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eHealth Digital Service Infrastructure
A service provided by the European Union

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

**Proposal number: 101128085**

# D9.1 Requirements and use cases on the availability of health data in cross-border telemedicine services

*(Co-)Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or HaDEA. Neither the European Union nor the granting authority can be held responsible for them.*

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## Executive Summary

Deliverable 9.1 – *Requirements and use cases on the availability of health data in cross-border telemedicine services* provides the requirements for cross-border telemedicine services, defining the enabling conditions, use cases and the business requirements, under MyHealth@EU infrastructure. This deliverable exploits the leveraging of MyHealth@EU infrastructure to support cross-border telemedicine services, in line with the proposed European Health Data Space (EHDS) regulation (as referred to in Article 24), to ensure the availability of health data in cross-border telemedicine services, including teleconsultations.

The identification of use cases was explored through workshops and meetings with participants, interviews conducted with telemedicine experts and a specific survey. The several use cases were discussed in the light of the proposed EHDS regulation, leading to the prioritization of two use cases selected from various possible forms of telemedicine and their use cases: i) **teleconsultation between patients and health professionals across borders**, and ii) **teleconsultation between health professionals from different countries discussing a patient's case**. In these two use cases, MyHealth@EU services applicability was explored and a use case description based on the eHealth Network guidelines was provided.

A patient journey was developed to highlight new requirements and specifications, enabling the analysis of potential solutions to address gaps. The patient journey includes four key phases of the process: i) scheduling, ii) pre-teleconsultation, iii) consultation, and iv) post-consultation phases. For each phase, the main involved actors and steps of the teleconsultation were described, and potential solutions were proposed to enable the usage of MyHealth@EU services to support a cross-border teleconsultation. Importantly, the current MyHealth@EU framework was used as the baseline for this analysis, and the solutions proposed in this document were based on the principle of favouring opportunities that have minimal impact on the existing MyHealth@EU infrastructure, in order to reduce the burden on countries and Central services/Core services. For instance, the reuse of International Search Mask (ISM) mechanism and the Patient Information Notice was investigated in this context.

The remote identification and authentication of patients was also thoroughly analysed, as in-person verification by health professionals in the country of treatment is not possible in the cross-border teleconsultation context. This new step is essential for verifying the patient's identity in a remote context to mitigate risks such as impersonation. As outlined in the proposed text of the EHDS regulation, the services to access electronic health data and the telemedicine platforms should ensure that individuals can exercise their rights to healthcare, regardless of their country of affiliation within the EU. To achieve this, these services should support the identification of individuals through any electronic identification and authentication methods recognized under Article 6 of Regulation (EU) No 910/2014. Therefore, this work analysed several approaches, with a consensus on a preferred solution for patient identification and authentication that involves reconciling this information within the infrastructure of the country of affiliation. Various mechanisms were considered, though a guiding principle is that each country of affiliation (country-A) should have the flexibility to decide on the exact implementation approach, taking into account its specific readiness and legal frameworks. In addition, a specific consent structure for cross-border teleconsultation and notification mechanisms to allow patients to track those who accessed their data and when were also explored, as well as the possible use of the EUDI Wallet for patient identification and authentication and sharing ISM attributes.

As part of the patient journey, it was also outlined that the information generated during teleconsultations may fall within EHDS priority data categories as defined in article 14 of the proposed text of the EHDS regulation, which include information such as diagnosis, or treatment plan. Therefore, considering patient continuity of care this information should be documented and shared with the patient's country of affiliation to further update the patient's electronic

health record. This report could follow the framework for the exchange of Discharge Reports in line with eHealth Network guidelines on Hospital Discharge Report.

Additionally, the eHDSI requirements catalogue was reviewed, aiming at identifying potential new requirements or existing requirements that may need amendment. While most requirements are also applicable to the cross-border teleconsultation within MyHealth@EU, a number of requirements will require an updated version to support cross-border telemedicine services, specifically regarding the patient identification and authentication, training, ePrescription and eDispensation, and discharge report.

The solutions that were proposed in this deliverable regarding the teleconsultation steps will be further explore on the deliverable (D) 9.2 – *Technical specifications on the availability of health data in cross-border telemedicine services* which will define the technical specifications for MyHealth@EU to ensure the availability of health data for telemedicine services, including teleconsultations. Moreover, D9.2 will take into consideration the electronic identification of the patient within the scope of MyHealth@EU infrastructure. A set of recommendations were put forward for the next steps that shall be discussed in D9.2.

Finally, this work identified additional use cases that could be supported by the MyHealth@EU infrastructure, such as the exchange of the S2 document for planned treatments in another EU or EFTA country, support for data exchange within the context of the European Reference Networks, and additional telemedicine use cases, including telemonitoring. This represent opportunities that may be further advance in the future.

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# ABBREVIATIONS AND ACRONYMS

| | |
|---|---|
| **-A** | Country of affiliation (e.g., NCP-A means national contact point of country of affiliation) |
| **-B** | Country of treatment (e.g., NCP-B means national contact point of country of treatment) |
| **CDA** | Clinical Document Architecture |
| **D** | Deliverable |
| **eD** | eDispensation |
| **EEHRxF** | European Electronic Health Record Exchange Format |
| **eAttestation** | electronic attestation |
| **eGOV** | Electronic Government |
| **EHDS** | European Health Data Space |
| **eHDSI** | eHealth Digital Service Infrastructure |
| **EHR** | Electronