workflow.

Information

- Define standardized data models, terminologies, and metadata schemas for cross-border imaging data sharing.
- Ensure interoperability by linking imaging data elements with common terminologies and metadata to enhance discoverability.

Applications

- Establish technical specifications for data transfer protocols (e.g., HL7, IHE XDS-I, DICOM) to ensure smooth import and export of imaging data.
- Implement secure and user-friendly applications that enable easy access to imaging data for clinicians and patients.

6.2.4 Key Recommendations from 3C-3P-TER

The following recommendations were identified in the process of the working group on Telehealth—Teleconsultation Encounter Report (3C-3P-TER):

Main recommendation: Replicate success stories from previous approaches for different adoption domains

To effectively advance the adoption domain for teleconsultation encounter reports, it is recommended to follow the structured approach used in developing priority domains such as Laboratory Reports and Hospital Discharge Reports. This entails establishing clear interoperability standards, engaging multi-stakeholder groups for co-creation, and ensuring alignment with the EHDS framework. Leveraging lessons learned from these priority domains will enable a systematic, scalable, and replicable model for teleconsultation. Such a strategy can support consistency, promote trust, and facilitate subsequent cross-border integration of TER services.

Other recommendations:

Technical: Standardise TER development (IHE XDS & HL7-based).

Legal/Policy: Align TER with GDPR, AI Act, and consent mechanisms.

Care Process: Physicians decide use-case; AI tools assist in TER generation with oversight.

IT Infrastructure: Ensure seamless upload and storage across systems.

7 Continuation and next steps

XpanDH has proposed a handover process that was extensively discussed during the European Digital Health Interoperability Days in Lisbon, 16 to 19 December 2024. Several ongoing projects and other initiatives have been proposed to continue the work of the current 4 working groups established but also to create new working groups. The projects that have been identified for this purpose to date are:

1. Xt-EHR, the Joint action project that is responsible for the primary use of data implementation of the new EHDS regulation
2. xShare, a Research and Innovation Action (RIA) project that focuses on demonstrating the value of patient mediated use cases especially the yellow button for sharing EEHRxF enabled document based on patient rights as defined in the upcoming the EHDS regulation. The project develops the xShare Standards and Policy Hub, which is fit for the purpose of becoming the entity acting as "secretariat" for the Community of Doers and/or part of its different current and future working groups. If acted, this should be formalised in the Hub's workplan.
3. myHealth@myHands a new project that will focus on extending citizen-based use of their data in the healthcare domain by demonstrating the results in practice of the EUDI Wallet architecture as well as the Patient Access results of the PATHED demonstration project.
4. i2X a new project that focuses on demonstrating the potential of the EEHRxF in new use cases and with the adoption of innovative tools to facilitate the adoption of EEHRxF by the healthcare provider community.

Those are just some of the proposals for the future immediate next step **in the short-term period**. In short, we depict the handover propositions of the 4 WGs as below:

Table 2 Possible handover of XpanDH's Community of Doers working groups

Working Group	Possible handover
3C-3P-MDT Multidisciplinary Tumour Boards for Cancer Patients	MyHealth@myHands and Xt-EHR
3C-3P- EPD eP/eD and electronic Product Information	MyHealth@myHands
3C-3P – MIM Multi-Country WG on Imaging - CoD	Xt-EHR, xShare and i2X
3C-3P-TER Telehealth— Teleconsultation Encounter Report	xShare and Xt-EHR

This will enable to continue the work initiated and expand the capabilities of co-creation for the adoption of the EEHRxF. During the discussion within the working groups, it was made clear that more time is needed to enable capacity building amongst the digital healthcare stakeholders to better adopt EEHRxF and the EHDS regulation. This process of engaging the stakeholders actively in the process of aligning the use of the EEHRxF and other EHDS regulation points is necessary to be continued during the whole process of MS engagement for the adoption and harmonisation of legal frameworks to the EHDS regulation.

As mid-term actions and next steps, the work of the CoD working groups depicted the need to:

1. Establish the concept of interoperability framework in national ehealth governance and regulation.
2. Ensure that bottom-up design where both users and vendors, demand side and supply side are able to communicate, co-create, discuss, create consensus, make proof of concepts, and test before implementation.
3. The COD approach enables the creation of stakeholders' collaborative ecosystems that will increase common understanding, increase capacity building, reduce the digital divide and enforce EHDS regulation faster and safer.

As long term actions it is recommended that CoD methodology should be funded by both (a) EU funds in continuation projects to ensure proper involvement of all stakeholders and especially (b) the market players that will deliver the future solutions within the EHDS regulation, enabling the common vision of a European digital single market and the European Health Union. The same approach should be done at each MS level to ensure national or regional stakeholders to actively contribute in practice to the EHDS regulation enforcement in a consensus-based approach.

8 References

Adlakha, S., Chhabra, D., & Vashistha, R. (2020). Efficacious Study of Specific Co-Creation Policies in the Healthcare Ecosystem: The Synergy Between Healthcare Providers, Policymakers, and Seekers. In G. Jain et al. (Eds.), *Technological Innovations for Sustainability and Business Growth* (pp. 199–220). IGI Global. https://doi.org/10.4018/978-1-5225-9940-1.ch011

Bowen, S., Sustar, H., Wolstenholme, D., & Dearden, A. (2013). Engaging teenagers productively in service design. *International Journal of Child-Computer Interaction, 1*(3–4). https://doi.org/10.1016/j.ijcci.2014.02.001

Boyd, H., McKernon, S., Mullin, B., & Old, A. (2012). Improving healthcare through the use of co-design. *New Zealand Medical Journal, 125*(1357).

Ceccagnoli, M., Forman, C., Huang, P., & Wu, D. J. (2012). Co-creation of value in a platform ecosystem: The case of enterprise software. *MIS Quarterly: Management Information Systems, 36*(1). https://doi.org/10.2307/41410417

De Koning, J. I., et al. (2016). Introducing co-design in healthcare. *Healthcare Quarterly, 19*(1).

Eckhardt, J., Kaletka, C., Krüger, D., Maldonado-Mariscal, K., & Schulz, A. C. (2021). Ecosystems of Co-Creation. *Frontiers in Sociology, 6*. https://doi.org/10.3389/fsoc.2021.642289

Indurti, A., et al. (2023). Co-create as a Participatory Design Methodology in Health Care. *Springer Proceedings in Business and Economics*. https://doi.org/10.1007/978-981-99-0428-0_38

Lewerenz S., Berler A., Martins H, Carmo A, Schulz C, Varntoumian E, Franconi S, Building the European Digital Health Ecosystem for the Format and the EHDS, HealthManagement, Volume 24 - Issue 5, 2024, https://healthmanagement.org/c/healthmanagement/issuearticle/building-the-european-digital-health-ecosystem-for-the-format-and-the-ehds

Thabrew, H., Fleming, T., Hetrick, S., & Merry, S. (2018). Co-design of eHealth Interventions With Children and Young People. *Frontiers in Psychiatry, 9*. https://doi.org/10.3389/fpsyt.2018.00481

Viglia, G., Pera, R., Dyussembayeva, S., Mifsud, M., & Hollebeek, L. D. (2023). Engagement and value co-creation within a multi-stakeholder service ecosystem. *Journal of Business Research, 157*. https://doi.org/10.1016/j.jbusres.2022.113584

Annexes

Annex 1

Template document for Working groups

Note: This template was left amendable to a certain extent to fit each group's focus and needs.

Double click to open

Community of Doers Working Group Report and Recommendations

For Teleconsultation Encounter Report

Scope

This document serves the purpose to collect all contributions from the Community of Doers (CoD)[4] regarding the idealisation, discussion, and recommendations for the formalisation of an evolution of an existing service into a new adoption domain, incorporating other EC-funded projects' knowledge and other experts' views through a process of cocreation with patients, professionals, and IT developers (programmers) following the logic of the CoD set forth by XpanDH.

Goal of Working Groups

Through a defined methodology of multi-stakeholders balanced cocreation as set forth by the CoD definition, the CoD is organised into Working Groups that aim to translate into teams of eHealth actors with one main objective: exploring and

[4] The Community of Doers and Co-creators brings together implementers and end-users of new and existing solutions, IT developers and vendors/suppliers; patients and healthcare professionals, in a 3C-3P community (co-creation community of Patients, Professionals and Programmers). The scope of this open community is to find use cases and business needs that would be reused in practice domains of the European EHR (Electronic Health Record) Exchange Format in a bottom-up co-creation approach.

delivering hard recommendations for formalising an evolution of the existing services in EHDS context into new adoption domains or new approaches to existing data categories specification.

This newly established working group focuses on teleconsultation encounter reports supported by the European Electronic Health Records Exchange Format (EEHRxF) to facilitate cross-border and national telehealth services in the EU. Having met in 4 online workshops to date, this group aims to further identify and address technical, regulatory, socio-cultural and clinical aspects required for teleconsultation reports to be interoperable across and within borders. Developments will build on lessons learnt from success stories of participating countries with related telehealth use cases.

Table of Contents

1 Background

1.1 Context and healthcare challenge

[*Expand on the context and identify then explain the problem which the format should solve.*]

1.2 Relevant scientific knowledge

[Develop arguments based on scientific literature that are relevant to the challenge at stake. Use knowledge that describe the challenge, support the approach taken, etc.]

1.3 Outputs from relevant EC-funded projects and other initiatives

[Relate to relevant knowledge and work from other EC-funded projects; examples and services from Denmark?]

2 Interoperability challenges description

2.1 Overview

[Fill in the framework below to characterise the interoperability challenges at stake. This framework is inspired by that for description of a use case in the eHealth Network's Refined eHealth European Interoperability Framework (ReEIF).

2.1.1 Title

Telehealth use case: Teleconsultation Encounter Report

2.1.2 Purpose

[the main functionality of the service – what is it, what does it do?]

The new service aims to

2.1.3 Relevance

[the "why", the rationale of the service: both medical (what problem does it solve?) and economical (business case, costs and benefits)]

2.1.4 Priority categories addressed

[from the 2024 EHDS regulation:
(a) patient summaries;
(b) electronic prescriptions;
(c) electronic dispensations;
(d) medical imaging studies and related imaging reports;
(e) medical test results, including laboratory and other diagnostic results and related reports;
(f) discharge reports.]

2.1.5 Scale

[- Cross-border

- National
- Regional
- Intra-organisational
- Citizens at home and on the move]

2.2 Evolution process

[Fill in the framework below to describe the process of evolving from the current 'AS-IS' situation to the target 'TO-BE' situation. This framework is a simplified adaptation of that which has been developed by the XpanDH X-Bubbles.]

2.2.1 Target group

[target group of the new service]

2.2.2 Stakeholders

[stakeholders involved in or impacted to some extent by the new service]

2.2.3 Context of use

[context around the use case describing the end use of the new service]

2.2.4 AS-IS situation

[current situation in one sentence]
[about technical specifications]
[about semantic elements]
[about master datasets and values sets]

2.2.5 TO-BE situation

[the ideal situation which this effort aims at achieving]

2.2.6 Description of Necessary Steps to Move from AS-IS to TO-BE Situation:

[Necessary steps to move from the AS-IS to the TO-BE situation
1. …
2. …
3. …]

2.2.7 Objectives

[the aim(s) of the new service, relating to the reason(s) why it needs to be developed]

2.2.8 Actors and Roles

Actor	**Role**
[e.g. physician, patient, laboratory information system]	*[e.g. Document creator and user]*

2.2.9 Preconditions

[the conditions required for the new service to be implemented and operative]

2.2.10 Trigger

[the action triggering the use of the new service]

2.2.11 Flow

[describe the path of information/data flow within the new service and the role of each actor]

2.2.12 Post conditions

[the conditions required for deeming the triggered service successful]

2.2.13 Requirements

User requirements
Technical requirements
Operational requirements
Ethics requirements

2.2.14 Major challenges foreseen

[main barriers foreseen to pose a risk to the new service's implementation, use, and success]

2.2.15 Architecture

[best presented as diagram e.g. of deployment nodes]

2.3 Inter-domain dependencies

[Analyse and highlight inter-domain dependencies: from existing domains, what is reusable for this new service? The aim of this exercise is to avoid the multiplication of ideas, making the development of new services more streamlined.]

3 Consultation process

[Describe the process of feedback collection and co-creation e.g. n° meetings, structure and governance if any]

4 Recommendations for relevant asset bundle

[Provide recommendations of steps to follow, precautions to be taken, material to be produced, or else, in the 6 interoperability levels outlined by the eHealth Network's refined eEIF (ReEIF).

Below we display two models that display how these 6 interoperability levels can be applied to (i) alignment activities between organisations, and (ii) stakeholders.]

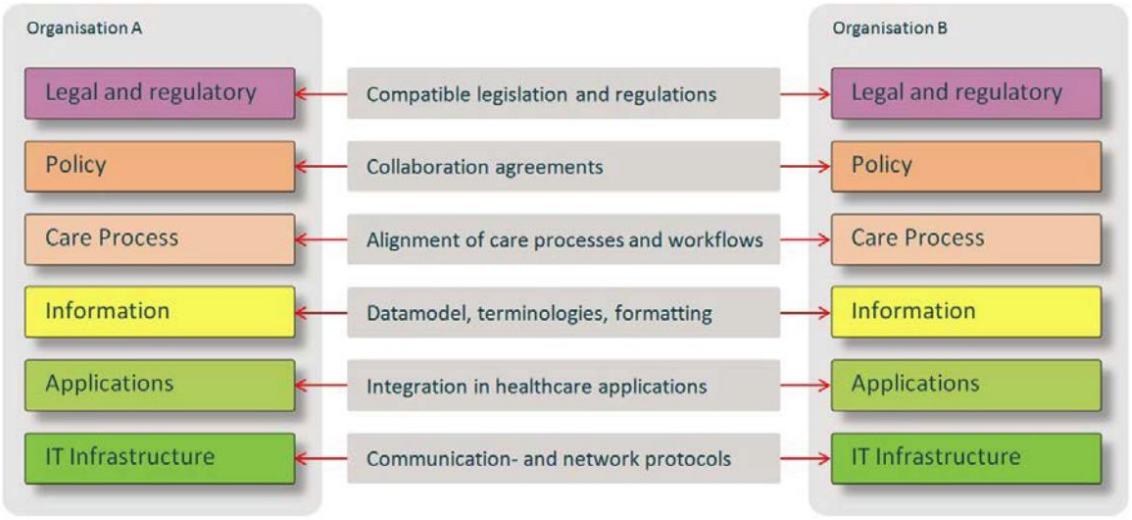


Figure 7 Refined eEIF (ReEIF) model – alignment activities between organisations

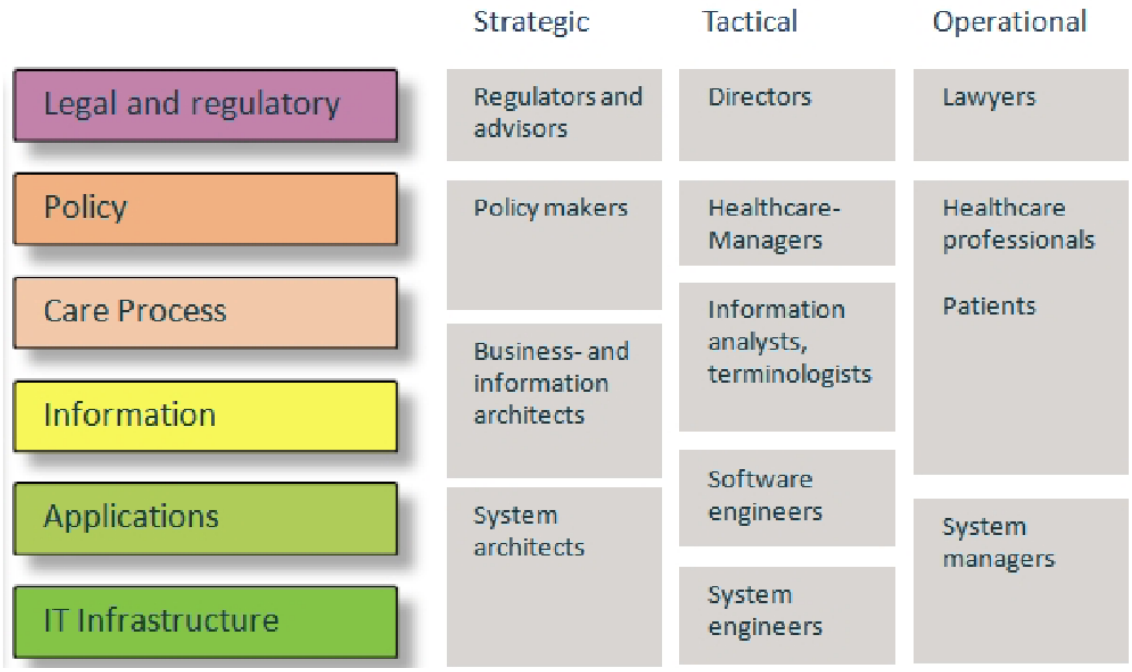


Figure 8 Refined eEIF (ReEIF) model – stakeholders

4.1 Legal and regulatory

[On this level, compatible legislation and regulatory guidelines define the boundaries for interoperability across borders, but also within a country or region.]

4.2 Policy

[On this level, contracts and agreements between organisations have to be made. The purpose and value of the collaboration must be set. Trust and responsibilities between the organisations are formalised on the Policy level. In governance documents the governance of collaboration is anchored.]

4.3 Care process

[After the organisations have agreed to work together, specific care processes are analysed and aligned, resulting in integrated care pathways and shared workflows. This level handles the tracking and management of the workflow processes. The shared workflow prescribes which information is needed in order to deliver the integrated care.]

4.4 Information

[This level represents the functional description of the data model, the data elements (concepts and possible values) and the linking of these data elements to terminologies that define the interoperability of the data elements.]

4.5 Applications

[On this level, agreements are made about the way import and export of medical information are handled by the healthcare information systems. The technical specification of how information is transported is at this level (communication standards). The information systems must be able to export and import using these communication standards.
Another aspect in this level is the integration and processing of exchanged information in user-friendly applications.]

4.6 IT infrastructure

[The generic communication and network protocols and standards, the storage, backup, and the database engines are on this level. It contains all the "generic" interoperability standards and protocols.]

Annex 2

Report and recommendations document prepared by Working group: Multidisciplinary tumour boards for cancer patients (3C-3P-MDT).

Double click to open

Community of Doers Working Group Report and Recommendations

Multidisciplinary tumour boards for cancer patients (3C-3P-MDT)

Scope

This document serves the purpose of collecting all contributions from the Community of Doers (CoD)[5] working groups regarding the idealization, discussion, and recommendations for the formalization of an evolution of an existing service into a new adoption domain, incorporating other EC-funded projects' knowledge and other experts' views through a process of co-creation with patients, professionals, and IT developers (programmers) following the logic of the CoD set forth by XpanDH. This report focus on the work done in the domain of multidisciplinary tumor boards..

[5] The Community of Doers and Co-creators brings together implementers and end-users of new and existing solutions, IT developers and vendors/suppliers; patients and healthcare professionals, in a 3C-3P community (co-creation community of Patients, Professionals and Programmers). The scope of this open community is to find use cases and business needs that would be reused in practice domains of the European EHR (Electronic Health Record) Exchange Format in a bottom-up co-creation approach.

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Through a defined methodology of multi-stakeholders balanced cocreation as set forth by the CoD definition, the CoD is organised into Working Groups that aim to translate into teams of eHealth actors with one main objective: exploring and delivering hard recommendations for formalising an evolution of the existing services in EHDS context into new adoption domains or new approaches to existing data categories specification.

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1 Background

1.1 Relevant existing material

Relevant material are the eHealth Network's (eHN) guidelines.

They include specific guidelines for five different services: ePrescription and eDispensation, Patient Summary, Laboratory results, Medical imaging studies and reports, and Hospital discharge reports.

They are based on the Commission Recommendation on a European Electronic Health Record exchange format's original 'health information domains'.

- eHealth Network General guidelines
- eHN guidelines on ePrescription and eDispensation
- eHN guidelines on Patient Summary
- eHN guidelines on laboratory results
- eHN guidelines on Medical imaging studies and reports
- eHN guidelines on Hospital discharge reports

The original 'health information domains' have evolved with the April 2024 EHDS regulation, to be recategorized into six 'priority categories of personal electronic health data':

(a) patient summaries;

(b) electronic prescriptions;

(c) electronic dispensations;

(d) medical imaging studies and related imaging reports;

(e) medical test results, including laboratory and other diagnostic results and related reports;

(f) discharge reports.

1.2 Healthcare challenge

The healthcare sector faces a range of critical challenges that demand innovative solutions. In particular, the rapid evolution of technology, combined with the increasing complexity of patient needs, has highlighted gaps in the current healthcare service. While the existing service has successfully addressed certain needs within its original domain, it is increasingly evident that it cannot fully respond to the challenges of [new adoption domain] without significant evolution.
One of the primary issues is the **lack of accessibility** for underserved populations, particularly those in remote or rural areas. The current service is limited in its reach, leaving many patients without timely access to critical care. This disparity is further exacerbated by the fragmentation of patient care, where communication between healthcare professionals and systems is disjointed, leading to delays in treatment and potential gaps in patient care continuity.
Moreover, **inefficient processes** remain a significant hurdle. The current service relies heavily on outdated manual workflows, causing delays in service delivery and unnecessary administrative burdens for healthcare professionals. These inefficiencies ultimately impact the quality of patient care, as healthcare professionals are forced to spend more time on administrative tasks rather than patient interaction. Another critical challenge lies in the **lack of integration** of healthcare data. In the current service model, data silos exist across various systems, preventing a comprehensive, real-time view of patient health information. This limits the ability of professionals to make data-driven decisions, which could otherwise improve patient outcomes and streamline care delivery.
From the patient perspective, there is a growing demand for **more personalized and engaging healthcare experiences**. Many patients feel that their role in managing their own health is undervalued, and they lack the tools and resources to actively participate in their care. This lack of engagement contributes to lower adherence to treatment plans and poorer health outcomes.
To address these pressing challenges, the existing service must evolve to better integrate advanced technologies, foster more robust communication between stakeholders, and ensure patients are at the center of care. This evolution must be co-created with input from patients, healthcare professionals, and IT developers, to ensure that the new service is both fit for purpose and adaptable to future healthcare needs. Without this evolution, the healthcare sector risks further entrenching inequalities and inefficiencies, undermining the quality of care delivered to patients.

1.3 Relevant scientific knowledge

An oncological council typically refers to a group of medical professionals who come together either physically or remotely, in order to discuss and decide on

treatment plans for cancer patients. This multidisciplinary team may include, among others, oncologists, surgeons, radiologists, pathologists, radiation therapists and nurses. Their goal is to ensure that patients receive most suitable care via comprehensive approach, which is tailored to their specific condition, considering the latest research and treatment options.

Medical professionals in an oncological council need a diverse set of knowledge and skills to effectively discuss and decide on course of treatment for patients with cancer. Key areas of expertise may include:

1. **Oncology**: In-depth understanding of various types of cancer, their biology, staging, and progression.
2. **Treatment Modalities**: Knowledge of different treatment options, including surgery, chemotherapy, radiation therapy, immunotherapy, and other targeted therapies.
3. **Clinical Guidelines**: Familiarity with current clinical guidelines and protocols for cancer treatment.
4. **Pathology**: Understanding tumor biology, histopathology, and molecular diagnostics to assess tumor characteristics.
5. **Radiology**: Ability to interpret imaging studies to determine tumor location, size, and metastasis.
6. **Patient Care**: Skills in managing side effects, supportive care, and palliative care options.
7. **Multidisciplinary Collaboration**: Experience working in a team environment, facilitating communication among various specialties.
8. **Ethics and Patient Advocacy**: Knowledge of ethical considerations in cancer care and the importance of considering patient preferences and values.
9. **Research and Clinical Trials**: Awareness of ongoing research, clinical trials, and emerging therapies that may benefit patients.
10. **Psycho-Social Aspects**: Understanding the psychological and social impacts of cancer on patients and their families.

By combining their expertise, members of the oncological council aim to create personalized and effective treatment plans that consider all aspects of a patient's health and well-being.

Challenges

Multidisciplinary Teams (MDT) performing Multidisciplinary Tumour Boards (MDTB) are a valuable tool in cancer care, aiming to facilitate treatment decisions or recommendation and provide a comprehensive approach by integrating insights from multiple specialists. However, the achievement of optimal outcomes requires addressing the following challenges.

1. **Data fragmentation:** A significant barrier to effective MDT discussions is data fragmentation, given that important patient data might be scattered across various hospitals and clinics, making it difficult for team members to have a holistic view of the medical history, diagnostic results, and treatment responses. Also, there is a lack of standardisation across platforms and data sources, which further burdens interoperability between different infrastructures.

2. **Information overload:** MDT often depends on multiple diagnostic data, including radiology, pathology, genomic sequencing, and patient history, which can overwhelm clinicians, underscoring the importance of developing data synthesis and summarisation tools.
3. **Coordination across specialities:** Effective MDT depends on effective communication and collaboration between diverse specialists. This is challenging, particularly due to the lack of interoperability within existing electronic health record (EHR) systems. Additionally, the absence of standardised communication platforms can lead to fragmented discussions and incomplete information sharing.
4. **Resource availability and representation gaps:** In some MDTs, some specialities have unequal representation, leading to biased decisions. Also, MDT held at non-academic centres or in remote regions often lack access to the full spectrum of oncological expertise and best practices, thereby limiting the effectiveness of multidisciplinary input.
5. **Structural variability and non-standardisation:** A non-standardized structure within MDT poses another barrier, as inconsistencies in the format, reporting standards, and feedback mechanisms can lead to variability in the quality of care across institutions.
6. **Time and resource constraints:** The preparation and conduction of MDT demand substantial time, diverting healthcare professionals from direct patient care. Physicians often face a trade-off between dedicating time to MDT meetings and attending to their clinical duties, particularly in settings where resources are limited. Time management solutions, such as streamlined meeting structures and focused case selections, are crucial to maximising the efficiency of MDT discussions without detracting from patient care.
7. **Limited access in remote areas:** Access to MDT might be limited in remote regions, and patients may not receive the same level of multidisciplinary input as those in urban centres or academic hospitals. Telemedicine and remote collaboration technologies could play an essential role in mitigating this gap.
8. **Consideration of sociodemographic factors:** MDT should aim to integrate a broader range of patient information, encompassing medical history and relevant social determinants of health, which are often overlooked. Incorporating social factors and demographic data into MDT deliberations is essential to personalised cancer care. Socioeconomic status, family support, and cultural factors can significantly impact treatment adherence and outcomes.

References

https://pubmed.ncbi.nlm.nih.gov/23613417/
https://doi.org/10.1007/s44178-024-00107-7
https://doi.org/10.14694/EdBook_AM.2014.34.e461
http://dx.doi.org/10.2217/fon-2021-0471

1.4 Outputs from relevant EC-funded projects

The evolution of Multidisciplinary Tumour Boards (MDTs) in Europe has been significantly supported by various EU-funded projects that address interoperability, patient-centric care, and collaborative decision-making. These outputs form the foundation for advancing MDTs towards more integrated and effective cancer care.

1. **iManageCancer**: This project developed digital tools to empower cancer patients, focusing on self-management and enhancing their role within MDTs. By providing applications that allow patients to access and share their health data seamlessly, iManageCancer promotes patient engagement and informed decision-making during MDT discussions.
2. **CanCon (Cancer Control Joint Action)**: A pivotal initiative in harmonizing cancer control strategies across Europe, CanCon emphasized the integration of MDTs as a critical component of effective cancer care. Its outputs include best practices and policy recommendations for improving collaboration across specialties.
3. **UNICOM**: While primarily focusing on medicinal product identification, UNICOM contributes to MDTs by standardizing data exchange related to oncology treatments, ensuring that therapeutic protocols are consistent and interoperable across healthcare systems.
4. **ASCAPE**: Leveraging artificial intelligence to personalize cancer care, ASCAPE provides decision-support tools that MDTs can use to predict outcomes and tailor interventions, enhancing the quality of multidisciplinary decisions.

References:
iManageCancer: https://cordis.europa.eu/project/id/643529/reporting
CanCon: https://cancercontrol.eu/archived/
UNICOM: https://unicom-project.eu/
ASCAPE: https://www.ascape-project.eu/

2 Interoperability gap description

2.1 Overview

Title	*Multidisciplinary Tumor Boards Documentation and Operation*
Purpose	The service facilitates the operation and documentation of Multidisciplinary Tumour Boards (MDTBs) by enabling collaboration among specialists to make evidence-based decisions for cancer patients. It supports seamless coordination and data exchange across different hospitals and within individual hospital systems. Through the integration of advanced digital tools, the service enables remote management and participation of MDTBs, ensuring comprehensive accessibility for all stakeholders regardless of location. This streamlined approach enhances case management, ensuring data accuracy, accessibility, compliance with regulatory standards, and improved patient outcomes.
Relevance	**Medical**: MDTBs address the complexity of cancer treatment by providing a structured platform for coordinated decision-making. This collaborative approach enhances diagnostic precision and enables the development of comprehensive, evidence-based treatment plans, leading to improved patient outcomes. **Economical**: By enabling enhanced and more effective treatment plans, MDTBs contribute to better treatment outcomes and improved patient health. This results in indirect benefits, such as lowering the ~~societal~~ costs associated with prolonged or ineffective

	treatments. Additionally, the optimized use of healthcare resources reduces unnecessary strain on the system, improving overall efficiency.
Priority category	*(a) patient summaries;* *(b) electronic prescriptions;* *(c) electronic dispensations;* *(d) medical imaging studies and related imaging reports;* *(e) medical test results, including laboratory and other diagnostic results and related reports;* *(f) discharge reports.]*
Scale	- **Cross-border**: Ensures MDTs can collaborate on complex cases involving specialists from multiple countries. - **National**: Facilitates consistent MDT operations within a national healthcare system. - **Regional**: Enhances coordination across regional cancer care centers. - **Intra-organisational**: Streamlines workflows within a single institution.

2.2 Evolution process

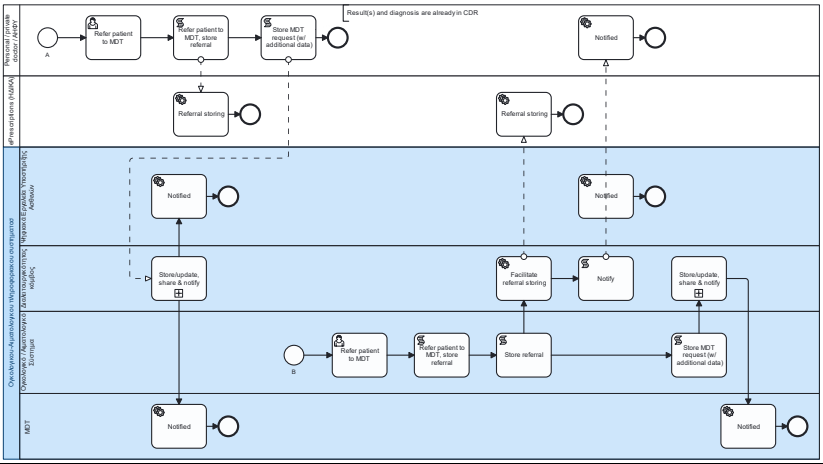
Target group	*[target group of the new service]* *The new service is designed to primarily empower and serve **patients**, particularly those in underserved regions who currently face challenges in accessing timely and coordinated healthcare. Additionally, it will benefit **healthcare professionals**, including doctors, nurses, and administrative staff, by providing them with more efficient tools to deliver care. **IT developers** will also be a key user group, as they will be involved in maintaining and enhancing the technical infrastructure needed for this service. Ultimately, the goal is to create a holistic ecosystem that serves all stakeholders engaged in the healthcare process.*

Stakeholders	***Patients:*** *The patient as an ultimate beneficiary who will experience improved care access and greater engagement in managing their own health.* ***Healthcare Professionals:*** *Doctors, nurses, and administrative staff who will interact with the service daily, benefiting from streamlined workflows, better access to patient data, and improved decision-making tools.* ***IT Developers:*** *Technical experts responsible for building, maintaining, and updating the platform to ensure its efficiency, security, and adaptability.* ***Healthcare Providers:*** *Key decision-makers who will oversee the service's implementation and ensure its alignment with broader healthcare goals.* ***Policy Makers:*** *Authorities who regulate healthcare practices and data privacy and ensure that the service adheres to legal and ethical guidelines.*
Context of use	*The new service will be implemented within the broader context of* ***digital health integration****, focusing on enhancing care delivery for patients with chronic diseases and those requiring long-term monitoring and treatment. The service aims to streamline the interaction between healthcare providers and patients through a unified platform that allows* ***Real time access to data through data sharing and data aggregation****,* ***communication, and collaboration****. This will be especially valuable in rural or underserved areas where healthcare services are scarce, and access to experts is limited. The new system will facilitate optimal healthcare services, better coordination****, Remote healthcare/tele-healthcare, also via remote patient monitoring****, and increased patient engagement, thereby improving overall health outcomes.*
AS-IS situation	***Current Situation (in one sentence):*** *The current service operates in silos, offering fragmented healthcare delivery with inefficient processes for patient-professional interaction and limited data sharing capabilities.* ***About Technical Specifications:*** *The current service relies on outdated legacy systems, which lack interoperability with newer technologies, leading to inefficiencies in data sharing between healthcare institutions. Manual processes dominate, causing delays and inaccuracies in patient information exchange.*

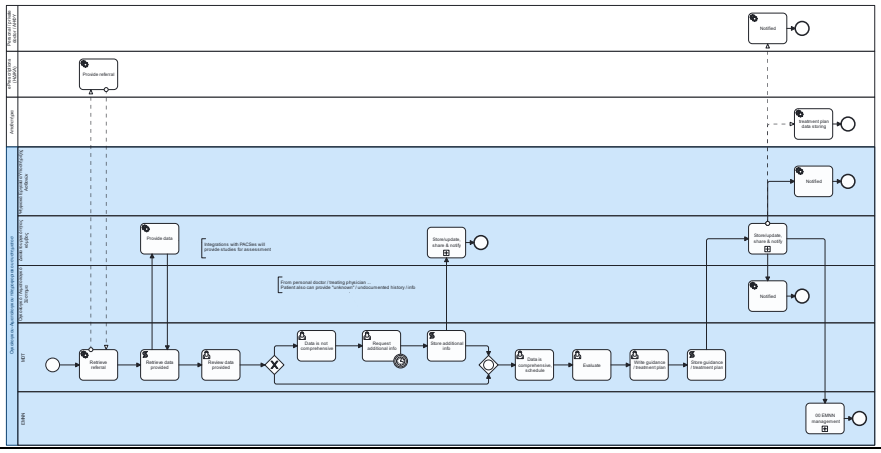
	About Semantic Elements: *There is inconsistent use of healthcare terminologies and standards, making it difficult for professionals across different domains to interpret and act on patient data uniformly. There is no seamless alignment with international health data standards like SNOMED CT or ICD (International Classification of Diseases).* ***About Master Datasets and Value Sets:*** *The existing service uses disparate datasets that are poorly aligned with one another, resulting in data silos. Data governance practices are underdeveloped, and there is minimal adherence to standardized value sets or terminologies that could improve data consistency and reuse across multiple platforms.*
TO-BE situation	• **Implementation of Standards**: Adoption of interoperability standards such as HL7 FHIR and EEHRxF to enable seamless data exchange and ensure uniformity across platforms. • **Unified Digital Platform**: Development of a comprehensive platform to facilitate MDT documentation and operation, providing real-time access to clinical data and supporting collaborative workflows. • **Enhanced Decision-Making**: Integration with national and cross-border systems to allow collaborative decision-making, where the MDT team can analyze all available information to craft enhanced and improved care plans. This includes supporting therapy effectiveness and overall health during treatment through additional or targeted testing and interventions. • **Automated Processes**: Streamlined workflows for generating and sharing reports, reducing administrative overhead, and focusing on creating improved and personalized treatment plans. • **Patient-Centered Approach**: Direct involvement of patients via digital tools, granting them access to treatment plans, facilitating active participation in decision-making, and enabling better overall outcomes through tailored therapies. • **Creation of a Structured MDT report** for adoption at the EU level under the EEHRxF as an additional Health Information Domain.
Description	1. ***Stakeholder Engagement****: Involve healthcare professionals, IT experts, and patients to define interoperability requirements and identify gaps.*

<table>
<tr><td></td><td colspan="2">2. Standard Adoption: Implement interoperability frameworks such as HL7 FHIR, IHE Profiles and integrate them into existing MDT workflows. Propose new Content profiles for MDT management.
3. Pilot and Test: Conduct pilot studies to test the new platform in diverse settings (regional, national, and cross-border) and refine based on feedback.
4. Capacity Building: Train MDT members on the use of new digital tools and workflows.
5. Implementation and Scale-up: Deploy the solution nationally and support cross-border collaboration.
6. Continuous Improvement: Use analytics and feedback to enhance platform usability, performance, and compliance.</td></tr>
<tr><td>Objective(s)</td><td colspan="2">Improved Access to Care: Ensure that patients, particularly those in underserved areas, have more timely and effective access to healthcare professionals and services.
Seamless Data Interoperability: Enable real-time, secure exchange of health data across different systems, platforms, and healthcare providers by adopting standardized protocols and improving system interoperability.
Enhanced Patient Engagement: Empower patients to take a more active role in managing their health through access to user-friendly tools for self-monitoring, real-time feedback, and direct communication with their healthcare teams.
Efficient Use of Resources: Reduce administrative burdens and streamline workflows for healthcare professionals, allowing them to focus more on patient care rather than paperwork.
Data-Driven Decision Making: Provide healthcare professionals with real-time access to complete patient records, allowing for more accurate and timely clinical decision-making based on comprehensive data.</td></tr>
<tr><td rowspan="4">Actors and Roles</td><td>Actor</td><td>Role</td></tr>
<tr><td>[e.g. physician, patient, laboratory information system]</td><td>[e.g. Document creator and user]</td></tr>
<tr><td>Oncologists</td><td>Lead case discussions, propose treatment plans.</td></tr>
<tr><td>Radiologists</td><td>Provide imaging reports and analysis.</td></tr>
</table>

	Pathologists	Contribute diagnostic insights from lab results.
	Surgeons	Offer surgical perspectives
	Nutritionist	Tailored dietary recommendations to support treatment and improve patient well-being
	Psychologist	Provides mental health support and strategies to enhance coping and treatment adherence
	General Practitioners	Offer a holistic view of patient history and health condition
Pre-conditions	*[the conditions required for the new service to be implemented and operative]* • The patient has been diagnosed with cancer and is deemed to benefit from MDT review due to the complexity of the case. • The referral to the MDT is made by the treating physician, personal doctor, or oncologist, based on clinical judgment. • Relevant patient data, including diagnostic results, imaging, and prior treatment history, must be prepared and accessible to MDT members prior to their meeting. This ensures cases are reviewed in advance, prioritized, and efficiently scheduled for discussion. • Cases are prioritized and scheduled for MDT meetings, allowing for a streamlined process where meetings focus on reviewing, discussing, amending, and enhancing care plans. • Consent for data sharing and MDT discussion has been obtained from the patient. • Not all cancer cases require MDT review; referrals are reserved for cases needing multidisciplinary input to refine diagnosis or treatment plans. • During meetings, the MDT collaborates to suggest support therapies, additional diagnostic tests, or modifications to the proposed treatment plan, ensuring comprehensive care.	

Trigger	*[the action triggering the use of the new service]* • A cancer diagnosis that necessitates multidisciplinary input due to the complexity of the case, ambivalent findings requiring verification, or the need for higher expertise. • A treating physician, personal doctor, or oncologist determines that the complexity of the case necessitates MDT involvement. • A significant change in the patient's condition prompting a reassessment of the current treatment strategy, potentially leading to modifications or additional support therapies for improved outcomes.
Flow	*Proposed from for MDT based on EEHRxF adoption.* 
Post-conditions	*MDT is triggered by the Treating Oncologist. An oncology use case is registered in the Cancer Patient Registry with at least one ICD-O code.* *An MDT is necessary for the oncology treating physician to collect expertise from other medical expertise.* *The successful post condition results in having a MDT tumour board structured report to be added both in the Cancer Patient Registry and in the Oncology Patient Record.*
Requirements	**User requirements** 1. **Ease of Use**: The platform should provide an intuitive interface that enables healthcare professionals to access patient data, participate in discussions, and document decisions efficiently. 2. **Secure Patient Access**: Patients must be able to access their records, manage consent(s) and participate in decision-making processes securely through user-friendly digital tools.

	3. **Role-Based Access Control**: Access to specific data and functionalities should be tailored to the roles of MDT members (e.g., oncologist, radiologist, surgeon). 4. **Collaboration Features**: Real-time collaboration tools, including video conferencing, shared documentation, and task tracking, should be integrated. 5. **Language and Terminology Localization**: Support for multiple languages and region-specific medical terminologies to ensure usability across borders.
	Technical requirements 1. **Interoperability**: Compliance with standards such as HL7 FHIR, relevant IHE profiles, mCODE, ICD-O, etc., for seamless data exchange between systems. 2. **Data Security and Privacy**: Robust encryption, GDPR compliance, and secure user authentication mechanisms are essential. 3. **Scalability**: The platform should handle increasing volumes of data and users across multiple regions or organizations without performance degradation. 4. **Integration Capabilities**: Ability to integrate with existing hospital systems (e.g., EHR, LIS, PACS) and external registries for comprehensive data access. 5. **Analytics and Reporting**: Tools for analyzing MDT performance and generating detailed reports on patient outcomes and decision processes.
	Operational requirements 1. Alignment with EU and National Regulation 2. Interoperability with Patient Cancer Registry and National Oncology System 3. Define the minimum medical specialties that are needed in the MDT tumour board
	Ethics requirements 1. Enforcement of GDPR rules especially the rule of minimal diffusion of personal data on a need to know basis 2. Patient informed consent procedures and treatment relationship confirmation between the patient and the medical team assisting. 3. No sharing of patient data without patient consent or treatment relationship confirmation

Major challenges foreseen	1. Semantic complexity 2. Capacity building and education of both patient and healthcare providers 3. Legal restrictions 4. Financial restrictions
Architecture	*The process of an MDT is depicted in the diagram below.* 

2.3 Inter-domain dependencies

Analyse and highlight inter-domain dependencies: from existing domains, what is reusable for this new service? The aim of this exercise is to avoid the multiplication of ideas, making the development of new services more streamlined.

2.3.1 Patients

To avoid redundancy and streamline new service development, the following existing resources and processes can be leveraged:

- Electronic health records (EHRs) already contain valuable patient data, including not only clinical but also sociodemographic information, which could be integrated with new services and ensure continuity of care without duplicating efforts.
- Protocols for patient case discussions, treatment planning, and follow-up care are already in place. Adapting these protocols for new tumour board services will prevent the need to develop new ones from scratch.
- Mechanisms are in place to ensure that the outcomes of the tumour board discussions are systematically documented in the patient's medical records. Patients are informed of the board's recommendations and can request

comprehensive details from their attending physician or any member of the tumour board.

2.3.2 Professionals

Establishing a digital form of the oncological council may involve several inter-domain dependencies. Addressing some of them is judged as critical, in order to enhance communication, streamline processes, and ultimately improve patient outcomes by means of a digital oncological council.

1. **Health IT Systems**: Integration and bridging with electronic health records (EHR) and/or oncology-specific software, in order to ensure seamless access to patient data, treatment history, and clinical notes.
2. **Collaboration Tools / Telemedicine Platforms**: Development of secure, user-friendly platforms for secure messaging, virtual consultations, enabling real-time discussions among professionals and with patients, in order to facilitate discussions and decision-making among the multidisciplinary team.
3. **Data Security and Compliance**: Ensuring adherence to healthcare EU policies (e.g. GDPR) to protect patient privacy and data integrity across all digital interactions.
4. **Interoperability Standards**: Adopting common data standards and transfer protocols to allow different systems and platforms to communicate effectively.
5. **Training and Support**: Providing ongoing training for all stakeholders to ensure effective use of digital tools and foster a collaborative culture.

Addressing some other inter-domain dependencies is probably optional, but, if feasible, it is judged as very helpful in further enhancing therapeutic effectiveness and overall quality of care via a digital oncological council.

6. **Clinical Decision Support Systems**: Implementing machine learning tools to assist in analyzing patient data and suggesting evidence-based treatment options.
7. **Patient Engagement Tools**: Creating digital resources for patient education and support, ensuring they can participate in discussions and decision-making regarding their care.
8. **Research and Analytics**: Integrating data analytics tools for real-time evaluation of anonymized treatment outcomes and trends, supporting continuous improvement in patient care.

2.3.3 Programmers

Interoperability and Standardization

Provide frictionless data exchange among various health information systems to facilitate vital patient data access across all platforms for MDTs.

- The clinical implementation shall utilize internationally recognized data and transport standards such as HL7 FHIR and HL7 CDA, LOINC, ICD-10, ICD-O-3, ATC and EMA's EDQM. Such standards enable the MDT platform to interface with other systems, such are EHRs or oncology-specific systems (sources of data), using a centralized interoperability hub.
- The hub utilizes standards, standard APIs (data and protocol) and various connectors to manage secure exchange and flows of structured and unstructured clinical data, required for the optimal MDT processes, enabling MDTB processes such are assessments, consultations and their outcomes.

Structured Data for Oncology

To standardize systems data points and ensure high-value, standardized oncology information for discussion at the MDT.

- To ensure structured data for oncology, developers can leverage HL7 FHIR Implementation Guides (FHIR IG) tailored for oncology use cases. These guides provide detailed frameworks for structuring clinical data, such as patient demographics, diagnosis, treatments, and outcomes, in a standardized format. By defining profiles, specific to oncology, FHIR IG supports consistent data representation while ensuring interoperability across systems. This approach enables seamless integration with existing healthcare infrastructure and aligns with EU requirements/specifications, and global best practices for managing oncology information.
- Developers can ensure MDTB members operate from the same foundation by reducing redundancy and enhancing overall quality in cancer care information.

Automated Data and Workflow Management

Streamlining workflows between MDT members to go ahead, without a glitch from one stage of patient care into the next.

- Automate clinical workflows. Steps in managing a case from screening and diagnosis to follow-up are a few of the key workflows. Treatment regiment, diagnostic checkups, treatment planning, and measured outcomes are among the common workflows.

- Supporting infrastructure should automatically notify MDTB members about the change in the patient record and any anticipated outcome of clinical pathway. The functionality is supportive of timely updates aimed at ensuring that all members are well-informed and prepared for every MDTB session.

Clinical Decision Support (CDS)

Support data-driven treatment recommendations for MDT members to make informed decisions on complicated cases.

Integration of a CDS tool, such is openCDS[6], which can process (structured) data and assist the treating physician with choices of treatment given current states of patient health and clinical guidelines. Most CDS solutions can ingest such information as diagnosis, staging, and prior treatments for a given patient and propose an individualized therapy plan.

CDS enables standardization of treatment pathways and ensures accuracy in decision-making by offering evidence-based recommendations. This module will be even more useful when MDT members consider various options in treatments or are concerned with infrequent complex cases. More precisely, CDS tool may help decide on appropriate treatment pathways through clinical data analysis and suggestion of evidence-based protocols that can be reviewed by the MDT members.

Patient Consent and Data Privacy

To protect the data of patients and adhere to various regulations such is GDPR.

- Strong data protection policies enabled with secure authentication through OAuth and RBAC/ABAC (Role-Based Access Control/Attribute-Based Access Control) and consent management shall be provided for patients. Since most of the sharing will be across systems, or even across borders, consent shall be managed explicitly.
- The system shall audit interactions and produce log, tracing every access and modification of the data, providing full accountability; it shall ensure that sensitive patient information is accessible only to authorized MDTB members.

Terminology Services and Data Coding

To ensure clinical terminology is standardized among MDT members for clearer understanding, thereby bringing consistency in data interpretation. • Implementation: It shall implement a terminology server that will integrate the coding standards in the form of ICD and ICD-O3 for diagnoses and ETIP (Grekk clinical practice procedures) the Greek DRG (Diagnosis-related group). Such a server

[6] https://www.opencds.org/

automates coding consistency and minimizes manual entry errors, thereby standardizing the clinical language across the platform.

Terminology services ensure that MDT interpret and react consistently to data. This allows more accurate and rapid decision making on a patient's diagnosis during MDT meetings.

3 Vision of the EEHRxF-supported service

MDTs are essential to cancer care since they provide a multidisciplinary setting for comprehensive case assessments. Their goal is to offer evidence-based, individualised treatment programs to cancer patients by considering the complex nature of their illness. Tumour boards should be operationally effective, patient-centred, and scientifically sound to optimise patient advantages. To achieve the greatest benefit for patients, tumour boards must adopt the following principles:

Multidisciplinary Collaboration:

- Diverse Expertise: Include specialists across all relevant fields, such as medical and radiation oncology, surgery, pathology, radiology, genetics, and psychosocial care.
- Defined Roles: Assign clear responsibilities to each member to ensure comprehensive evaluation and efficient use of time.

Patient-Centred Decision-Making:

- Individualised Plans: Tailor recommendations to the patient's unique clinical and personal circumstances.

Evidence-Based Approach:

- Utilise the latest clinical guidelines, research findings, and diagnostic tools to inform decisions.
- Leverage molecular and genetic insights to personalise treatment.

Integration of Advanced Technology:

- Data Sharing Platforms: Use interoperable electronic health records (EHRs) to ensure seamless access to patient information.
- AI and Analytics: Employ predictive tools to analyse data and support decision-making.
- Telemedicine: Facilitate virtual tumour boards for patients in remote areas to ensure equitable access to expertise.

Note on Virtual Tumour Boards: Virtual boards bring lower cost (having many people in the same room assessing patient data for the first time is expensive. Virtual allows them to asses data before the meeting when they have time and use meeting to confirm that all are in agreement), easier planning (it's harder to find free room for all and free time for every member. Virtual enables them to have meeting anywhere and at any time), faster decision (case assessment is asynchronous. Instead of spending ~30 minutes per case combined in the meeting, doctors are spending 30 minutes when they can and on their own and

spend 5~7 minutes to confirm and agree during the meeting. Such approach enables them to assess more cases per meeting and prevent patient to unnecessary wait for the next board meeting just because meeting allocated time ran out).

Standardised Governance and Operations:

- Clear Frameworks: Establish operational guidelines, including meeting schedules, documentation standards, and decision-making protocols.
- Consensus Building: Employ structured procedures to resolve differing opinions and ensure unified recommendations.

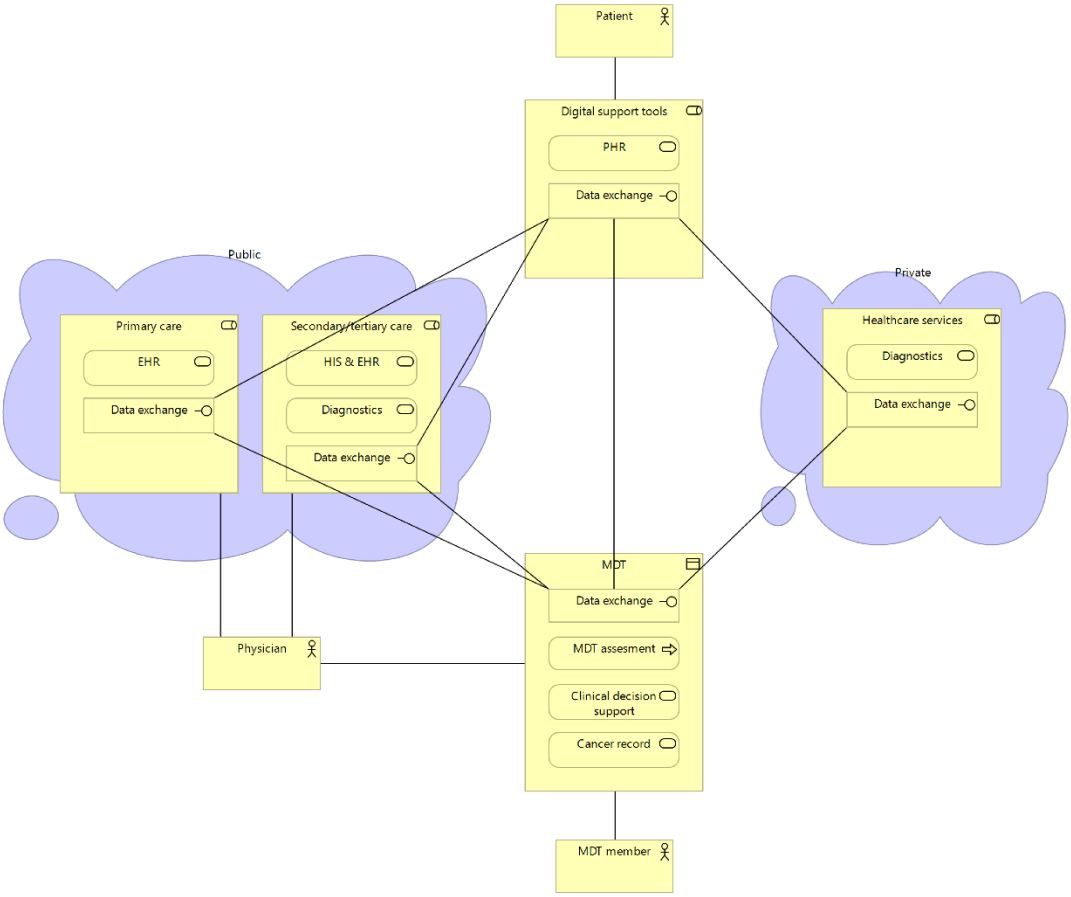
Transparency and Communication:

- Communicate the outcomes of tumour board discussions in a clear, accessible manner, including the reasoning behind recommendations.
- Provide opportunities for patients and families to ask questions and seek clarifications.

Capacity Building and Continuous Improvement:

- Education and Training: Regularly update tumour board members on advancements in cancer care.
- Outcome Monitoring: Evaluate the impact of tumour board decisions on patient outcomes to refine processes.

The following high-level schema depicts envisioned MDT service and its role and interaction within healthcare.



It is highly desired that systems are interoperable and integrated enabling secure and immediate access to data, either for MDT to propose or decide on treatment, or for treating physician and patient to access MDT decision.

Cancer is a complex condition and almost all available data is beneficial for the MDT assessment and decision.

This means that MDT system shall be integrated with:

- primary care systems to retrieve EHR data
- secondary and tertiary care systems to retrieve EHR and diagnostics data
- private service providers for retrieving diagnostics data
- patient systems to retrieve PHR data

Data from those systems should contextual, as without context data value is lower and there is risk of misinterpretation.

Almost all data required for the MDT processes can be mapped to European EHRxF. Deciding to implement EEHRxF in the MDT will also enable MDT to utilize EHDS. Such decision will also lower the effort of healthcare providers, as implementation of the

EEHRxF is also beneficial for their own reasons such is preparation for the EHDS compliancy.

EHR and PHR data

European Patient Summary contains all information that MDT needs from electronic health record. It provides important health information about patient, current and historical status. Thus, it is sufficient and suitable for the MDT integration with primary, secondary and tertiary electronic health records and systems shall utilize it for this purpose.

HIS data

After hospitalization patient is discharged from the hospital and hospital provides discharge information. This information is useful and needed for the MDT assessment as it contains the reason for hospitalization, performed procedures, and provided treatment. Additionally, it contains patient condition and status (disposition) at discharge, as well as follow-up care guidelines.

EEHRxF defines European Hospital discharge reports which is suitable format to share information with MDT, and this format shall be used to retrieve data from the hospital information system.

Diagnostics data

The MDT decision is largely driven by results of various diagnostics procedures. Such procedures are various laboratory examinations, radiology examinations, and clinical assessments. Again, the EEHRxF is sufficient and suitable.

The MDT shall utilize

- the European Laboratory results and reports format for retrieving data from hospitals laboratory diagnostics and from private diagnostic centers.
- The European Medical imaging studies and reports format for radiology diagnostics from hospitals radiology diagnostics and from private diagnostic centers

MDT outcome

The result of an MDT assessment is decision or recommendation of treatment. The result shall contain assessment report and plan of care information.

The EEHRxF does not provide any suitable dataset and/or specification.

The future work will look at and assess the HL7 C-CDA specifications for CarePlan document and Consultation Note document. Those will be used as starting discussion point with stakeholders. The process will collect required dataset and propose additional EEHRxF based on HL7 FHIR document paradigm for documenting and sharing the MDT decision. As MDT can be seen as a consultation with an expert, the proposed format will be suitable also for other types of clinical consultations as well as for 2nd opinion.

Cancer record

The MDT needs to maintain their own record for various reasons which include legal requirements and analytics.

The cancer record contains data assessed during decision making. Such data is introduced to the system via integrations as EEHRxF documents – patient summary, laboratory/radiology reports and clinical images, so cancer record is a document repository maintaining record as a set of documents that belongs together.

Due to use of the EEHRxF, which are structured and properly clinically coded documents, the cancer record shall also enable data operations on fine grained level, fulfilling various requirements for analytics and precise queries over data and smallest data points.

4 Recommendations for relevant asset bundle

[Provide recommendations of steps to follow, precautions to be taken, material to be produced, or else, in the 6 interoperability levels outlined by the eHealth Network's refined eEIF (ReEIF).

Below we display two models that display how these 6 interoperability levels can be applied to (i) alignment activities between organisations, and (ii) stakeholders.]

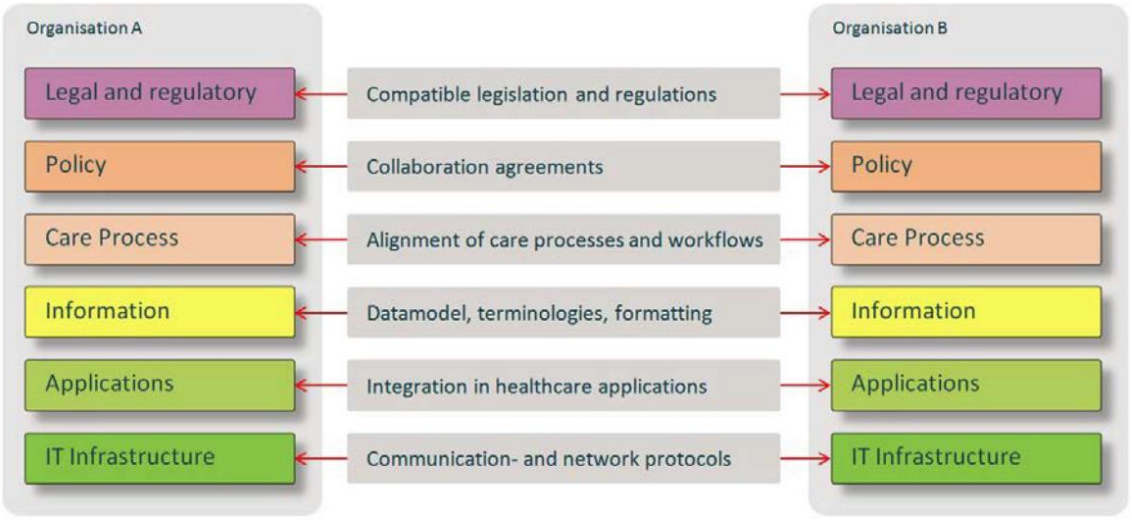


Figure 9 Refined eEIF (ReEIF) model – alignment activities between organisations

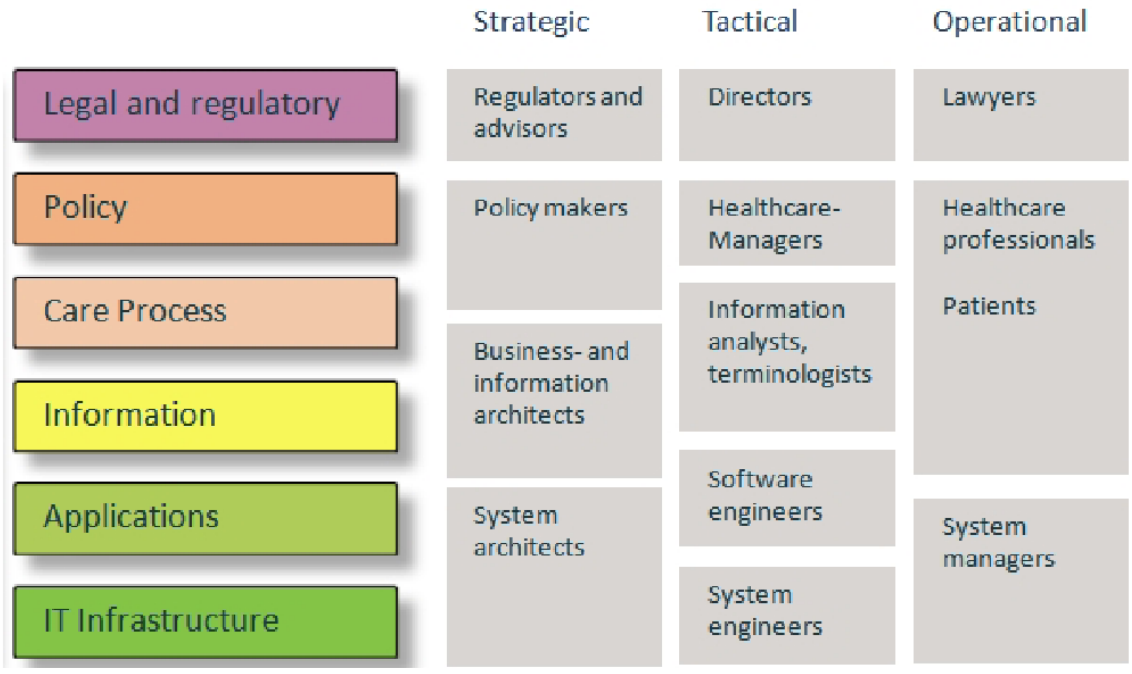


Figure 10 Refined eEIF (ReEIF) model – stakeholders

4.1 Legal and regulatory

Patient Consent & Privacy

- **Informed and written consent**: Required before discussing the patient's case in the Multi-Disciplinary Team (MDT). The question arises as to whether the person to whom the patient grants consent is only the treating physician or all members of the team especially in cases where a member of the team is not a member of the hospital staff.
- **Anonymization and data protection**: Patients identity should not be known during MDT discussions, and confidentiality and anonymity must be maintained.
- **EHDS and GDPR compliance**: Ensures compliance with EHDS for secure data interoperability and with GDPR for protecting patient privacy.

Duty of Care & Physician Responsibility

- **Individual accountability of MDT members**: Each member of the medical team has a duty of care and responsibility for their decisions within their area of expertise.
- **Timely communication of treatment plan**: The final treatment plan is shared promptly with the treating physician and the patient.
- **Shared liability**: Physicians contributing to treatment recommendations may be jointly liable in cases of medical negligence.

Differing Opinions on Treatment

- **Documentation of disagreements**: All differences of opinion among physicians are recorded in the patient's MDT report.
- **Discussion of alternative treatment options**: Alternative treatments are discussed with the patient, ensuring their involvement in the decision-making process. The patient is informed after the completion of the MDT session by his treating physician.

Data Interoperability & Security (EHDS)

- **Electronic Health Records (EHR)**: Establishment of interoperability of EHR systems for secure and immediate access to patient data by medical professionals.
- In Greece, there are in principle fragmentary regulations concerning interoperability, which mostly establish more than one competent body for interoperability issues. The National Interoperability Framework, which directly refers to basic principles of interoperability, is not binding. It follows from the above that there are obvious legal gaps and weaknesses in national law in the area of interoperability, which the EHDS is expected to resolve.
- The medical record should be interoperable and compliant with common specifications.
- **Data encryption**: All information must be encrypted to protect patient privacy against third parties.

- **Ensuring consent for access**: Access to data is permitted only with the patient's explicit consent.

Participation of oncology patients

- The Greek regulation on oncology councils refers to a specific category of patients. It is questionable whether it should refer to all oncology patients.

4.2 Policy

To ensure the effective functioning of MDT, a collaboration between relevant stakeholders and organisations is crucial. The selection of these organisations should be based on specific criteria that ensure comprehensive, patient-centred care and efficient decision-making. Below is an analysis of the suggested types of organisations that could be involved.

1. **Healthcare providers:** hospitals, oncology clinics, diagnostic centres
2. **Healthcare professional societies:** nonprofit scientific organisation dedicated to promoting and facilitating the exchange of up-to-date information and ideas concerning clinical research, prevention, diagnosis, and treatment of cancer.
3. **Research and academic institutions:** universities, cancer research institutes.
4. **Patient advocacy organisations:** cancer patient associations
5. **Government and regulatory bodies:** Ministry of Health, Regional Health Authorities
6. **Technology providers:** health IT companies, telemedicine providers
7. **Pharmaceutical companies**
8. **Organisations that perform cancer screening and early detection**

The overarching purpose of this collaboration should focus on improving cancer care quality, which will be achieved by ensuring a multidisciplinary approach covering aspects of early detection, diagnosis, treatment, and follow-up while safeguarding support at a policy and regulatory level. Furthermore, the establishment of this collaboration is crucial for the promotion of a person-centred perspective that will prioritise patients' needs and contribute to the enhancement of care efficiency and the improvement of health outcomes. Collaboration will build trust among healthcare providers and patients, as responsibilities will be clearly defined, and accountability will be shared. Also, this environment will encourage research, innovation, and the adoption of best practices, ultimately advancing the field of oncology.

Specific criteria should be defined to safeguard the smooth and effective collaboration of the abovementioned organisations. Below are the key cross-organizational criteria for collaboration, incorporating essential elements such as role allocation, decision-making, capacity building, consensus-building, and governance.

1.Shared vision and goals

All participating organisations must align on the overarching objective of delivering comprehensive, patient-centred cancer care. This includes a commitment to improving patient outcomes through collaborative decision-making.

2. Clear communication channels

Establishing structured pathways for seamless and secure communication.

3. Defined roles and responsibilities

Clearly defining the roles and contributions of each stakeholder group.

4. Decision-making procedures

Implementing protocols for evidence-based decision-making.

5. Consensus procedures

Using structured methods such as moderated discussions or Delphi techniques to build agreement among stakeholders.

6. Capacity-building activities

Offering knowledge exchange opportunities and access to tools, technologies, and research findings while promoting stakeholder collaboration.

7. Standardized governance framework

Establishing standardised governance structures to guide the functioning of tumour boards, including meeting schedules, documentation protocols, and data security measures.

4.3 Care process

One critical aspect of MDTs' effective operation is aligning the care process to achieve person-centered care. This involves designing Integrated Care Pathways (ICPs) and Shared Workflows to ensure effective communication, information exchange, and stakeholder decision-making.

ICPs are structured multidisciplinary care plans that outline the essential steps in the care process for specific patient groups. In the context of MDTs, ICPs need to ensure that care is coordinated, consistent, and patient focused. The key components that should be taken into consideration include:

- The definition of care milestones, through identifying the patient's cancer care journey, from diagnosis to treatment and follow-up.
- The assignment of roles among the organisations and the involved professionals for specific tasks at each stage.
- The standardisation of approaches based on best practices and evidence.
- The establishment of benchmarks for care quality and patient health.
- The inclusion of key performance indicators (KPIs) to measure the effectiveness of the care pathway.

Shared workflows represent the practical implementation of ICPs by specifying how information, tasks, and responsibilities flow between organisations. This is necessary to ensure that all MDT members are aligned and informed at every step, to minimise delays and redundancies, speeding up the care process and providing patients with seamless, high-quality care tailored to their needs.

These recommendations aim to ensure that processes are tracked and managed efficiently and that all required information is available timely for evidence-based decision-making. Hence, the following elements should be determined:

- It is crucial and should be prioritised to identify the data required at each stage of the care process. This data includes, for example, patient medical history and diagnostic results, genomic or molecular testing outcomes, treatment options, and past responses to therapy. Data formats should also be standardised for better compatibility across systems and stakeholders.
- It is important to create workflow diagrams that highlight dependencies, timelines, and critical checkpoints to manage all the processes needed throughout the care pathway more efficiently. Identifying where clinical decisions are required and standardising decision-making through protocols and consensus meetings is also important. This will ensure accountability and prevent task overlap or duplication.
- Digital tools could facilitate monitoring workflows and help healthcare professionals adhere better to timelines and milestones.
- Establishing structured methods for communication, such as real-time messaging, email summaries, and periodic meetings, should be a critical component for supporting comprehensive patient care management

4.4 Information

To ensure that the new service operates with high levels of data interoperability and supports effective information exchange, it is crucial to adopt a well-defined asset bundle that standardizes the data model, data elements, and their relationship to relevant healthcare terminologies. This approach will enhance the accuracy and consistency of information shared across different systems and stakeholders.

Functional Description of the Data Model:
The data model for the new service should be designed to support comprehensive ***patient care management*** *by structuring data in a way that enables easy integration with external systems. This includes:*

- ***Modular and Distributed Architecture:*** *The data model should be flexible and modular, allowing for the addition of new components or functionalities*

as the service evolves. For example, different patient categories (e.g., chronic diseases, telemedicine) may require specialized data elements.

- ***Relational Structure:*** *The model should use a relational structure to connect different data types, such as patient demographics, clinical records, treatment plans, and care outcomes, ensuring that all relevant information is accessible in real-time for decision-making.*

Data Elements (Concepts and Possible Values):

To promote interoperability and ensure consistency across systems, the data elements should adhere to ***standardized terminologies and value sets****. Key recommendations include:*

- ***Use of Standard Terminologies:*** *Adopt widely accepted healthcare terminologies such as* ***SNOMED CT*** *(Systematized Nomenclature of Medicine – Clinical Terms) and* ***ICD-10/11*** *(International Classification of Diseases) to define medical conditions, treatments, and patient characteristics. This will ensure that data elements are recognized and understood across different systems. Other standard terminologies that apply to the oncology domain are ICD-O, ICCC-3 and ORPHA Codes for rare cancers.*
- ***Well-Defined Concepts and Value Sets:*** *Each data element (e.g., diagnosis, medication, lab results) should be accompanied by a clearly defined concept and possible value sets. For example, a "diagnosis" field would contain a list of standardized diagnosis codes from ICD-10/11, while "medication" would refer to a controlled list of pharmaceuticals from a database such as* ***ATC*** *(Anatomical Therapeutic Chemical classification system).*
- ***Metadata and Annotations:*** *Each data element should include metadata and context, such as timestamps, healthcare provider details, or device information, ensuring accurate data traceability and quality management.*

Linking of Data Elements to Terminologies:

To ensure **semantic interoperability**, it is essential that data elements are mapped to relevant terminologies and coding systems. This can be achieved through:

- **Unified Coding Standards:** All data elements should be binded to internationally recognized standards (e.g., SNOMED, ICD, LOINC) to facilitate seamless data exchange across healthcare providers and systems. These bindings will also ensure that data can be shared, aggregated, and analyzed without the risk of misinterpretation.
- **Interoperability Frameworks:** The new service should adopt interoperability frameworks based on IHE Integration profiles and international standards such as **HL7 FHIR,** which provides a standard for exchanging healthcare information electronically. This will allow healthcare providers and IT systems to access, manage, and use data elements consistently across platforms, adhering to EEHRxF to support further use cases.

Recommendations for Implementation:

- **Data Governance:** Establish strong data governance policies to ensure the consistent use of terminologies, value sets, and data mappings across the system. This includes regular updates to align with new medical standards and practices.
- **Terminology Management Tools:** Use terminology management systems to automate the process of mapping data elements to standard terminologies, ensuring consistency and accuracy.
- **Training for Stakeholders:** Ensure that healthcare professionals, IT developers, and data managers receive training on the importance of standardized data use, coding, and interoperability to facilitate smooth transitions and system adoption.

4.5 Applications

At this level, the focus is on ensuring seamless **exchange of medical information** between healthcare information systems, as well as integrating that information into **user-friendly applications** that support the needs of all stakeholders. This requires careful consideration of communication standards, data integration, and usability.

Handling Exchange of Medical Information:
To facilitate efficient and secure exchange of medical information, the new service must adopt widely accepted **communication standards** that ensure interoperability between different healthcare information systems. The following recommendations are key:

- **Adoption of HL7 FHIR:**

The service should implement the FHIR standard, which is increasingly becoming the global norm for healthcare data exchange. FHIR simplifies the process of importing and exporting medical information by using **RESTful APIs**, which support the transfer of data between various platforms and systems. This will allow healthcare providers to retrieve patient information in real time and in a secure, standardized format, regardless of the originating system. HL7 FHIR implementation guides should build on top of EEHRxF FHIR implementation guides to be developed by Xt-EHR project.

- **Use of HL7 Messaging Standard:**

Along with FHIR, the **HL7 (Health Level Seven)** standard should be integrated into the system to enable comprehensive data exchange. HL7 support the transmission of clinical, administrative, and financial data across various healthcare environments. This standard will facilitate the secure exchange of **structured clinical data**, ensuring that both sending and receiving systems maintain consistency.

- **Data Security and Privacy Protocols (GDPR Compliance):**

Ensuring compliance with GDPR and other relevant data protection regulations is essential when handling the import and export of sensitive medical data. This includes implementing **encryption protocols** for data in transit and at rest, as well as ensuring that patients have control over who can access their information.

Technical Specifications for Information Transport:
The technical specifications at this level should ensure that the flow of medical information between systems is both secure and efficient. This can be achieved by adopting the following technical approaches:

- **RESTful APIs** for real-time data retrieval and interaction. These APIs should be designed to allow third-party applications (e.g., Electronic Health Records, remote patient monitoring tools) to interact with the healthcare system seamlessly.
- **OAuth 2.0 and OpenID Connect:** These are recommended for authentication and authorization, ensuring that only authorized users and systems can access sensitive health information during the import/export process.

Integration of Exchanged Information in User-Friendly Applications:
A crucial aspect of this process is not only ensuring that information is exchanged between systems but also that it is integrated into **user-friendly applications**. For this purpose, the following strategies should be adopted:

- **Intuitive User Interfaces (UI) and User Experience (UX) Design:** The applications built around the service must focus on ease of use for all stakeholders—patients, healthcare professionals, and administrators. This includes designing dashboard views for healthcare professionals that summarize patient data and provide actionable insights. For patients, applications should offer easy access to their medical records, real-time communication with healthcare providers, and clear tracking of health data (e.g., monitoring chronic conditions).

- **Data Visualization Tools:** To help healthcare professionals and patients make sense of the imported data, applications should include advanced data visualization tools, such as **graphs, charts, and trend analysis**, particularly for patient health records and treatment progress. This will improve decision-making and patient engagement.

- **Seamless Integration with Existing Systems:** The new service must be capable of integrating with existing **Electronic Health Records (EHRs), Personal Health Records (PHRs), and Clinical Decision Support Systems (CDSS),** without requiring a complete overhaul of legacy systems. This will make adoption smoother for healthcare institutions and reduce the need for extensive retraining.

- **Interoperability with Wearable and IoT Devices:** To ensure that patients can contribute real-time health data (such as vital signs, activity levels, or glucose readings), the service should support integration with **wearables and Internet of Things (IoT) devices**. This data should be securely imported into the system, processed, and displayed in a way that is both meaningful and actionable for healthcare providers.

Recommendations for Implementation:

- **Pilot Testing for Communication Standards:** Before full implementation, conduct pilot tests to ensure that standards work as expected in the real-world healthcare environment, addressing any compatibility issues with existing systems. It is recommended to organise MDT projectathons to enable testing and formal testing prior to implementation.
- **User-Centered Design Approach:** Engage users (patients, professionals, and developers) in the design and testing process to ensure that the applications meet their needs and expectations in terms of usability, accessibility, and functionality. This is the co-creation approach proposed by XpanDH COD methodology.
- **Continuous Updates:** Given the rapid pace of technological advances, it is critical to implement a system that can evolve and scale easily. Regular updates should be scheduled to ensure continued alignment with emerging standards and technologies.

4.6 IT infrastructure

1. **Communication and Network Protocols**:

The infrastructure should support a range of network and communication protocols that ensure secure and consistent data flow between systems. This includes:

- **RESTful APIs** for efficient real-time data exchange and interaction across systems, particularly for patient records and clinical data.
- **Authentication and Authorization Standards** such as OAuth 2.0 to ensure that only authorized users can access sensitive health data.

2. **Data Storage and Backup Solutions**:

The platform requires reliable storage solutions to handle large volumes of medical data, including imaging, test results, and patient histories. Programmers should focus on:

- **Scalable Database Engines**: Databases like PostgreSQL or MongoDB can support structured and unstructured data formats, allowing for flexible data handling.

- **Regular Backup and Recovery Systems**: Automated backups and disaster recovery solutions are critical for ensuring data availability and resilience against potential data loss.

3. **Compliance with Interoperability Standards**:

Interoperability standards must be implemented at every level of the IT infrastructure. This includes:

- **HL7** standards (FHIR and or CDA) for structuring and exchanging healthcare information.
- **LOINC, ICD-10, ICD-O-3, SNOMED CT and ATC** coding standards to maintain consistency in medical terminology, enabling reliable data exchange across different healthcare systems.

4. **Scalability and Flexibility**:

The infrastructure should be designed to adapt to future needs, supporting both horizontal (adding more servers) and vertical scaling (increasing the capacity of existing servers) as data volumes grow. Cloud-based solutions, hybrid systems, or on-premises options can be evaluated based on the healthcare organization's requirements.

5. **Data Privacy and Security Measures**:

Compliance with privacy regulations such as GDPR is non-negotiable. This requires:

- **Encryption** for data both at rest and in transit.
- **Attribute-based access control (ABAC)** to restrict access to patient data based on user roles, ensuring that only necessary personnel can access sensitive information.
- **Audit Logs** for tracking data access and modifications, which help maintain accountability within the system.

6. **Network Redundancy and Load Balancing**:

For a reliable MDT platform, the network infrastructure should incorporate redundancy and load balancing to handle high traffic volumes without disruption. Load balancing distributes requests across multiple servers, ensuring that no single server is overwhelmed, thus maintaining performance and uptime.

Annex 3

Report and recommendations document prepared by Working group: Electronic prescription, electronic dispensation and electronic product information (3C-3P-EPD).

Double click to open

Community of Doers Working Group Report and Recommendations

ePrescription/ eDispensation/ eProduct Information for patients

[eD – eP] + ePI

06 December 2024

Scope

This document presents all collected contributions from the Community of Doers (CoD)[7] regarding the idealisation, discussion, and recommendations for formalisation of augmentation and evolution of the existing service of ePrescription / eDispensation [eP-eD] into a richer adoption domain provisionally called [eP-eD] + ePI (electronic Product Information: "ePI") as defined by EMA–HMA-EC[8]). This augmented service incorporates contributions from UNICOM project, Gravitate-Health project, and other experts' views through a process of co-creation with patients, professionals, and IT developers (programmers) following the logic of the CoD set forth by XpanDH. This report captures in a snapshot the ongoing discussions for the purpose of enabling their continuation in legacy initiatives, providing description and recommendations for ultimately permitting the piloting, testing and deployment of the proposed augmented [eP-eD] + ePI service.

Goal of Working Group

The XpanDH Community of Doers employs a methodology of balanced co-creation among multiple stakeholders, as outlined in its foundational principles. To facilitate this collaborative approach, the CoD is organized into topical Working Groups (WGs). These WGs bring together teams of eHealth actors with a primary objective: to explore and deliver recommendations for evolving existing services within the context of the European Health Data Space (EHDS). This includes identifying new data categories for adoption or proposing new approaches to specifying existing priority data categories.

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[7] The Community of Doers and Co-creators brings together implementers and end-users of new and existing solutions, IT developers and vendors/suppliers; patients and healthcare professionals, in a 3C-3P community (co-creation community of Patients, Professionals and Programmers). The scope of this open community is to find use cases and business needs that would be reused in practice domains of the European EHR (Electronic Health Record) Exchange Format in a bottom-up co-creation approach.
[8] See *Electronic product information for human medicines in the EU: key principles* https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/electronic-product-information-human-medicines-european-union-key-principles_en.pdf

Table of abbreviations

eD	eDispensation
EMA	European Medicines Agency
eP	ePrescription
ePI	Electronic Medicinal Product Information (required to provide for patients)
EU	European Union
EUDI Wallet	European Digital Identity Wallet
FHIR	Fast Healthcare Interoperability Resources
HCP	Healthcare professional
IDMP	Identification of Medicinal Products
IPS	International Patient Summary
IT	Information technology
LLM	Large Language Model
OTC	Over-the-Counter
POM	Prescription-Only-Medicines
PS	Patient Summary
NCA	National Competent Authorities

1 Background

1.1 Context and healthcare challenge

The European healthcare landscape is increasingly characterised by the movement of citizens and cross-border interactions, necessitating robust and interoperable eHealth services. Central to this evolution are electronic Prescription (ePrescription - eP) and Dispensation where the user is (eDispensation - eD). Under EHDS primary use ePrescription – eDispensation [eP – eD], can facilitate seamless issuance and fulfilment of medical prescriptions across member states. Despite the establishment of these services, significant challenges persist, particularly concerning safe use of medicines and the provision of comprehensive drug information to patients in their chosen language during cross-border dispensations.

Current ePrescription and eDispensation [eP - eD] services primarily focus on the electronic transfer and verification of prescription data for dispensation at the recipient preferred place. However, [eP-eD] often fall short in delivering essential drug-related information, such as usage instructions, measuring dosage, observation of potential side effects, and interaction warnings, in a manner that is both accessible and understandable to patients when navigating healthcare systems in different linguistic, cultural and health literacy contexts. These challenges not only hamper patient understanding and adherence but also elevate the risk of medication errors, undermining patient safety and the overall effectiveness of cross-border healthcare provision.

The proposed augmented service, termed [eP-eD] +ePI (ePrescription-eDispensation + eProduct Information for patients)[9], aims to bridge this interoperability challenge by integrating multilingual drug information, i.e., ePI into the existing [eP-eD] framework. This enhancement is particularly critical for translations, meeting mobile and displaced populations' needs such as individuals relocating due to geopolitical conflicts (e.g., refugees), who require access to accurate and comprehensible medication information in another (EU) language of choice complementing language of jurisdiction where dispensation takes place . By providing regulatory information and translated medicinal product information (digital or leaflet) at the point of dispensation, the service ensures that patients receive necessary information to manage their medications safely and effectively, irrespective of their location within the EU.

Key assumptions underpinning this initiative include the prior resolution of country-specific peculiarities, the balanced distribution of national and cross-

[9] The term ePI "electronic product information for medicines" is used in alignment with the key principles on electronic product information for human medicines in the EU, produced jointly by the European Medicines Agency (EMA), Heads of Medicines Agencies (HMA) and the European Commission in 2020.
Retrieved from: https://www.ema.europa.eu/en/news/key-principles-use-electronic-product-information-eu-medicines

border responsibilities, and the establishment of essential infrastructures such as International Patient Summary (IPS), patient identification and healthcare professional (prescriber) identification. Additionally, the project operates within the framework of the European Health Data Space (EHDS), adhering to its standards and format specifications to ensure seamless integration and interoperability across member states. Finally, for the purpose of the first version of this document, the focus is on adding value for the user of medicines, and dispensation of ePrescriptions mainly via of pharmacies serving the public. Further expansion can address two distinct aspects: hospital prescriptions dispensed in pharmacies serving patients—such as community pharmacies operated by hospitals—and online pharmacies, which primarily focus on medication dispensation and introduce different considerations for Prescription-Only Medicines (POM) and prescription verification.
The scope of the augmented service "[eP - eD] +ePI" excludes online pharmacies and non-physical dispensations, focusing instead on augmenting the traditional, in-person medication dispensation to maintain clarity and manageability of the project. Furthermore, data security matters are seen as foundational for EHDS and excluded from this scope, allowing the working group to concentrate on the functional and informational aspects of the service without delving into the complexities of data protection protocols.
Augmenting the [eP- eD] services with ePI (electronic medicinal product Information)for patients entails several critical considerations:

- **Regulatory Compliance in Multiple Languages:** Ensuring that all regulatory information is available in a patient's preferred / chosen (EU) language, which is essential for mobile and displaced persons for safe use of medicines.
- **Privacy-Preserving Mechanisms:** Implementing strategies that safeguard patient privacy while providing necessary medication information.
- **Patient Safety and Transcultural Considerations:** Addressing patient safety by considering translation of key instructions, transcultural factors and variations in practice that may affect the understanding and use of medications.

Additional factors to be mindful of may include:

- **Prescription Label Standardisation:** Considering the potential benefits of standardising certain elements of the text on prescription labels—the sticky labels added by pharmacies during dispensing. Standardised expressions can facilitate programmed translations and enable the provision of printed, personalised instructions in the patient's language of jurisdiction or choice. This approach may contribute to decreasing medication errors. However, it is important to acknowledge that the creation and format of prescription labels are often part of national dispensing practices. Therefore, any recommendations should be sensitive to the acceptability of EU-wide standardisation in this area. A hybrid approach, combining standardised text where feasible with necessary free text, could be suggested to balance consistency and flexibility.

- **Language Support:** Assessing the need for the inclusion of additional languages, including extra-European ones, to accommodate the diverse linguistic needs of populations within the European region. Advanced technologies, such as trusted and safe artificial intelligence, may play a role in facilitating accurate translations, thereby enhancing understanding and compliance.
- **Cross-border Prescription Conditions:** Managing the length, type, and informational requirements of prescriptions issued abroad, ensuring that written information and electronic medicinal product information (drug e-Leaflets) are available in language of jurisdiction where dispensed (local) and the patient's chosen language, and maintaining adequate medication stock levels.
- **Security Concerns:** Protecting the system against cyberattacks to maintain the integrity and confidentiality of patient data.
- **IPS Standard Inclusion:** Integrating IPS standards for critical patient information, such as allergies, while allowing pharmacies to manage dispensation responsibilities based on available data and patient consent through opt-in/out mechanisms.
- **European Digital Identity Wallet (EUDI) integration:** Account for possible intersection with the upcoming EUDI Wallet, and more broadly the increasing availability of mobile solutions empowering patients.
- Increasing **availability of AI technologies** and digital solutions– and more specifically Large Language Models (LLM) – to provide explanation on treatment to patients and support to healthcare professionals (HCP).

By addressing these challenges, the [eP-eD] +ePI service aims to enhance the interoperability and functionality of existing eHealth systems, and support a thriving EHDS, ultimately contributing to safer and more efficient use of medicines, improved patient outcomes, increased medication adherence, and a more cohesive European healthcare ecosystem.

1.2 Relevant scientific knowledge

WHO reports that more than 50% of all medicines are prescribed, dispensed, or sold inappropriately worldwide[10], and OECD estimates that around 200,000 premature deaths annually in Europe relate to poor medication adherence[11]. The primary source of product information intended for patients is the paper leaflet[12] in the language of the jurisdiction where the medicinal product is dispensed. Distribution, production and dissemination of new/revised information is time-

[10] https://apps.who.int/iris/bitstream/handle/10665/67438/WHO_EDM_2002.3.pdf
[11] https://www.oecd-ilibrary.org/docserver/health_glance_eur-2018-en.pdf
[12] https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/product-information-requirements

consuming, costly, and information may not be up to date by the time the medicine is dispensed[13].

Empirical studies of medication management, use and information flows show complex, fragmentation and often broken chains of activity, largely due to lack of interoperability of processes and information flow. Medication information management is scattered, unavailable or not used, introducing risks of which the user may be unaware, including risk of errors[14], adverse events, disability, and even death[15]. ePrescriptions are in active use in many member states, offering convenience to meet citizens' medicine needs, cross-border availability, for patients, support to the prescriber, time-savings for the pharmacy, health systems overview and control with dispensed medication as well as supply chain and environmental considerations[16]. Digital tools for ePrescription, eDispensation (cross-border) and information about the medicinal product information (ePI) contributes to safe use of medicines, access to medicine at the point of need, and information about them coupled with convenience and more efficient resource use. Such tools and services are consistent with the aims of the EU Digital Single Market Strategy, and the European Health Data Space (EHDS) to support mobility, patient safety and a healthier Europe[17].

Cross-border ePrescription (eP), getting information about prescribed medicine from State A to State B and eDispensation (eD), getting information of dispensed medicine from State B dispensed and information sent back to State A to rescind the prescription helps drive quality of medication use practices domestically and for cross-border use. Usually, this service is referred to as [eP-eD][18]. By February 2023, nine EU countries have already shown some capability of cross-border health service – four actively exchange electronic prescription data (Croatia, Estonia, Finland, Portugal) and eight can exchange patient summary data (Croatia, Czech Republic, Finland, France, Malta, Portugal, Spain)[18]. By December 2024, this number increased to 14 countries[19].

Assessment of Cross-border ePrescription and eDispensation available between Finland and Estonia; it has been possible to have medication dispensed (purchase) from community pharmacies in Estonia using a Finnish ePrescription from 2019,

[13] Health Policy Partnership. Electronic product information ePI Securing the future for accessible delivery of medicine information through digitalisation. Report, 2024.

[14] Coiera, E., Aarts, J., & Kulikowski, C. The dangerous decade. *J Am Med Inform Assoc*, 2011, 19(1), 2–5.

[15] https://www.euda.europa.eu/publications/european-drug-report/2024_en

[16] Wang B, Manskow US. Health professionals' experience and perceived obstacles with managing patients' medication information in Norway: cross-sectional survey. BMC Heal Serv Res. 2024;24(1):68.

[17] https://ec.europa.eu/digital-single-market/en/news/communication-enabling-digital-transformation-health-and-care-digital-single-market-empowering

[18] Bruthans J, Jiráková K. The Current State and Usage of European Electronic Cross-border Health Services (eHDSI). J Med Syst. 2023 Feb 11;47(1):21. doi: 10.1007/s10916-023-01920-9. PMID: 36773082; PMCID: PMC9918835.

[19] eHDSI Monitoring Framework (KPIs), as of 9 December 2024. https://experience.arcgis.com/experience/77f459be23e545b48f46a79cfaf19423/page/1_1/

and for Estonian ePrescriptions to be dispensed in Finnish pharmacies from 2020[20]. Surveys of pharmacists' perspectives on ePrescriptions and electronic storing of prescriptions demonstrate that they are seen as providing benefits, convenience and safety for patients, cost-effectiveness and timesaving for a pharmacy, and opportunity to improve pharmacists' communication and relationships with patients and prescribers[21], [22]. Reported experiences from the Finland-Estonia's cross border ePrescription – eDispensation points to interoperability challenges, including: a) ambiguities or errors in cross-border ePrescriptions (e.g., use of abbreviations and typographical errors), b) different selection of active ingredients, strengths, package sizes, and dosage forms for eDispensation, c) practices on generic substitution (from mandatory – prohibited), d) language / translations since dosage instructions in cross-border ePrescriptions are written in the patient's native language, and not translated in the system[18, 20] or the required product information is in the language(s) of the jurisdiction of dispensation. Such challenges become obstacles or problems for a patient in need of the medication. The workload of pharmacists can increase if any of these challenges occurs[23]. Overall, the interoperability challenges also compromise medication safety.

To overcome barriers faced by users, providing access to information about medicines in their language of choice is crucial for ensuring good understanding. This includes enabling patients to monitor the effects of their medications, report symptoms, and recognize possible side effects or adverse events. Clear and understandable oral guidance from pharmacists or physicians, along with written medicinal product information provided at the time of dispensing, further enhance patient comprehension and safety.

[20] Jõgi R, Timonen J, Saastamoinen L, Laius O, Volmer D. Implementation of European Cross-border Electronic Prescription and Electronic Dispensing Service: Cross-sectional Survey. J Med Internet Res. 2023 Apr 4;25:e42453. doi: 10.2196/42453. PMID: 37014689

[21] Hammar, T., Nyström, S., Petersson, G., Rydberg, T. and Åstrand, B. (2010), Swedish pharmacists value ePrescribing: a survey of a nationwide implementation. Journal of Pharmaceutical Health Services Research, 1: 23-32. https://doi.org/10.1211/jphsr.01.01.0012

[22] Wang B, Manskow US. Health professionals' experience and perceived obstacles with managing patients' medication information in Norway: cross-sectional survey. BMC Heal Serv Res. 2024;24(1):68.

[23] Bruthans J, Jiráková K. The Current State and Usage of European Electronic Cross-border Health Services (eHDSI). J Med Syst. 2023 Feb 11;47(1):21. doi: 10.1007/s10916-023-01920-9. PMID: 36773082; PMCID: PMC9918835.

1.3 Outputs from relevant EC-funded projects and other initiatives

1. epSOS (European Patients Smart Open Services) and the Cross-Border Directive

The epSOS project, (2008 – 2013), was a pioneering EU-funded initiative aimed at facilitating secure and interoperable health data exchange across member states. Complementing this, the Cross-Border Directive (Directive 2011/24/EU) established the legal framework to support patients' rights to seek medical treatment in any EU member state, ensuring reimbursement under specific conditions. The epSOS project's advancements in interoperability and the Cross-Border Directive's regulatory provisions provide a critical foundation for enhancing [eP-eD] services. These outputs inform the working group's approach to ensuring seamless data exchange and regulatory compliance, particularly in the context of cross-border dispensations. Lessons learned from epSOS pilot implementations guide the development of robust, interoperable systems that cater to the diverse needs of EU member states.

2. myHealth@EU

myHealth@EU is an EU-funded initiative focused on empowering patients through access to their health data and enhancing the interoperability of eHealth services across Europe. The platform aims to provide patients with a centralized portal to manage their health information, facilitating better-informed healthcare decisions. myHealth@EU's focus on patient empowerment and data accessibility aligns closely with the working group's objectives to enhance patient understanding and safety through multilingual ePatient Information (ePI). The interoperability solutions developed by myHealth@EU provide a blueprint for integrating ePI into existing [eP-eD] frameworks, ensuring that patients can access comprehensive medication information in their chosen language across borders.

3. UNICOM (Understanding Commonalities and Improving Modularization for eHealth Interoperability)

UNICOM (2020-2025) is an EC-funded project dedicated to enhancing eHealth interoperability through the development of modular and standardized solutions. The project emphasizes creating patient-facing applications that streamline medication management and data exchange. UNICOM's patient-facing app exemplifies the integration of user-centric design with technical interoperability, a core principle of the working group's [eP-eD] +ePI augmentation. The ability to generate QR codes and manage substitution drugs enhances the functionality and usability of [eP-eD] services, ensuring that patients receive accurate and personalized medication information. The modular interoperability framework developed by UNICOM supports the seamless integration of ePI into existing systems, facilitating cross-border data exchange and enhancing overall service efficiency.

4. Gravitate-Health (Empowering and Equipping Europeans with Health Information for Active, Personal Health Management and Adherence to Treatment) Gravitate-Health (2020 – 2026) is an IMI-JU funded public-private partnership aimed at improving access to and understanding of electronic medicinal product information. The project focuses on the development of electronic medicinal Product Information (ePI) leaflets that are available in multiple languages, ensuring that patients receive comprehensible and culturally relevant medication information. Gravitate-Health's work on multilingual ePIs directly supports the working group's objective to provide regulator approved drug information in the patient's language of choice. The preparation of and adoption of HL7 FHIR standards for ePI (FHIR ePI IG) ensures that the augmented [eP-eD] +ePI service adheres to internationally recognized interoperability standards, facilitating seamless integration and data exchange. Gravitate-Health's emphasis on patient safety and comprehension through G-lens technology aligns with the working group's focus on enhancing patient understanding and medication adherence.

5. xShare

xShare (2023 - 2026) is an EC-funded project under the Horizon 2020 program, designed to facilitate the secure and efficient sharing of health data across Europe. The project aims to create a trusted environment where health data can be shared seamlessly among healthcare providers, researchers, and patients while ensuring compliance with data protection regulations. xShare's focus on secure and interoperable health data sharing is highly relevant to the working group's efforts to augment [eP - eD] services with ePI. The secure data sharing tools and interoperable platforms developed by xShare provide essential infrastructure that supports the safe exchange of multilingual ePI data across borders. Additionally, the patient control features align with the working group's emphasis on patient empowerment and privacy-preserving mechanisms, ensuring that patients have control over their medication information.

6. Xt-EHR (Cross-border Transversal Electronic Health Records)

Xt-EHR (2023 - 2026) is an EC-funded project aimed at developing inputs for the upcoming EHDS implementing acts that will impact cross-border and national level/domestic markets for enabling electronic health records (EHR) that facilitate the seamless exchange of patient health data across European member states. The project focuses on creating interoperable EHR systems that support both clinical and administrative processes, enhancing the quality and continuity of care for patients traveling or residing in multiple countries. Xt-EHR's efforts to create standardized and interoperable EHR systems complement the working group's goal of enhancing [eP-eD] services with multilingual ePI. The standardized EHR formats developed by Xt-EHR ensure that ePI data can be seamlessly integrated and exchanged across different health IT systems, facilitating efficient cross-border dispensations. Furthermore, the pilot implementations and best practices documented by Xt-EHR provide valuable insights and proven strategies that the working group can adopt to ensure the successful implementation and scalability of the augmented [eP-eD] +ePI service.

2 Interoperability challenge description

2.1 Overview

2.1.1 Title

Cross-border ePrescription/eDispensation eProduct Information Augmented Service [eP – eD] + ePI

2.1.2 Purpose

The new service aims to augment the value provided to patients by the existing ePrescription/eDispensation [eP - eD] service through the provision of drug information electronically at the dispensation point, termed as "electronic medicinal Product Information" (ePI). This augmentation, collectively referred to as "[eP - eD] +ePI]", seeks to enhance patient understanding and safety by delivering comprehensive medication management information directly to them when they receive their prescriptions, especially in cross-border contexts.

2.1.3 Relevance

Medical. The current [eP - eD] services lack comprehensive and understandable patient-friendly medication information at the point of dispensation across different EU member states, i.e. information in the language(s) of the jurisdiction (market) as well as information in the patient's language of choice. This challenge can lead to misunderstandings about medication usage, compromise patient safety from potential side effects and interactions, thereby increasing risk of medication errors, un-safe use and non-adherence. Prescriptions in another language (country A) can present a challenge when dispensing cross-border (country B). Furthermore, handwritten prescriptions can be difficult to read, leading to potential misinterpretation by the pharmacy. At the same time, information may be incorrectly transcribed from the prescription to pharmacy records or patient charts. By integrating [eP - eD] + ePI, patients (all users) will have immediate access to regulator's approved, clear and standardised medicinal product information, reducing errors that can occur when transcribing the prescription details into the pharmacy system and reduce any delays from the manual process of data.

Economic – health systems. Addressing this interoperability challenge can lead to significant cost savings for healthcare systems e.g. by reducing medication errors and addressing further issues in supply chain, medicine shortages and allergies (either mediated through the use of information in a Patient Summary (PS) or a limited responsibility from pharmacist).

Additionally, standardised ePI, already available in language of jurisdiction and complemented by the versions in a person's language of choice can streamline the dispensation process across borders, reducing administrative burdens and enhancing the efficiency of cross-border healthcare services. Improved patient adherence and safety can also contribute to better health outcomes, potentially lowering long-term healthcare costs.

Overall. The integration of ePI into the existing framework as "[eP - eD] +ePI" aligns with the European Health Data Space (EHDS) objectives to enhance interoperability, patient empowerment, and cross-border healthcare delivery. This augmentation supports a more holistic approach to patient care, ensuring that individuals receive not only their medications but also the necessary information to use them safely and effectively, regardless of where the dispensation occurs within the EU.

The service facilitates the seamless provision of ePatient Information across different EU member states, enabling patients to receive standardised drug information irrespective of where the prescription is filled.

EHDS priority categories addressed

(a) patient summaries (if applicable);

(b) electronic prescriptions;

(c) electronic dispensations.

2.1.4 Scale

- ***Cross-border.*** The service facilitates the seamless provision of ePI across different EU member states, enabling patients to receive standardised drug information irrespective of where the prescription is filled.

- *Citizens at home and on the move.* Caters to both residents and travellers within the EU, ensuring that all citizens have access to essential medication information whether they are at home or abroad.

2.2 Evolution process

2.2.1 Target group

Patients who receive prescriptions and/or wish to have their medication dispensed across different EU member states, particularly those who require drug information

in their chosen language that is different from the local language of the jurisdiction where dispensation takes place.

2.2.2 Stakeholders

- **Patients**: End-users who will benefit from the augmented [eP - eD] + ePI services.
- **Informal Caregivers**: Support network individuals who attend to the needs of a person with temporary or permanent limitations due to illness, injury, or disability.
- **Healthcare Professionals and Health Managers**: Physicians, pharmacists, and other healthcare staff involved in prescribing and dispensing medications.
- **Health Care Systems**: Entities responsible for the availability of medicines, managing costs, and ensuring consistent supply to meet patient needs.
- **Supply Chain and Access Stakeholders**: Manufacturers, wholesalers, distributors, and logistics providers involved in the production, transportation, storage, and distribution of medications. Their role is crucial in ensuring timely access to medicines and preventing shortages.
- **IT Developers/Programmers**: Responsible for developing and maintaining the technical aspects of the service, ensuring seamless integration and user-friendly interfaces.
- **Regulatory Bodies**: Organizations that ensure compliance with EU regulations and national laws, safeguarding patient safety and data privacy.
- **Pharmaceutical Companies**: Responsible for providing accurate drug information, updating ePI content, and ensuring easy access to any updates.
- **Health Insurance Payers**: Entities that may have an interest in improving medication adherence, reducing costs, and optimizing healthcare outcomes.
- **Data Standardisation Organisations**: Bodies that ensure consistent data formats, interoperability, and adherence to international standards, enhancing the efficiency and reliability of health information exchange.

2.2.3 Context of use

Patients traveling or residing in different member states will receive their prescriptions with accompanying electronic medicinal Product Information (ePI) in their chosen language. This ensures that patients access understandable information about their medications, including usage instructions, potential side effects, and interactions, regardless of where the dispensation occurs. Healthcare professionals across member states will use the system to issue and dispense prescriptions that systematically include multilingual drug information, enhancing patient safety and adherence in cross-border scenarios, as well as HCP's work in situations that require translation.

2.2.4 AS-IS situation

The current ePrescription/eDispensation [eP - eD] services in Europe does not consistently provide medicinal product information in the patient's chosen language at the point of dispensation, leading to misunderstandings and potential medication errors, especially in cross-border contexts.

2.2.5 TO-BE situation

The augmented [eP-eD]+ePI service provides comprehensive drug information electronically at the point of dispensation, in the patient's language of choice. This ensures clarity, understanding, and safer medication use across all EU member states during cross-border healthcare interactions.

By integrating ePI into the eP-eD framework, patients receive immediate access to up-to-date, authorized medicinal product information directly linked to their prescribed and dispensed medication. This includes detailed information on:

- **Dosage Instructions (Posology):** Clear guidance on the amount of medication to take, the frequency, and the duration of treatment.
- **Method of Administration:** Instructions on how to correctly administer the medication (e.g., orally, intravenously, topically).
- **Potential Side Effects:** Comprehensive lists of common and serious adverse effects, along with advice on what actions to take if they occur.
- **Contraindications and Precautions:** Information on conditions or situations where the medication should not be used or used with caution.
- **Drug Interactions:** Details about other medications, foods, or substances that could interact negatively with the prescribed drug.
- **Storage Conditions:** Guidelines on how to store the medication properly to maintain its effectiveness.
- **Additional Patient Support:** Links to multimedia resources such as instructional videos, diagrams, or patient support programs that enhance understanding.

Additionally, the augmented service includes a **dispensation confirmation or follow-up message in electronic form**, which is sent to the patient through their preferred communication channel (e.g., email, SMS, secure patient portal). This message reinforces key medication instructions and may provide:

- **Personalized Medication Schedules:** Tailored calendars or reminders to assist patients in adhering to their medication regimen.
- **ePI** – the version of regulator approved information in a chosen language, complementing language of jurisdiction, where dispensation takes place
- **Safety Alerts:** Notifications about important safety information, such as recalls or new contraindications.

- **Feedback Mechanisms:** Options for patients to report side effects or ask questions directly to healthcare providers.
- **Educational Materials:** Access to brochures, FAQs, or support groups relevant to their health condition or treatment.

By leveraging these digital tools, the augmented [eP - eD] + ePI service enhances patient empowerment and engagement. It supports medication adherence by making essential information readily accessible and understandable, tailored to individual needs and language preferences. This holistic approach promotes better health outcomes by reducing the risk of medication errors, improving patient satisfaction, and fostering a more informed patient population.

Key Benefits of the Augmented Service:

- **Safer use of medicines:** regulator approved information about the specific, dispensed medication is made available for the user at point of dispensation, complementing existing information in language of the jurisdiction.
- **Consistency Across Borders:** Standardized information ensures that patients receive the same high-quality information regardless of where they receive care within the EU.
- **Improved Communication:** Enhanced channels for patient-provider communication facilitate timely interventions and support.
- **Accessibility:** Digital formats overcome barriers associated with lost or damaged paper leaflets, ensuring information is always available when needed.
- **Environmental Impact:** Reducing reliance on printed materials supports sustainability efforts.

This envisioned system represents a significant advancement in how medicinal product information is delivered and utilized, prioritizing patient needs and leveraging technology to improve healthcare delivery across Europe.

2.2.6 Description of Necessary Steps to Move from AS-IS to TO-BE Situation:

1. **Requirement Analysis and Stakeholder Engagement:**

- Conduct workshops with stakeholders to gather detailed requirements capturing cross-border needs.
- Identify language preferences, translation needs, and other cross-border-specific factors such as local regulatory requirements, availability of generic drugs, product availability, OTC vs. POM, and cultural variations in pharmacy practices.
- Translation of key information on the prescription label with instructions /e.g. take with food, no milk or in the morning.

2. **Standardisation and Data Integration:**

- Align standardised data formats for drug information that support multilingual data taking advantage of FHIR ePI Implementation Guide, and ISO-IDMP standard).
- Integrate multilingual capabilities into the existing [eP - eD] systems to support the cross-border provision of medicinal product information and safe use of medicines.

3. **Development and Implementation:**

- Collaborate with IT developers to build the ePI module with robust multilingual support, exploring potential of LLM models.
- Ensure that the development process accounts for regional regulatory differences, medication availability, and cultural nuances in drug information presentation.
- Implement translation services and ensure accuracy and cultural appropriateness of translations.

4. **Testing and Validation:**

- Perform rigorous testing across different languages and cross-border scenarios.
- Validate the system with real-world cross-border use cases and gather feedback.

5. **Training and Deployment:**

- Train healthcare professionals on the new system features with an emphasis on cross-border usage.
- Roll out the service across member states in phases, prioritising high cross-border traffic areas.

6. **Monitoring and Continuous Improvement:**

- Monitor usage and gather cross-border-specific feedback for ongoing enhancements.
- Regularly review compliance with local regulations, medication availability updates, and cultural effectiveness of the ePI content.
- Regularly update drug information and translations to maintain accuracy and relevance.

2.2.7 Objectives

- **Enhance Patient Understanding:** Ensure that patients have access to information they can comprehend, to fully understand their medications by providing drug information and related regimen in their chosen language during cross-border interactions.
- **Improve Medication Adherence and Safety:** Reduce the risk of medication errors and improve adherence by making information accessible and comprehensible across borders.
- **Facilitate Seamless Cross-Border Healthcare:** Enable seamless healthcare experiences for patients traveling or residing in different EU member states.

- **Align with EHDS Objectives:** Support the European Health Data Space's goals of interoperability, patient empowerment, and integrated healthcare delivery, specifically within cross-border contexts.

2.2.8 Actors and Roles

Actor	Role
Physician	Physicians, as the creators of electronic prescriptions, play a critical role in ensuring that prescription information is documented clearly within the health record. Even without harmonised terminology being in use, physicians can facilitate the translation of prescription information by using clear and unambiguous language.
Pharmacist	Pharmacists are responsible for dispensing the correct medications (originally prescribed product or a biosimilar approved in the country) and facilitating patient access to the translated electronic Product Information (ePI). Their role ensures that patients receive clear and understandable information about their medications—in their own language and national context—which is crucial for adherence and safety, especially in cross-border contexts. While printing the ePI at the point of dispensation may not be an integral part of their service, pharmacists can provide access through alternative means. This could include offering a flyer with a QR code for digital access to the ePI or sending a link via an automated digital dispensing confirmation message, provided the patient's contact details are shared with and consented for use by the dispensing pharmacy.
Nurse	Nurses, when administering medications, provide essential information about the medicines they give to patients. They reinforce medication instructions, monitor patient responses, and serve as a point of contact for any questions or concerns the patient may have regarding their medication regimen. Nurses ensure that patients understand how to take their medications correctly and safely.
Patient	Patients are the end-users who benefit directly from the service. By receiving ePI in their chosen language, they can better understand information about their medications, leading to improved adherence and reduced risk of errors.
Support Network / Informal Caregiver	Support network individuals, such as family members or friends who, at the patient's discretion and with consent, need to know and contribute to observing medicine use. They assist patients with medication adherence, help monitor for side effects or adverse reactions, and communicate with healthcare professionals as needed to support the patient's health and well-being.

IT Developer	IT Developer IT developers ensure that the [eP-eD] +ePI system is technically robust, supporting multiple languages and enabling seamless data integration across different healthcare systems and member states. Additionally, they are responsible for implementing a dispensation documentation component to confirm the dispensation event, which currently does not exist. This component should aim at two receivers: 1. Patient Communication: Provide confirmation of dispensation to the patient, including any electronic Product Information (ePI) or prescription instructions. This enhances patient awareness and supports adherence. 2. Prescriber Authority Notification: Notify the prescriber or relevant authority to avoid duplication of dispensing, ensuring patient safety and regulatory compliance. This aligns with initiatives such as MyHealth@EU, aiming to improve cross-border healthcare services within the EU.
Regulatory Body	Regulatory bodies ensure that the service complies with all relevant EU and national regulations. Their oversight is crucial for maintaining legal standards and protecting patient data across borders.
Pharmaceutical Company	Pharmaceutical companies supply the necessary drug information that is included in the ePI as part of market authorisation of a product. Their role ensures that the information is accurate, up-to-date, and consistent across different languages and regions.
Standards Developing Organisation	These organisations work to standardise data formats, ensuring interoperability between different healthcare systems. This standardisation is essential for the seamless exchange of information across borders.

2.2.9 Preconditions

Standardised Data Formats: Adoption of unified formats for drug information and patient data across EU member states to support cross-border interoperability, such as the European Electronic Health Record Exchange Format (EEHRxF). Unique ID (ISO-IDMP) standardisation can help «fetch» the exisiting ePI in chosen language.

Multilingual Translation Services: Availability of reliable and accurate translation capabilities for multiple languages. This includes leveraging manufacturer-provided drug information in local languages where the product is marketed or dispensed, as these resources are reliable and continuously maintained.

Regulatory Compliance: Adherence to EU regulations and national laws related to cross-border eHealth services and data protection, including GDPR and relevant health data directives.

Technical Infrastructure: Implementation of robust IT infrastructure to support secure cross-border data integration, storage, and retrieval. This goes beyond just having digital identities and digital wallets (DW). While **Digital Identity** solutions and **Digital Wallets** (such as the EUDI Wallet) are crucial for authenticating users and managing consent, additional components are necessary:

- **Secure Data Exchange Protocols**: Utilize standardized protocols (e.g., HL7 FHIR) for the secure transmission of health data between systems.
- **Interoperability Standards**: Ensure systems can communicate effectively by adhering to interoperability standards across different healthcare IT systems in member states.
- **Patient Portals and Access Platforms**: Provide patients with platforms where they can securely access their health information, ePrescriptions, and ePI.
- **Data Security Measures**: Implement encryption, anonymization, and other security measures to protect patient data during transmission and storage.

In summary, while digital identity and digital wallets are essential components, a comprehensive IT infrastructure is required to facilitate seamless and secure data sharing across borders.

Digital Contact Information: Ensure the availability and accuracy of patients' digital contact information (e.g., email addresses, mobile numbers) to enable direct sharing of data, such as ePI and dispensation confirmations, with the patient.

Cultural and Linguistic Adaptability: Ensure that translations are not only linguistically accurate but also culturally appropriate and contextually relevant for different member states. This enhances patient understanding and engagement by respecting cultural nuances and health literacy levels.

2.2.10 Trigger

Action Triggering the Use of the New Service:
A patient with a prescription received in one EU member state seeks to have it dispensed in another member state, activating the provision of eProduct patient Information (ePI) in the patient's selected language at the point of dispensation.

2.2.11 Flow

General workflow

1. **Prescription Issuance:**
   - **Physician creates an ePrescription** within the [eP - eD] system, ensuring the accuracy and legality of the prescription.

- **Key information from the paper product leaflet (PIL)** is included to maximize compliance.
- **Patient Engagement:** The physician provides oral guidance, discussing the medication's purpose, usage instructions, potential side effects, and addressing any patient questions. This early interaction ensures the patient understands the treatment plan and feels comfortable with their medication regimen.
- **Feedback Opportunity:** At this stage, the patient can provide immediate feedback or express concerns, allowing the physician to clarify any misunderstandings.

2. **Data Transmission:**
   - **The prescription data,** including medication details and language preference, is securely transmitted to the dispensing pharmacy in a different member state.
   - **Pharmacist receives the ePrescription** and assesses the validity of the document.
3. **Patient Interaction at Dispensing:**
   - **Upon arrival,** the pharmacist confirms the patient's chosen language for receiving the ePI and any translated instructions.
   - **Pharmacist finds the medication and the corresponding electronic Product Information (ePI)** in the patient's chosen language.
   - **Generates a standardised prescription label ("sticky label")** with usage instructions, translated as necessary into the patient's chosen language.
   - **Provides additional guidance as needed,** possibly offering a flyer with a QR code for digital access to the ePI or sending a link via an automated digital confirmation message.
   - **Feedback Opportunity:** The pharmacist engages with the patient, addressing any additional questions or concerns, and collects immediate feedback on the clarity of the information provided.
4. **eDispensation:**
   - **Pharmacist dispenses the medication along with the ePI,** ensuring the patient fully understands the usage instructions and other relevant information.
   - **Ensures comprehension,** possibly by asking the patient to repeat key instructions or by providing supplemental educational materials.
5. **Continuous Improvement Feedback Loop:**
   - **Feedback Collection:** Patient feedback on the clarity and usefulness of the ePI, as well as the information provided by both the physician and pharmacist, is gathered during both the issuance and dispensing stages.
   - **Data Utilisation:** This feedback is used to refine and improve the service, including updating standardized instructions and enhancing communication strategies.

- **Stakeholder Collaboration:** Insights are shared among healthcare professionals, IT developers, and regulatory bodies to facilitate ongoing improvements in the system.

Workflow with Digital Wallet

1. **Prescription Issuance:**
    - **Physician Interaction:**
        - The physician creates an ePrescription using their system and, with patient consent, sends it directly to the patient's Digital Health Wallet.
        - Provides clear and unambiguous medication instructions, facilitating understanding and future translation.
        - Engages with the patient to discuss medication details and address any questions.
2. **Data Access and Consent:**
    - **Patient Control:**
        - The patient reviews the ePrescription in their Digital Wallet.
        - Grants access permissions to pharmacists when seeking dispensation.
3. **Dispensation:**
    - **Pharmacist Interaction:**
        - The patient presents their Digital Wallet (e.g., via QR code or secure digital token) at the pharmacy.
        - The pharmacist retrieves the ePrescription from the patient's wallet with consent.
        - Verifies prescription validity and accesses the ePI in the patient's chosen language.
        - Generates standardized prescription labels with translated instructions, which are added to the patient's Digital Wallet.
4. **Medication Dispensing and Information Sharing:**
    - **Dispensation Record:**
        - The pharmacist updates the eDispensation record in the patient's Digital Wallet.
        - Confirms that the patient understands usage instructions and provides additional guidance if needed.
        - Offers digital or printed materials (e.g., QR codes, links) for accessing the ePI.
5. **Patient Engagement:**
    - **Access to Information:**

- The patient accesses medication details and ePI through their Digital Wallet at any time.
- Receives notifications for medication schedules, reminders, and safety alerts.

Feedback can be securely communicated to healthcare providers or regulatory agencies, respecting privacy regulations.

2.2.12 Post conditions

- **Successful Provision of ePI:** The patient receives drug information in their chosen language, ensuring understanding and safe medication use across borders.
- supply chain, mitigate shortage –
- **Improved Medication Adherence:** Increased patient adherence to prescribed medications due to better understanding in cross-border contexts.
- **Reduced Medication Errors:** Fewer errors related to misunderstanding medication instructions during cross-border dispensation.
- **Positive Stakeholder Feedback:** Healthcare professionals and patients report satisfaction with the augmented cross-border service.
- **Compliance Achieved:** The service meets all regulatory and interoperability standards set by the EHDS and national regulations.
- **System Stability:** The [eP - eD] + ePI system operates smoothly across member states without technical issues, ensuring reliable cross-border service delivery.

2.2.13 Requirements

User requirements - Patients must be able to select their chosen language for receiving ePI during cross-border interactions as a [eP - eD] + ePI - Patients should find the ePI comprehensible in their chosen language. - Healthcare professionals should easily access ePI in their existing workflows, specifically for cross-border prescriptions.
Technical requirements - Support for multiple languages with accurate and culturally appropriate translations. - Seamless integration with existing [eP - eD] systems, adding ePI across different member states. - Robust data security measures to protect sensitive health information during cross-border data transmission. - Scalability to accommodate cross-border usage and high volumes of data.
Operational requirements

- Reliable and timely updates to drug information relevant across different member states. - Efficient translation processes of prescription label – written text - unique identification of medicinal product and ePI to ensure up-to-date and accurate ePI in multiple languages is available for dispended medicine. - Comprehensive training programs for healthcare professionals on using the new cross-border system.
Ethics requirements - Ensure patient consent for data usage and language preferences. - Maintain data privacy and comply with GDPR and other relevant cross-border regulations. - Provide equitable access to information regardless of language or location.

2.2.14 Major challenges foreseen

- **Language Accuracy and Cultural Appropriateness:** Ensuring translations are not only accurate but also culturally relevant to avoid misunderstandings.
- **Data Standardisation Across Borders:** Definition and deployment of EEHRxF and guidance related to [eP - eD] + ePI to achieve consistent data formats across diverse healthcare systems and languages.
- **Regulatory Compliance:** Navigating and complying with varying national regulations and encouraging the use of EEHRxF related to cross-border eHealth services. Making regulator-approved ePI available for cross-border use by adopting universal/unique medicine product IDs (e.g., ISO-IDMP, - in particular PhPID and MPID) and standardising terms and translations for expressions used in prescription labels.
- **Technical Integration Across Member States:** Seamlessly integrating the ePI module with existing [eP - eD] systems across different member states without disrupting current workflows.
- **Stakeholder Alignment Across Borders:** Ensuring all stakeholders from different member states are aligned in terms of goals, responsibilities, and expectations.
- **Resource Allocation for Cross-border Implementation:** Securing sufficient resources (financial, technical, human) to develop, implement, and maintain the augmented service across borders.
- **User Adoption in Diverse Settings:** Encouraging healthcare professionals and patients across different member states to adopt and effectively use the new cross-border service.
- **Scalability for Cross-border Operations:** Ensuring the system can handle cross-border operations and high volumes of data without performance issues.
- **Maintenance and Updates Across Languages:** Keeping the drug information and translations up-to-date in multiple languages in a timely manner.

- **Privacy and Security in Cross-border Data Transmission:** Safeguarding sensitive patient data against breaches and ensuring compliance with data protection laws across different member states.

2.2.15 Architecture

Description:

The architecture leverages **Digital Wallets** to decentralize data storage and enhance patient control over their health information. This approach minimizes reliance on centralized nodes, promoting privacy, security, and seamless cross-border healthcare services.

Deployment Components:

- **Digital Health Wallet (Patient Wallet):**
  - A secure, personal digital wallet held by the patient, accessible via web or mobile applications.
  - Stores the patient's ePrescriptions (eP), eDispensation records (eD), and electronic Product Information (ePI) in their chosen language.
  - Allows patients to manage their health data, control access permissions, and receive updates directly.
  - Supports offline access to essential health information when internet connectivity is unavailable.
- **Healthcare Professional Interface:**
  - **Physician Module:**
    - Integrated within existing ePrescription systems.
    - Enables physicians to issue ePrescriptions directly to the patient's Digital Health Wallet.
    - Facilitates secure communication with patients, including sending key medication information.
  - **Pharmacist Module:**
    - Integrated within eDispensation systems.
    - Allows pharmacists to retrieve ePrescriptions from the patient's Digital Health Wallet with patient consent.
    - Enables updating of dispensation records and adding standardized, translated instructions to the patient's wallet.
- **Translation Service Module:**
  - **Decentralized Translation Services:**
    - Embedded within the Digital Wallet and Healthcare Professional Interfaces.
    - Handles real-time translation of drug information based on the patient's language preference.

        - Ensures cultural and contextual accuracy without relying on a centralized translation node.
    - **Utilization of Existing Translations:**
        - Leverages manufacturer-provided drug information in local languages where the product is marketed.
        - Ensures that translations are accurate and maintained up-to-date.
- **Interoperability and Data Exchange Layer:**
    - **Standards Compliance:**
        - Adheres to interoperability standards like HL7 FHIR and ISO norms.
        - Ensures seamless data exchange between different healthcare systems and the patient's Digital Wallet across member states.
    - **Decentralized Data Exchange Protocols:**
        - Uses secure, decentralized protocols (e.g., blockchain or distributed ledger technologies) for data transmission.
        - Reduces dependence on centralized databases, enhancing data integrity and availability.
- **Security and Privacy Infrastructure:**
    - **Encryption and Authentication:**
        - Implements robust encryption methods for data at rest and in transit.
        - Utilizes multi-factor authentication to ensure only authorized access to the Digital Wallet.
    - **Consent Management:**
        - Provides patients with granular control over data sharing.
        - Integrates consent mechanisms for patients to grant or revoke access to specific healthcare providers or services.
    - **Regulatory Compliance Layer:**
        - Ensures all data transactions comply with EU regulations (e.g., GDPR) and national laws.
        - Incorporates features to handle data subject rights, such as data portability and the right to be forgotten.
- **ePI Access Mechanism:**
    - **Distributed ePI Retrieval:**
        - Accesses ePI from a network of authorized sources (e.g., EMA databases, national regulatory agencies).
        - Ensures patients and healthcare providers have the most current and authorized product information.
    - **Caching and Offline Access:**

        - Allows caching of frequently used ePI documents within the Digital Wallet for quick and offline access.
- **Notification and Alert System:**
    - **Patient Notifications:**
        - Sends real-time alerts to patients about medication updates, recalls, or safety information.
        - Provides medication reminders and adherence support within the Digital Wallet.
    - **Healthcare Provider Alerts:**
        - Notifies physicians and pharmacists about important updates related to medications prescribed or dispensed.

3 Recommendations

3.1 Service recommendations

Recommendation 1: Add ePI in language of choice to [eP-eD] as "[ePI-eD] + ePI"

Align with regulators (EMA and NCAs), compendia and other relevant dissemination parties at EU and national level to make regulator-approved ePI available in a chosen language (patient – pharmacist) at dispensation to complement current arrangements with paper inserts (PIL) in language(s) of the jurisdiction where a medicinal product is dispensed.

Recommendation 2: Explore feasibility of standardisation – translation of person specific instructions by prescriber and recommendations by dispenser

Viability of efforts to standardise the person-specific instructions – printed on label and added when dispensation of a medicinal product – to allow for selection and presentations in a chosen language (patient – pharmacist) to promote intended use of a product, also in cross-border [eP –eD] scenarios, and overall safe use of medicines across Europe.

3.2 Legal, regulatory and Policy

1. **Consider applicable legal and regulatory texts:**
   - Cross-border directive
   - EHDS and its EEHRxF provisions
   - Pharmaceutical Strategy for Europe
   - European Medicines Agency mandate, National Competent Authorities mandates and Critical Medicines Alliance
   - NIS2 Directive

Overcoming legal and regulatory hurdles is crucial for implementing [eP - eD] + ePI. Early involvement of legal experts helps ensure compliance with key EU frameworks, such as the General Data Protection Regulation (GDPR) for data privacy and security, and relevant pharmaceutical legislation (e.g., Directive 2001/83/EC and Delegated Regulation (EU) 2016/161). Likewise, adherence to the evolving EHDS and the Directive on patients' rights in cross-border healthcare (Directive 2011/24/EU) is essential for cross-border data exchange.
As these rules evolve—particularly through updates to EHDS guidelines, the EMA's product information requirements, and national implementation measures—organisations must continuously monitor changes. This proactive approach reduces risks of non-compliance and supports secure, patient-centric digital medication services.
Comprehensive documentation and reporting further demonstrate adherence to these frameworks. By maintaining detailed records of policies, procedures, and

training—aligned with EU legal standards and guidance from bodies such as the EMA—organisations can provide clear evidence of compliance during audits or inspections.

3.3 Information

1. **Consider the existing information assets**, such as:
   - Existing [eP - eD] guidelines
   - EU PS guidelines
   - Consider the IPS as future convergence is foreseen
   - EU ePI common standard; ISO IDMP, FHIR ePI IG

2. **Provide information and training possibilities** to end-users, from health professionals to citizens as ways to foster awareness, understanding and ultimately acceptance and use of the service.

3.4 IT infrastructure

1. **Vendor selection.** Choosing a vendor with a strong track record of successful integrations is essential, as their experience can significantly impact the overall effectiveness of the project. A vendor that specialises in healthcare solutions understands the unique challenges faced by the industry, including compliance requirements and data privacy concerns. Furthermore, robust support services are crucial during and after implementation. Vendors that offer ongoing technical assistance can help organisations troubleshoot issues as they arise. This support may include training for staff, regular system updates, and access to a dedicated help desk, which enhances user experience and system reliability.
2. **Conducting pilot testing** is another effective strategy for addressing potential technical challenges. By rolling out the new system in a controlled environment, organisations can identify and resolve issues before full-scale implementation. Pilot testing allows for thorough examination of the system's functionality, enabling to detect bugs, compatibility issues, or user interface challenges. Gathering feedback from end-users during this phase is invaluable. Adjustments made during pilot testing can lead to a smoother transition when the system is finally launched organisation-wide, minimising disruption to daily operations.
3. **Network and Security Protocols:** Recommend adopting secure protocols (e.g., TLS/SSL) for all ePrescription-related data exchanges across networks, ensuring compliance with EHDS data security standards and EU cybersecurity requirements. Can be based on existing used protocols such as the TESTA network.

Annex 4

Report and recommendations document prepared by Working group: Multi-Country working group on Imaging (3C-3P-MIM).

Double click to open

Community of Doers Working Group Report and Recommendations

Multi-Country working group on Imaging (3C-3P-MIM).

Scope

This document presents all collected contributions from the Community of Doers (CoD)[24] regarding the idealisation, discussion, and recommendations for the formalisation of an evolution of existing teleconsultation services into a new adoption domain, incorporating other European knowledge and experts' views through a process of cocreation with patients, professionals, and IT developers (programmers) following the logic of the CoD set forth by XpanDH. This report captures in a snapshot the ongoing discussions for the purpose of enabling their continuation in legacy initiatives, providing description and recommendations for

[24] The Community of Doers and Co-creators brings together implementers and end-users of new and existing solutions, IT developers and vendors/suppliers; patients and healthcare professionals, in a 3C-3P community (co-creation community of Patients, Professionals and Programmers). The scope of this open community is to find use cases and business needs that would be reused in practice domains of the European EHR (Electronic Health Record) Exchange Format in a bottom-up co-creation approach.

ultimately permitting the piloting, testing and deployment of the proposed augmented teleconsultation encounter report service.

Goal of Working Groups

The XpanDH Community of Doers employs a methodology of balanced co-creation among multiple stakeholders, as outlined in its foundational principles. To facilitate this collaborative approach, the CoD is organized into topical Working Groups (WGs). These WGs bring together teams of eHealth actors with a primary objective: to explore and deliver recommendations for evolving existing services within the context of the European Health Data Space (EHDS). This includes identifying new data categories for adoption or proposing new approaches to specifying existing priority data categories.

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Executive Summary

The Multi-Country Working Group (MCWG) Community of Doers (CoD), formally recognized by the XpanDH project and supported by IHE-Europe, aims to enhance medical imaging data sharing and interoperability across Europe under the European Health Data Space (EHDS). This initiative addresses challenges such as fragmented standards, inconsistent metadata definitions, and unreliable workflows that hinder cross-border and national data exchange. Through collaboration with national representatives, eHealth agencies, and technical experts, the MCWG CoD has developed key recommendations to align imaging practices with the EHDS and the European Electronic Health Record Exchange Format (EEHRxF).

The MCWG has produced five key reports:

1. *Positioning Imaging Standards and Profiles*, which shows how IHE Profiles and eHealth Network (eHN) guidelines can enable secure, standardized cross-border interoperability.
2. *Imaging Sharing Metadata and Linkages*, which emphasizes the importance of standardized metadata for effective imaging study discovery and sharing.
3. *KOS Imaging Study Manifest*, which provides technical guidance on creating and sharing imaging manifests for consistent workflows and reliable data sharing.
4. *Flagging Significant Images in shared Imaging Studies* which adds the interoperable capability for a source flagging of significant images that is fully and easily accessible to the imaging consuming health professional.
5. **A quick user guide to help clinicians better understand the query parameters or search metadata** associated with "search cards" for clinical documents or objects that need to be shared such as medical imaging studies and medical imaging reports.

These reports are essential resources for aligning imaging practices with EHDS objectives. The document also highlights the balanced co-creation methodology used by the MCWG, involving patients, healthcare professionals, IT developers, and policymakers to ensure practical and comprehensive recommendations. It also draws on insights from European Commission-funded projects, such as XpanDH and Xt-EHR, to align with existing eHealth Network guidelines.

The MCWG aims to address the challenges of cross-border and national interoperability, fragmented workflows, and metadata inconsistencies, proposing solutions that support clinicians in accessing accurate and relevant imaging information efficiently. The reports provide recommendations across various levels of the Refined eHealth European Interoperability Framework (ReEIF), including legal,

regulatory, policy, and technical aspects, guiding countries and organizations toward improved imaging data interoperability.

1 Background

1.1 Relevant existing material

Relevant material are the eHealth Network's (eHN) guidelines.

They include specific guidelines for five different services: ePrescription and eDispensation, Patient Summary, Laboratory results, Medical imaging studies and reports, and Hospital discharge reports.

They are based on the Commission Recommendation on a European Electronic Health Record exchange format's original 'health information domains'.

- eHealth Network General guidelines
- eHN guidelines on ePrescription and eDispensation
- eHN guidelines on Patient Summary
- eHN guidelines on laboratory results
- eHN guidelines on Medical imaging studies and reports
- eHN guidelines on Hospital discharge reports

The original 'health information domains' have evolved with the April 2024 EHDS regulation, to be recategorized into five 'priority categories of personal electronic health data':

(a) patient summaries;

(b) electronic prescriptions; electronic dispensations;

(c) medical imaging studies and related imaging reports;

(d) medical test results, including laboratory and other diagnostic results and related reports;

(e) discharge reports.

1.2 Description of the MCWG and XpanDH partnership

The **Multi-Country Working Group (MCWG),** with participation from more than 10 countries (including France, Austria, Netherlands, Spain, and Belgium, etc…) is hosted by IHE-Europe and plays a critical role in advancing healthcare interoperability by providing recommendations based on eHealth Network (eHN) guidelines and established implementable specifications based on international standards and profiles. These recommendations, that are approved by

the participating countries, ensure secure, standardized imaging data exchange ready to be deployed at a national and regional level. These recommendations are designed to be extendable to the Cross-border. This makes MCWG a robust consensus essential to the EEHRxF and European Health Data Space. MCWG maintains an active relationship with Xt-EHR WP7.2 through several common country representatives.

To support this, the **Multi-Country Working Group on Imaging - Community of Doers (MCWG-Imaging CoD)** has been established. This group unites a wide range of stakeholders, including other XpanDH Communities of Doers across Europe. Within it, the **MCWG-Imaging Core** subgroup brings a necessary leadership with national representatives from eHealth Agencies, Ministries, and Competence Centers, with a focus to deliver recommendations on aligning imaging practices and standards at the national level for improved interoperability. Input and feedback from the MCWG on Imaging – CoD Stakeholders is been leveraged in a constructive and efficient manner.

XpanDH formally recognizes the **MCWG on Imaging** as a Community of Doers, promoting collaboration, resource sharing, and a stronger platform for shaping European healthcare interoperability policies and standards.

1.3 Healthcare challenges in imaging approached by MCWG

- Lack of cross-border interoperability for imaging data due to fragmented adoption of standards and inconsistencies in implementation.
- Inconsistent metadata definitions and management, which hinder discoverability and usability of imaging data across multiple systems and countries.
- Fragmented imaging workflows and unreliable data consistency across systems.

1.4 Relevant scientific recommendations

MCWG addresses these issues by providing recommendations and developing interoperability specifications to align imaging practices with the **European Health Data Space (EHDS)** and **EEHRxF** goals with the following deliverables:

- **Positioning imaging standards and profiles:** Outlines the application of IHE Profiles and eHealth Network (eHN) guidelines to support cross-border interoperability.
  Read the full report here.

- **Imaging Sharing Metadata and Linkages:** Focuses on the importance of metadata management for discoverability and effective imaging study sharing, including practical recommendations for implementation. Read the full report here.
- **KOS (Key Object Selection) Imaging Study Manifest:** Provides technical recommendations for creating and sharing KOS manifests for imaging Studies, which enhance data reliability and facilitate consistent imaging workflows.
  Read the full report here.

1.5 Inputs from relevant EC-funded projects and other initiatives

XpanDH Project : MCWG builds on XpanDH's framework for creating interoperable solutions across the EU. The XpanDH approach emphasizes stakeholder co-creation and the adoption of consensus-based recommendations, ensuring practical alignment with the European Electronic Health Record Exchange Format (EEHRxF).

Xt-EHR Joint Action : Contributions from Xt-EHR, particularly in WP7 (Task 7.2), are integrated into MCWG's efforts. Several MCWG members are also part of this Joint Action, ensuring knowledge transfer and alignment with EU cross-border interoperability goals.

eHealth Network : The MCWG draws heavily on the guidelines developed by the eHN, such as those for imaging studies and imaging reports sharing. These guidelines are used as a basis for refining use cases and proposing metadata specifications.
Link to eHN Guidelines

European eHealth Digital Service Infrastructure (eHDSI) and MyHealth@EU: eHDSI's cross-border data-sharing framework and technical standards provide foundational inputs for MCWG's recommendations, particularly in ensuring GDPR compliance and secure data exchange.

1.6 Characteristics

[Fill in the framework below to describe the user story at stake. This framework is inspired by that for description of a use case in the eHealth Network's Refined eHealth European Interoperability Framework (ReEIF).]

Title	**Enhancing cross-border interoperability of Medical Imaging**
Purpose	Enable seamless sharing and accessibility of medical imaging data across EU Member States to improve patient care, optimize workflows, and align with the European Health Data Space (EHDS) and EEHRxF objectives.
Relevance	**Medical rationale**: Reduces redundant imaging exams and radiation exposure, improves access for clinicians without imaging facilities, and facilitates timely specialist review with increase clinical quality by comparing with prior studies. Promotes fluid patient pathways by addressing delays caused by interoperability gaps. **Economic rationale**: Eliminates duplication of imaging studies, reducing costs for patients and healthcare systems. Enhances efficiency by streamlining workflows and supporting secondary use of imaging data.
Priority category	*[from the 2024 EHDS regulation:* *(a) patient summaries;* *(b) electronic prescriptions;* *(c) electronic dispensations;* *(d) medical imaging studies and related imaging reports;* *(e) medical test results, including laboratory and other diagnostic results and related reports;* *(f) discharge reports.]*
Scale	Cross-border, national, regional, and intra-organization interoperability, with potential to empower patients through controlled data sharing (e.g., via EEHRxF)

Target group	Healthcare professionals, including radiologists, general practitioners, and specialists, alongside patients needing accessible imaging services across regions.
Stakeholders	Patients, radiologists, system architects, healthcare IT implementers, regulatory bodies, and policymakers involved in the EHDS framework.
Context of use	**Challenges:** • Fragmented adoption of standards • Metadata inconsistencies affecting discoverability and usability. • Limited awareness among clinicians and patients about imaging tools. • Cross-border GDPR compliance and data security concerns. • Technological and workflow integration barriers due to regional disparities.

AS-IS situation	**Technical:** Inconsistent application of IHE Profiles and insufficient alignment with eHN guidelines. **Semantic:** Metadata variability hampers efficient and robust search and understanding. **Operational:** Limited engagement from clinicians and patients, siloed systems, and uneven digital infrastructure.	
TO-BE situation	A unified framework supporting cross-border imaging interoperability, standardized metadata for discoverability, seamless integration of imaging workflows, enhanced user awareness, and robust data security measures.	
Description	**Steps to transition:** 1. Implement the **Positioning Imaging Standards and Profiles** recommendations to align the use of IHE Profiles (MHD, XDS-I, XCA-I, WIA) with eHN guidelines. 2. Adopt **Imaging Sharing Metadata and Linkages** guidelines to establish consistent metadata practices for enhanced discoverability and usability. 3. Utilize **Key Object Selection (KOS) Manifest** to ensure reliable data sharing and workflow integration. 4. Conduct awareness campaigns to engage clinicians and empower patients with tools for data access and sharing.	
Objective(s)	Ensure cross-border and intra-country interoperability of medical imaging to enhance patient care, streamline workflows, and foster compliance with EHDS and EEHRxF goals.	
Actors and Roles	**Actor**	**Role**
	[e.g. physician, patient, laboratory information system]	*[e.g. Document creator and user]*
Pre-conditions	Availability of a standardized infrastructure, adoption of IHE Profiles and metadata guidelines, and clinician/patient engagement.	
Trigger	Cross-border care scenarios, referrals to specialists, or requests for secondary use of imaging data.	

Flow	*[describe the path of information/data flow with the role of each actor]*
Post-conditions	Successful cross-border exchange and intra country of imaging data, enhancing clinical decision-making, patient outcomes, and system efficiency.
Requirements	**User requirements** Accessible and intuitive tools for clinicians and patients.
	Technical requirements Standardized metadata definitions, secure data-sharing protocols ensuring clinically safe search of relevant imaging studies.
	Operational requirements Training programs and user engagement initiatives.
	Ethics requirements GDPR compliance and trust-building measures.
Major challenges foreseen	Fragmented standards adoption, metadata inconsistencies, limited awareness, data privacy concerns, and infrastructure disparities.
Architecture	A federated system incorporating IHE Profiles (e.g., MHD, XDS-I, XCA-I, WIA), metadata linkages, and secure sharing frameworks, aligned with EHDS objectives.

1.7 Inter-domain dependencies

To streamline the development of cross-border medical imaging interoperability, inter-domain dependencies are analysed across three key groups: Patients, Professionals, and Programmers. This ensures that existing systems and frameworks are reused effectively, reducing duplication of effort and promoting alignment with current standards and practices.

Category	Reusable components	Key dependencies
Patients	- MyHealth@EU Platform - GDPR-Compliant consent Frameworks	- Imaging data portability - Clear consent options for sharing images.
Professionals	- IHE Profiles - DICOM and HL7 FHIR Standards - eHN Guidelines	- Intra-country and Cross-border interoperability - Metadata consistency for imaging data.
Programmers	- eHDSI - KOS Manifests	- Seamless integration with clinical workflows. - GDPR compliance.

	- FHIR and Metadata Management Standards	

2 Vision of the EEHRxF-supported service

The **EEHRxF-supported service** aims to enable seamless, interoperable access to medical imaging data across borders and healthcare settings, enhancing both patient care and clinical workflows.

Context: The service is designed to address the growing need for cross-border and national access to medical imaging, with particular emphasis on the EHDS. Patients, regardless of location, should be able to have their medical images shared securely across multiple healthcare systems, minimizing unnecessary procedures like repeat imaging exams or delayed diagnosis.

Aims:

1. Enhance accessibility for healthcare professionals to imaging data, irrespective of location. This ensures timely diagnosis and consultation, particularly for specialists in regions with limited access to imaging facilities.
2. Prevent the repetition of imaging tests, reducing the need for patients to undergo unnecessary procedures. This improves patient outcomes and reduces the burden on healthcare systems.
3. Establish a standardized approach to imaging data exchange by using **IHE profiles based on FHIR and DICOM**, **FHIR standards**, and other interoperability frameworks to support cross-border exchanges and efficient workflows.

Benefits:

1. **Medical benefits**:
    - Faster diagnosis and treatment by providing specialists access to up-to-date imaging data from any healthcare setting within Europe. Increases clinical quality by comparing with prior studies.
    - Reduced radiation exposure from unnecessary repeat imaging tests.
    - Easier collaboration between healthcare professionals across borders, supporting a more integrated approach to patient care.
2. **Economic benefits**:
    - Cost-saving through the elimination of redundant imaging tests.
    - Streamlined clinical workflows, reducing wait times and enhancing healthcare efficiency.
    - Improved resource allocation, ensuring that imaging facilities are used optimally across different regions.

Expected outcomes:

- Simplified access to cross-border medical imaging data for patients and professionals.
- Increased adoption of interoperable services and standards within healthcare institutions across Europe.
- Enhancement of the EHDS and EEHRxF goals for a more connected, efficient, and patient-centered healthcare ecosystem.

3 Targeted Recommendations Developed by MCWG

3.1 Sharing the information about Significant Images along with a shared imaging study

This requirement is identified in the eHN Guideline on sharing Imaging Studies and Imaging Reports, to flag significant images for a variety of reasons.

It is proposed to add this information to an imaging study so that it is conveyed independently from a specific imaging report associated to such a study. Indeed there may be multiple such reports, or no report at all depending on the imaging workflow at the producing institution.

This has been recognized very early by DICOM by the creation of a Key Object Selection instance to document within a study the reference and associated information to flag such images as key. This strategic direction has been confirmed by IHE Radiology with the widely deployed IHE KIN (Key Image Note) Profile, introducing the concept of a sticky note on one or more images that share the same reason to be flagged.

The MCWG identified that the work so far done by IHE Radiology with the IHE KIN Profile was effective when the imaging study and the Key Image Note reside within a single imaging system. In this case, the imaging study that contains one or more Key Image Note instances may be transferred by networking or media interchange. Such transfer fully preserves the Key Image Note referencing mechanism information in the destination system. Therefore, every system that complies with the IHE KIN profile as a creator or as a consumer is fully interoperable.

However, when imaging studies are shared in large scale cross-border and national eHealth imaging infrastructures, the knowledge that a specific study includes flagged significant images, the reason for such flagging and access to any comment added by the source producing imaging specialist, is not known without extra transactions and corresponding delays.

The implementable specifications to add such a capability to the existing three MCWG Recommendations have been documented so that it can be implemented in an interoperable way, thus ensuring that the source producing imaging specialist effort to perform such a flagging of significant images is fully and easily accessible to the imaging consuming health professional.

This contribution is expected to greatly facilitate addressing this requirement in EHDS.

3.2 A Quick User Guide for clinicians to best use search metadata for filtering relevant imaging studies

When searching for a book in a library, each book is represented by a "library card" that contains only key information about the book it represents: the title of the book, the name of the author, the publication data, type of book (novel, history, scientific paper, etc.), the number of pages, the location of the book in the library, etc. Such information is defined by the generic term "metadata". Different objects may be associated with a "search card" that contains different metadata, for example metadata about seeds in a plant nursery.

In this quick guide, we speak of metadata associated with "search cards" for clinical documents or objects that need to be shared such as medical images and medical imaging reports.

Health professionals need to understand the information elements that are recorded in a patient record, using such "search cards", to assist in filtering information objects, such as radiology reports, patient summaries, or laboratory reports. This will help health professionals to be efficient in filtering out those documents that are not relevant in order to keep only those that are likely relevant.

An "imaging timeline" is an overview of imaging examinations of a single patient, compiled from the information elements: examination data, image(s), and report(s) and filtered, if desired based on key metadata elements such as date span, modality and body-part. These information elements are made available by potentially all care delivery entities in a region, country or even cross-border (e.g. MyHealth@EU).

An imaging examination belongs to one patient. Multiple examinations from various imaging specialties (radiology, cardiology, endoscopy, etc) can take place for one patient. An imaging examination is a set of imaging reports, images and other evidence from imaging studies.

MCWG developed this User Guide primarily for clinicians so they understand how the search metadata has been (or should be) designed for the sharing of imaging information so their needs are best served. It also educates them on the way to leverage such search metadata to best meet their need in specific clinical contexts. A series of use cases are used in this quick User Guide to make such awareness more easily accessible to health professionals.

The User Guide also includes a final chapter with more detailed information about the entire set of search metadata needed for imaging which should help care institutions administrators, manufacturers designing products and policy makers.

4 Recommendations for relevant asset bundle

[Provide recommendations of steps to follow, precautions to be taken, material to be produced, or else, in the 6 interoperability levels outlined by the eHealth Network's refined eEIF (ReEIF).

Below we display two models that display how these 6 interoperability levels can be applied to (i) alignment activities between organisations, and (ii) stakeholders.]

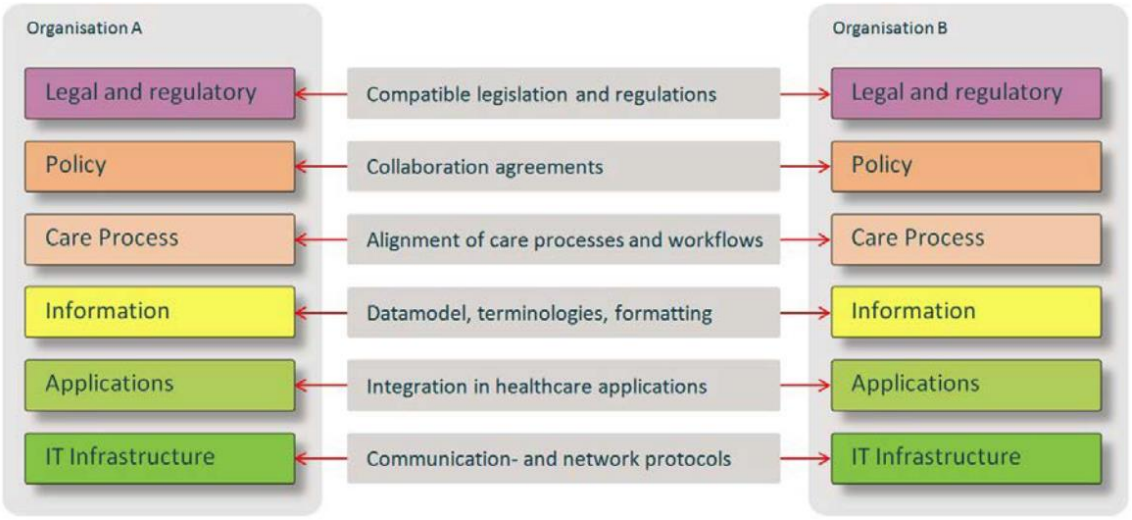

Figure 11 Refined eEIF (ReEIF) model – alignment activities between organisations

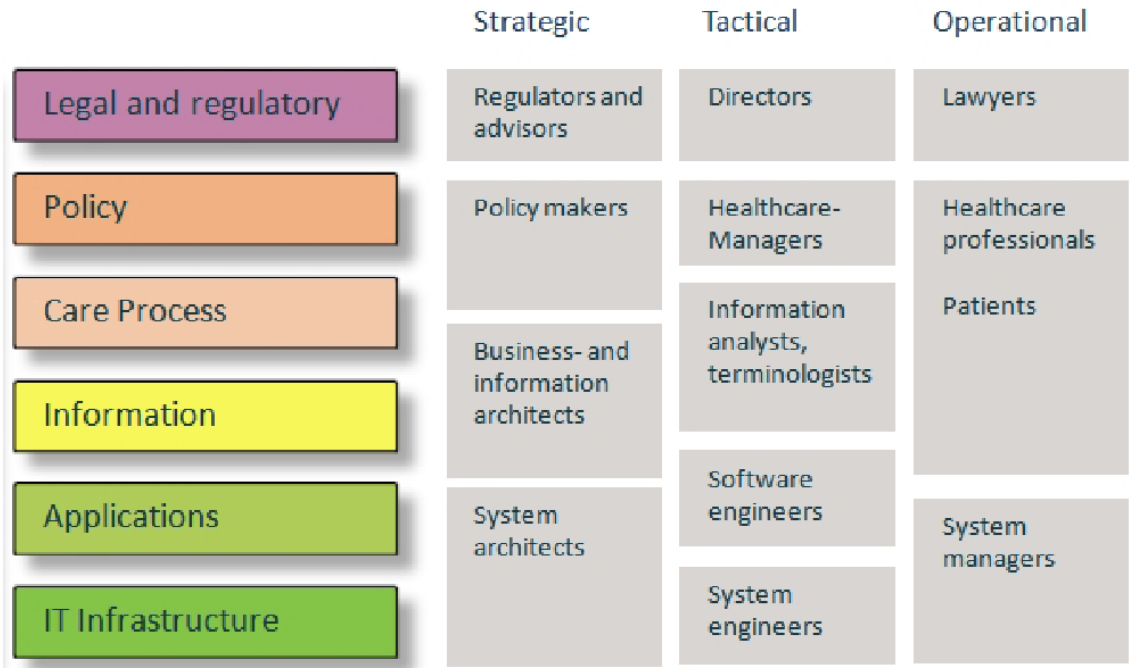

Figure 12 Refined eEIF (ReEIF) model – stakeholders

4.1 Legal and regulatory

Steps:
- Harmonize legal frameworks, including compliance with GDPR and patient consent across borders.
- Address data sovereignty issues to ensure consistent cross-border exchange of medical data, particularly for imaging.

Precautions:
- Ensure national regulations are harmonized, particularly with respect to cross-border data sharing and patient privacy.
- Maintain clarity on consent management and legal liability.

Materials to Produce:
- Legal and regulatory guidelines document for cross-border data exchange in imaging.
- Data privacy and security frameworks ensuring GDPR compliance.

4.2 Policy

Steps:
- Formalize collaboration agreements between healthcare organizations, focusing on data sharing in imaging.
- Define mutual responsibilities and the trust-building processes between countries or organizations for cross-border data exchange.

Precautions:
- Ensure all parties are aligned on data sharing purposes, security measures, and compliance responsibilities.
- Prevent ambiguity in roles and responsibilities during cross-border collaborations.

Materials to Produce:
- Collaboration agreements for data sharing and cross-border medical imaging.
- Governance framework defining roles, policies, and security protocols.

4.3 Care process

Steps:
- Align clinical workflows for the exchange of imaging data across borders.
- Standardize care pathways for cross-border interoperability, ensuring seamless integration of medical imaging data in the clinical workflow.

Precautions:

- Adapt workflows to different healthcare settings while maintaining consistency in the data needed for treatment.
- Prevent clinical errors due to inconsistent workflows or missing data.

Materials to Produce:

- Clinical workflow documentation with standardized imaging data integration.
- Guidelines on aligning care processes for interoperable cross-border healthcare services.

4.4 Information

Steps:

- Define standardized data models, terminologies, and metadata schemas for cross-border imaging data sharing.
- Ensure interoperability by linking imaging data elements with common terminologies and metadata to enhance discoverability.

Precautions:

- Ensure consistency in metadata definitions to reduce errors and ambiguities.
- Utilize existing standards (e.g., IHE, HL7, DICOM) to support cross-border data exchange.

Materials to Produce:

- Metadata for imaging data exchange.
- Terminology and data model guidelines for interoperable healthcare systems.

4.5 Applications

Steps:

- Establish technical specifications for data transfer protocols (e.g., HL7, IHE XDS-I, DICOM) to ensure smooth import and export of imaging data.
- Implement secure and user-friendly applications that enable easy access to imaging data for clinicians and patients.

Precautions:

- Ensure seamless integration of interoperable systems into existing clinical applications.
- Prioritize security in the data exchange protocols, especially in cross-border scenarios.

Materials to Produce:

- Communication and application integration standards for medical imaging.
- Technical documentation and user manuals for clinicians on new interoperable systems.

4.6 IT infrastructure

Steps:

- Implement standardized network protocols (e.g., IHE, DICOM, HL7) for reliable communication across borders.
- Ensure secure storage and backup of imaging data, with attention to scalability to accommodate future demands.

Precautions:

- Ensure robust data protection and encryption measures for patient data security.
- Minimize system downtime to avoid interruptions in cross-border data sharing.

Materials to Produce:

- Technical specifications for communication standards and protocols.
- Security and infrastructure guidelines for implementing cross-border data exchange.

Annex 5

Report and recommendations document prepared by Working group: Telehealth—Teleconsultation Encounter Report (3C-3P-TER).

Double click to open

Community of Doers Working Group Report and Recommendations

Telehealth: Teleconsultation encounter report

TER

Scope

This document presents all collected contributions from the Community of Doers (CoD)[25] regarding the idealisation, discussion, and recommendations for the formalisation of an evolution of existing teleconsultation services into a new data category, incorporating other European knowledge and experts' views through a process of cocreation with patients, professionals, and IT developers (programmers) following the logic of the CoD set forth by XpanDH. This report captures in a snapshot the ongoing discussions for the purpose of enabling their continuation in legacy initiatives, providing description and recommendations for ultimately permitting the piloting, testing and deployment of the proposed augmented teleconsultation encounter report service.

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- eHN guidelines on Medical imaging studies and reports
- eHN guidelines on Hospital discharge reports

The original 'health information domains' have evolved with the 2024 EHDS regulation, to be recategorized into six 'priority categories of personal electronic health data':

(a) patient summaries;

(b) electronic prescriptions;

(c) electronic dispensations;

(d) medical imaging studies and related imaging reports;

(e) medical test results, including laboratory and other diagnostic results and related reports;

(f) discharge reports.

1.2 Healthcare challenge

When patients are hospitalised, sharing of discharge letters are taking place in several EU Member States, but besides the encounters during the hospital admission, further encounters can take place outside the hospital, and documentation of these encounters holds important clinical information for the overall holistic view of the patients' condition.

When clinical notes are documented in public EHR systems, several encounter types are registered the same way and can be uploaded to a national repository or indexed in a national registry. Some services in the private market perform teleconsultation and there is need for at teleconsultation encounter report for sharing information of these encounters.

1.3 Relevant scientific knowledge

Teleconsultation has been extensively evaluated across various settings in Denmark, offering valuable insights into its implementation, effectiveness, and challenges. Key evaluations highlight its impact on general practice, municipal healthcare, cross-sector collaboration, and public sector digitisation.

1. **Evaluation of Teleconsultation in General Practice (CIMT, 2020)**[26]
   This study assessed the use of video consultations in general practice, focusing on the suitability of teleconsultation for specific patient groups and conditions. The findings indicated that teleconsultation can enhance patient access and convenience, particularly for follow-up visits and non-urgent consultations. However, the study also emphasised the need for physicians to assess patient suitability, as teleconsultation may not be appropriate for complex or sensitive cases. The evaluation highlighted the importance of integrating teleconsultation seamlessly into general practice workflows to maximise its potential.
2. **Evaluation of Teleconsultation in Municipalities (MedCom, 2023)**[27]
   This evaluation explored the use of video consultations in municipal healthcare services, particularly in the context of home nursing and elderly care. The findings demonstrated that teleconsultation improves efficiency, enabling healthcare professionals to deliver timely care while reducing travel time. However, challenges were identified in ensuring adequate technical infrastructure and in training staff to use teleconsultation platforms

[26] Evaluation of teleconsultation in general practice (CIMT 2020). Available at: https://cimt.dk/projekter/forsknings-og-evalueringsprojekter/evaluering-af-video-i-almen-praksis

[27] Evaluation of teleconsultation in municipalities (MedCom 2023). Available at: https://medcom.dk/wp-content/uploads/2023/07/6-1-kontakt-laege-evalueringsrapport-feb-23.pdf

effectively. The report recommended targeted interventions to address these barriers and improve the uptake of teleconsultation across municipalities.

3. **Evaluation of Cross-Sector Teleconsultations (VIVE, 2022-2025)**[28]
   This ongoing evaluation focuses on teleconsultations in cross-sector settings, particularly for complex patient pathways involving multiple stakeholders. Preliminary results suggest that teleconsultations facilitate improved communication and coordination between sectors, enhancing continuity of care for patients with chronic or multifaceted conditions. However, the study identified challenges in establishing clear workflows and shared responsibilities among stakeholders, underscoring the need for robust governance and interoperability standards.
4. **Evaluation of Teleconsultations by the Danish Digitisation Authority (2023)**[29]
   The Danish Digitisation Authority's evaluation investigated the broader use of video meetings across the public sector, including healthcare. The study highlighted the efficiency gains of teleconsultation, such as reduced travel and waiting times, while also addressing barriers such as user acceptance and technical stability. The report stressed the importance of ensuring data security and compliance with GDPR to build trust in teleconsultation solutions. Furthermore, it emphasised the potential of teleconsultation to improve service delivery in underserved areas, provided that infrastructure investments and training are prioritised.

These evaluations collectively demonstrate the transformative potential of teleconsultation in enhancing healthcare delivery, while also highlighting the need for tailored approaches to address contextual challenges in different healthcare settings. The findings provide a strong foundation for the further development of teleconsultation services under frameworks such as the European Health Data Space (EHDS).

1.4 Inputs from relevant projects and national scenarios

Denmark:

[28] Evaluation of cross-sector teleconsultations (VIVE 2022-2025). Available at: https://www.vive.dk/da/undersoegelser-i-gang/vive-evaluerer-tvaersektorielle-videomoeder-om-det-komplekse-patientforloeb-0dx4nkvo/

[29] Evaluation of teleconsultations by the Danish Digitization Authority (2023). Available at: https://digst.dk/media/bmcn2c5d/digitaliseringsstyrelsen-videomoeder-i-den-offentlige-sektor-april-2023.pdf

The architecture for Danish healthcare data-sharing is based on IHE XDS document-sharing, but since Denmark has been an early implementor, there is a number of national repositories still in progress to be upgraded from national format and use of webservices to HL7 document format and sharing in IHE XDS infrastructure.

All discharge letters are uploaded with use of the Danish EHR exchange format, "SUP", and the same standard also contains clinical notes from a number of encounters during the hospital admission.[30] The Danish strategy for adoption of the European EHR exchange format is about re-using this format for national upload from EHR systems to national data-sharing, and looking at replacing the Danish "SUP" standard with the EEHRxF for a new data category provisionally labelled "Teleconsultation Encounter Report".

[30] Knut Bernstein, Morten Bruun-Rasmussen, Søren Vingtoft, Stig Kjær Andersen, Christian Nøhr, Modelling and implementing electronic health records in Denmark, International Journal of Medical Informatics, Volume 74, Issues 2–4, 2005, Pages 213-220, ISSN 1386-5056, https://doi.org/10.1016/j.ijmedinf.2004.07.007.

2 Interoperability challenge description

2.1 Overview

Title

Teleconsultation encounter report

Purpose

Document the encounter taking place remotely between patient and/or healthcare professionals, and make the information shareable for patient and other healthcare professionals.

Relevance

Physical encounters in clinics, whether performed at hospital, during homecare in municipality, or at visit to general practitioner, is documented in the local EHR system used. Most EHR systems can export a discharge letter, but that does not include all the encounter documentation.

When an encounter can be performed as teleconsultation instead of a physical consultation, the patients save a long travel, that for elderly citizens can be several days due to rural transportation, but also younger patients have benefits from teleconsulting, participating in short time from their workplace, and don't have to take leave from work for a full day.

By giving other healthcare professionals access to these teleconsultation encounter reports, the patient no longer has to explain the same issues several times.

It also serves as a benefit for the patients and their families, being able to read the encounter reports, and better remember the outcome of the encounter, possibly enhancing the compliance to care plans and reducing medication errors.

Priority category

The *teleconsultation encounter report* would refer to a new data category, but by nature is very similar to discharge reports priority data category.

Scale

At first, national scales, with potential for cross-border exchange using the EEHRxF and EU-level service when this data category is transformed into a new priority category within the EHDS.

2.2 Evolution process

Target group

Healthcare professionals performing a teleconsultation with a patient or with other professionals.

Patients and their families.

Stakeholders

Hospital managers of EHR-systems, and EHR-systems in municipalities and at general practitioners-level, and other systems performing teleconsultation.

Context of use

When all teleconsultations is shared in the national infrastructure, the teleconsultation encounter report is accessible from national health portals and citizen-centric Apps.

AS-IS situation

Teleconsultations are documented in the EHR system, but resulting information is not shared with other healthcare professionals or the patient. EHR systems store the clinical notes, containing what happened during a teleconsultation, but these are either not shared as part of discharge letters, or the clinic doesn't send discharge letters.

The teleconsultation encounter could be text-based only, but could also have optional relation to structured information for relevant diagnosis. The encounter is sometimes related to a specific disease, but in other cases the teleconsultation requires the holistic overview of the patient's situation.

Since encounters can be performed in multiple ways, there is a need for an encounter type. Besides teleconsultation through dedicated web portals, other encounter types such as telephone consultation and email-consultations take place.

TO-BE situation

Sharing the clinical note describing a performed teleconsultation gives the next healthcare professional better knowledge of the present condition of the patient, and the patient is not as often asked the same questions multiple times.

The patient and family is given an overview of all consultation with the healthcare system, for a better understanding of what has been taking place during encounters during an episode of care. This insight for the patient also empowers the patient to take ownership of own disease.

Description

1. Add teleconsultation encounter report as a data category for the EEHRxF

2. Perform a pilot, for example within an EU-funed project, testing and refining the structure, scope and use of a teleconsultation encounter report uploaded from one EHR system to the national infrastructure

3. Make national support for upload from the other EHR and other relevant systems.

4. Pilot and implement cross-border exchange of the teleconsultation encounter report. This step can be considered to be undertaken jointly with or in parallel of step 2.

Actors and Roles

Actor	Role
Physician	*Document creator* *User, viewer* *Data validation? (if AI as support)*
Patient	*User, viewer* *Data validation? (if AI as support)*
Family	*Assisting user*
Other Physician	*User, viewer*

Pre-conditions

- EEHRxF scope is expanded with new data category "Teleconsultation encounter report".
- The performer of teleconsultations needs to have a connection to an EHR system or other system compliant with the EHDS requirements including its provisions on the harmonised software components, where documentation of the encounter takes place.
- A national repository for storing the teleconsultation encounter report is established. Each member state can have different strategy for this, e.g. number of repositories.

Trigger

A teleconsultation encounter takes place. The service for storing a teleconsultation encounter report is used at the end of the consultation, or shortly after.

Flow

Physician registers the clinical note in the EHR system, after the teleconsultation has taken place. The clinical note is related to the patients disease, care plan or episode of care, if relevant.

Then the teleconsultation encounter report is uploaded to the national repository.

Post-conditions

A successful upload is ensured by the IHE XDS infrastructure.

Failure during upload needs to be handled by the EHR, either by automatic re-load from queue, or by inspection of logs.

Requirements

User requirements Patients need to be able to distinguish to the minimum who performed the encounter, the type and time of encounter, reason for the encounter and its key outcomes.
Technical requirements Access for upload to national infrastructure by IHE XDS infrastructure or equivalent.
Operational requirements It should be transparent for the healthcare professional that the upload of the teleconsultation encounter report has taken place successfully, but in case of failure someone has to take action with mitigating adjustment before re-load is done. Since sharing of clinical notes can hold a lot of information, it must be analysed if EHR systems need information on each clinical note whether it is relevant to share, to reduce the burden of the healthcare professionals using the teleconsultation encounter reports
Ethics requirements The EHR system must support a consent functionality, to respect the patients wish to not share given information.

Major challenges foreseen

General Physicians can be concerned about sharing all clinical notes, as encounter reports are of different types, and worry how it can potentially impact the trust relationship between patient and physician.

Architecture

Use existing IHE XDS document sharing.

Use the national solution for teleconsultations, if such exists.

2.3 Inter-domain dependencies

Development of the teleconsultation encounter report is expected to be done similarly as has been done prior for the priority data categories Lab report and Hospital discharge letter, with participation from many stakeholders and member states, compliant with the eHN guidelines and conformant with the international HL7 specifications.

Since infrastructure for document sharing and videocall platforms can be very differently implemented in different member states, it is vital to profile the teleconsultation encounter report agnostic of these infrastructures.

3 Example: the case of Denmark

3.1 Infrastructure

Denmark has an infrastructure that builds upon five paradigms for data sharing

1. Messaging using a private operated network, sending messages in Danish EDIFACT and XML formats, message types like referrals, discharge letters and laboratory reports, just to mention a few examples. As part of the modernisation process in Denmark, it is planned to substitute this old message network with use of eDelivery. The messaging paradigm is linked to the existing IHE XDS document sharing in Denmark, so messages can be shared with patients and all relevant health professionals. This enhanced eDelivery infrastructure is named EHMI.

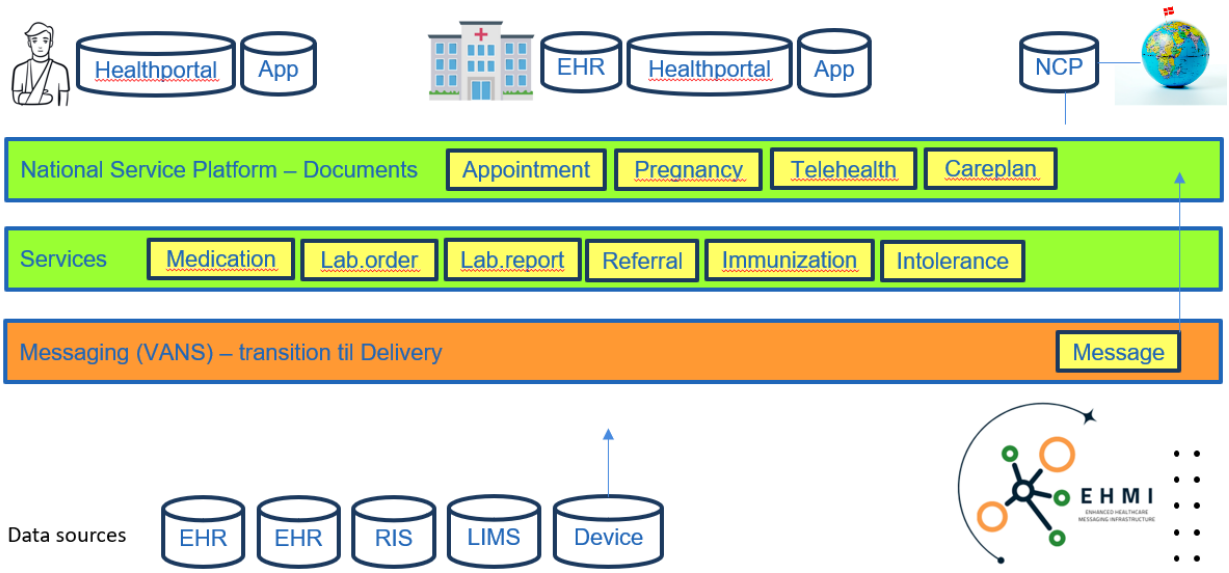
2. Linking has been implemented in some cases, for an quick, easy and temporary solutions, ex. from EHR systems to the national health portal, keeping the patient in context. These kind of integrations are good for

lookups, but has the disadvantage of each user interface is in different design, terminology and use. Relevant information that needs documented must be manually re-typed.

3. MedCom is responsible for the Danish backbone service based infrastructure, used to publish services and make service request from systems, and also hosting website based solution operating on this secure network instead of the open internet. The Danish health data authorities publish a national service platform (NSP), with services for security, consent, logging etc. Use of the network is free of charge, but there is a small fee for onboarding the network.

4. The national service platform contains IHE XDS document sharing, and have a number of registries and repositories in a federated ecosystem. The registry contains the metadata, and the repositories contains uploaded documents. For some document types, the documents are generated at the time of request, and Denmark has a mix of these two storage forms, either in a national repository, and generated from central or local systems.

5. Videocall infrastructure (VDX) is free of charge, since MedCom has acquired a large number of licenses for use in regions, municipalities and primary sector. This videocall solutions is established in 2009 and integrated into EHR systems and other systems, portal and Apps.



Denmark established sharing of discharge letter from hospital many years ago, before implementing IHE XDS document sharing, so discharge letters and clinical notes is uploaded with a national EHR exchange format "SUP", and stored in a national database on the backbone service based network using webservice technology. The

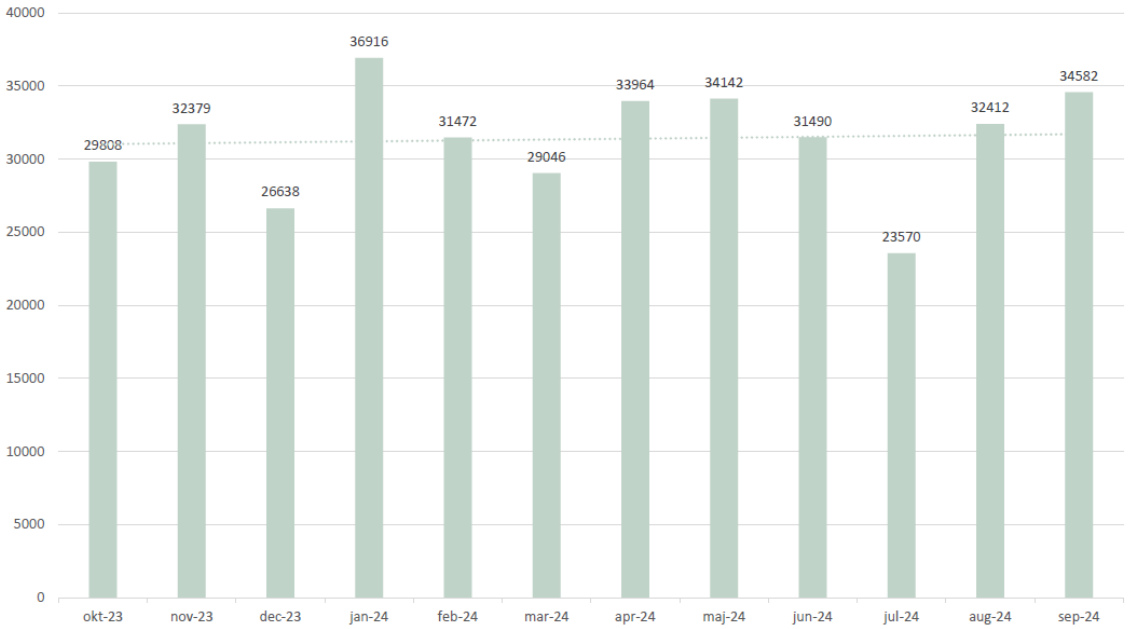
Danish strategy is to substitute this old "SUP" format with the European EHR exchange format EEHRxF, possibly added extensions for local need.

The national service platform has a repository for telehealth, containing documents with measurements and questionnaire responses from the citizens homes. The strategy is to add new repository that can store teleconsultation encounter reports, and these three types of telehealth data is the Danish understanding of telemedicine. It uses two infrastructures, one for videocalls and the other one for document sharing.

3.2 Teleconsultation: types and use

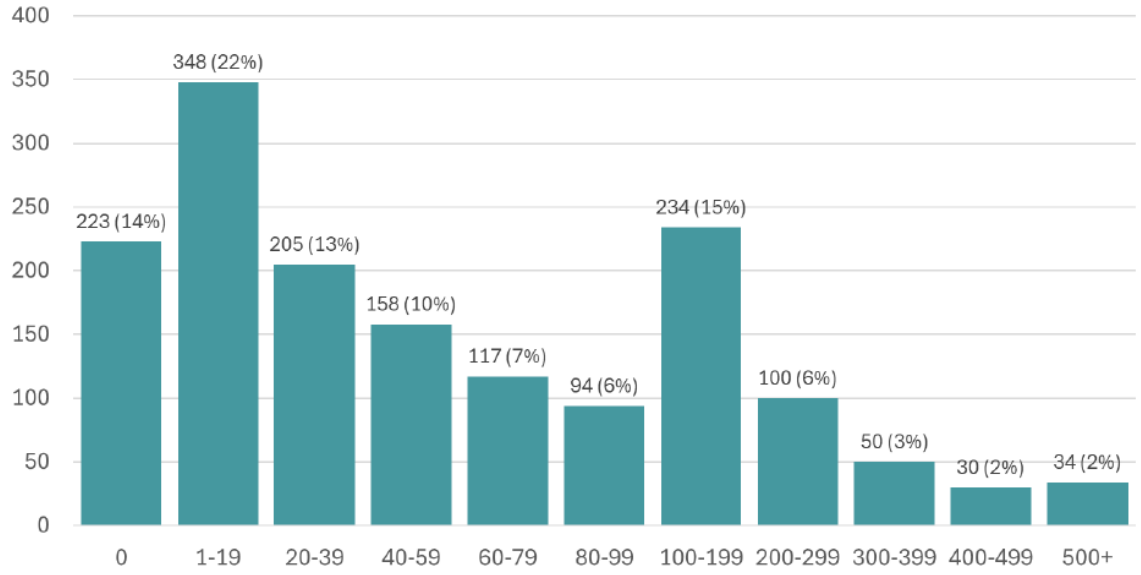
EHR systems has developed integrations for the national videocall infrastructure, so regardless from where a teleconsultation encounter is performed, the citizen is meeting the same user interface, which makes it easier for the citizens to use.

During covid19 pandemic, this already implemented infrastructure made in easy to up-scale nationally use of teleconsultations, and after the pandemic the uptake seems to stay at the same level or steadily grow.



Above is shown number of teleconsultations each month by general practitioners

Uptake by general practitioners is 86%

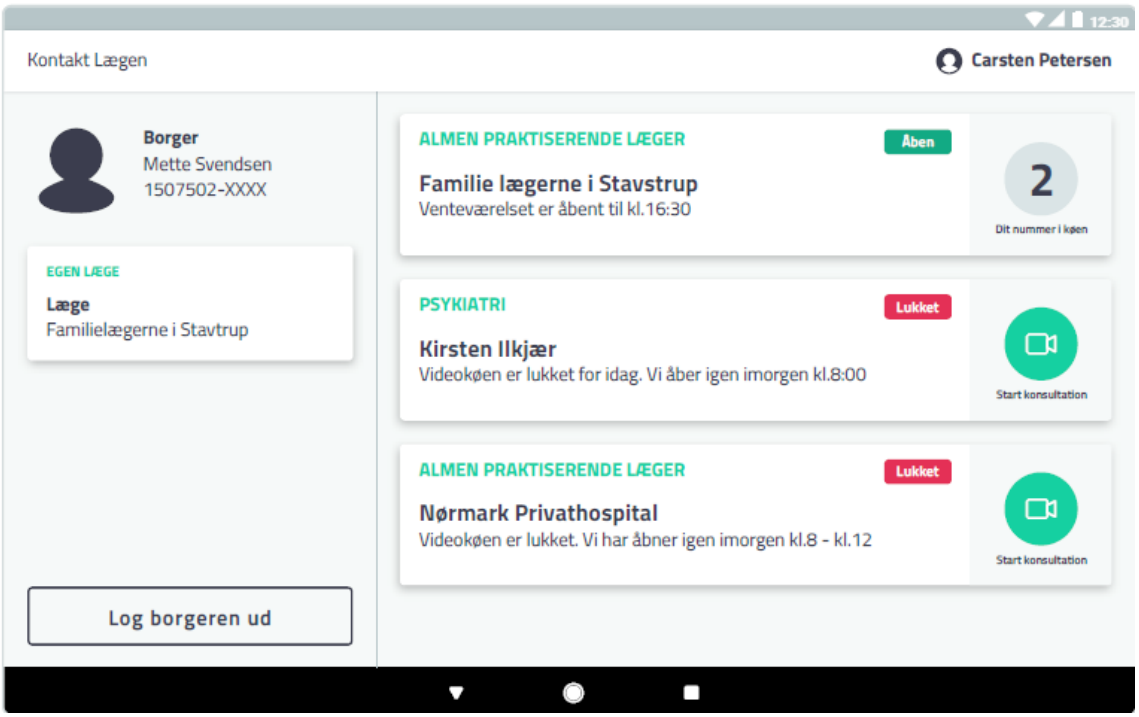


Above shows number of clinics performing a number of teleconsultations.

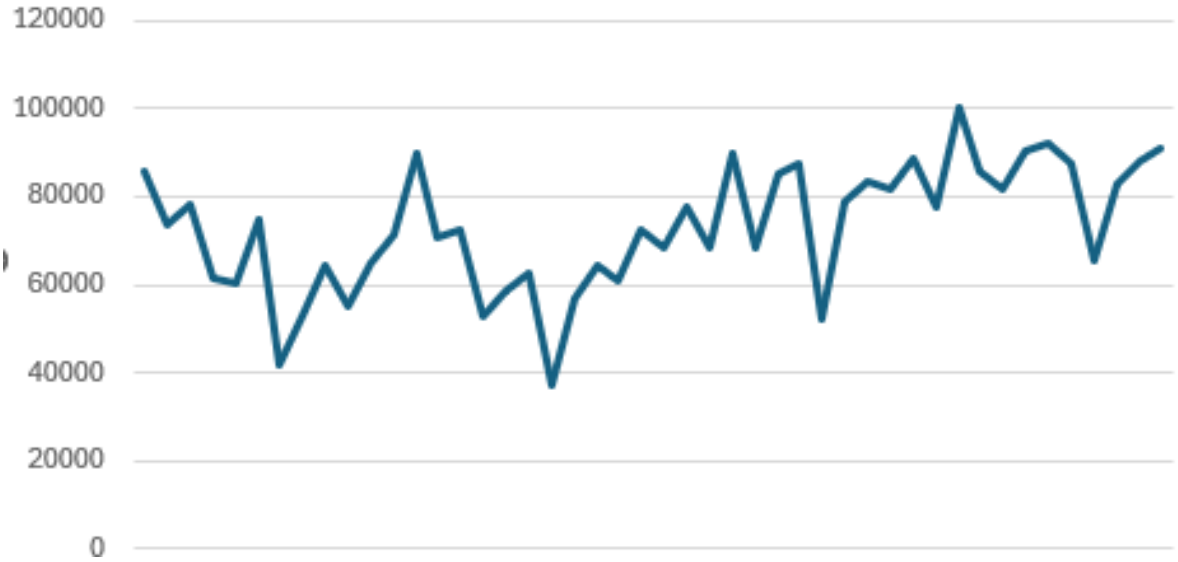
For contact to general practitioners, there was developed a virtual waiting room, where the citizens from their App "MyDoctor" can request a teleconsultation with their usual physician. At the general practitioners clinic, the patients could be invited to the teleconsultation with use of a link send in a SMS, or popup in the App.

Alongside teleconsultations there is also performed encounters as telephone consultations or e-consultations (secure chat between MyDoctor App and the general practitioners EHR. The teleconsultations encounter report is expected to be followed by report types for the two other encounter types.

The videocall infrastructure is also used for conferences between healthcare professionals, and in these use cases, the outcome of the conference is stored in both EHR systems. Healthcare professionals in the municipalities use the same queue system in the general practitioner EHR system. As shown below the healthcare professionals is waiting as number two in the queue system.



A critical criteria for uptake and use, is the videocall platform stability and easy use. Busy healthcare professionals experience errors or bad usability stop using the solution, and according to evaluation they are highly resistant to come back.



Above is shown overall number of teleconsultation and teleconferences during a four years

4 Next steps and open questions

4.1 Recommendations for next steps

To effectively advance the data category for teleconsultation encounter reports, it is recommended to follow the structured approach used in developing priority domains such as Laboratory Reports and Hospital Discharge Reports. This entails establishing clear interoperability standards, engaging multi-stakeholder groups for co-creation, and ensuring alignment with the EHDS framework. Leveraging lessons learned from these priority domains will enable a systematic, scalable, and replicable model for teleconsultation. Such a strategy can support consistency, promote trust, and facilitate subsequent cross-border integration of TER services.

4.1.1 Legal, regulatory and policy

To ensure cross-border interoperability of teleconsultation encounter reports, member states must establish regulatory guidelines that respect diverse consent models while promoting harmonisation under the EHDS. Consent mechanisms should align with GDPR requirements, allowing secure and ethical data sharing across borders. Additionally, clear policies must address the use of AI models, specifying transparent training methodologies and datasets to uphold data protection, inclusivity, and bias mitigation, in alignment with the AI Act. This dual focus on consent and AI regulation is critical for fostering trust and compliance across diverse healthcare systems.

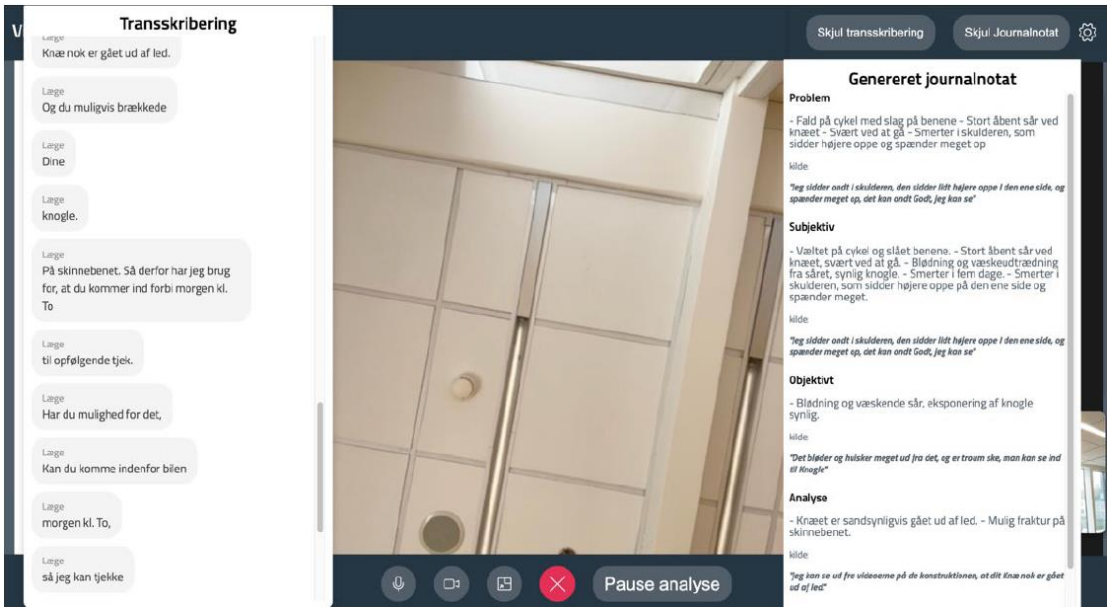
At the policy level, formal contracts and agreements must define the purpose, value, and governance of collaborations between organisations to enable seamless interoperability of teleconsultation services. Trust and responsibilities should be explicitly outlined to anchor the governance of these partnerships. Recognising the cultural challenges in altering healthcare professionals' workflows, targeted legislation may be required to standardise teleconsultation practices and ensure consistent adoption by physicians. Clear governance frameworks and legislative support will facilitate sustainable and trusted collaborations within and across borders.

4.1.2 Care process

Despite years of teleconsultation use, there remains ongoing debate about which patients are best suited to use this mode of healthcare delivery. Findings from the Danish evaluation suggest that this decision should rest with the physician, as they are best positioned to assess the patient's literacy, health status, and social

conditions. Physicians can determine whether teleconsultation will provide adequate care or if alternative encounter types are more appropriate.

To enhance the efficiency of teleconsultation workflows, AI tools should be employed to generate clinical documentation seamlessly. During or immediately after the teleconsultation, these tools can produce both a transcript and a structured clinical note. This documentation should be exportable from the teleconsultation platform directly into the EHR system, ensuring that the same clinical note is available locally for continuity of care.
However, it is critical to allow physicians full editorial control over AI-generated text. This flexibility enables them to make necessary adjustments to reflect the nuances of the patient's situation accurately. By incorporating these refinements, teleconsultation workflows can maintain high standards of clinical precision while streamlining documentation processes.



4.1.3 Information

At the information level, teleconsultation documentation must account for diverse data requirements across member states. While some encounters may only require plain text documentation, others may necessitate more structured data based on the patient's disease or the specific episode of care. For example, in cases like diabetes management, some member states link all consultations and related data to a single episode of care, enabling continuity and holistic care management. To support this variability, the teleconsultation framework should include an optional functionality that allows encounters to be linked to an episode of care, ensuring flexibility and interoperability across healthcare systems.

4.1.4 Applications

At the applications level, agreements must standardise how medical information is imported and exported across diverse healthcare information systems while accommodating the differing infrastructures implemented by member states. For instance, some member states may use a national registry with metadata for document searches, while others may store documents locally in EHR systems or upload them to a national XDS repository. Regardless of these infrastructure variations, it is essential that the teleconsultation encounter document remains interoperable and usable across all systems. Adopting universal communication standards and ensuring seamless integration into user-friendly applications will facilitate consistent handling and processing of shared information.

4.1.5 IT infrastructure

At the IT infrastructure level, generic interoperability standards and protocols must ensure seamless communication, storage, and backup of teleconsultation encounter reports. Member states that lack IHE XDS-based document sharing in their national infrastructure will need to establish this capability or implement an alternative infrastructure that supports secure and efficient exchange of these reports. Regardless of the chosen solution, compliance with standardised protocols is critical to enable interoperability and ensure reliable access to teleconsultation data across different healthcare systems.

4.2 Open questions

To guide further discussions and facilitate informed decision-making, several open questions remain to be addressed within the context of teleconsultation encounter reports:

1. **Scope**:
    - What specific aspects of teleconsultation should be prioritised for standardisation under the EHDS framework?
    - How can the framework balance flexibility for member states while maintaining consistency across borders?
    - Should the teleconsultation scope extend to all clinical specialities or focus on select domains where its value is most evident?
2. **AI Support for Summarising Tele-encounters**:

- What level of automation is appropriate for AI tools in summarising teleconsultation encounters, and how should these tools balance automation with human oversight?
- What data privacy and bias mitigation measures are required to ensure these AI tools align with the GDPR and AI Act?
- How can accuracy and trustworthiness of AI-generated summaries be validated and continuously improved?

3. **Access Rights**:
   - What should the access control framework look like for teleconsultation data?
   - Should distinct rights be defined for "share-to-view" (read-only access) and "share-to-share" (allowing further dissemination), and how should these rights be enforced?
   - What protocols should govern access between patients and doctors, as well as between doctors, to ensure both usability and data security?
4. **Data Repository and Exchange**:
   - How can duplication of teleconsultation encounter data with existing stored clinical notes be avoided?
   - Should national repositories (as seen in Denmark) or private company infrastructures be favoured, and what criteria should govern this choice?
   - How can the EEHRxF framework support seamless linking between public and private storage solutions to promote interoperability and continuity of care?

Addressing these questions is crucial for advancing the implementation and integration of teleconsultation encounter reports across member states. They highlight key challenges at the intersection of technology, policy, and patient-centric care, requiring collaborative input from all stakeholders.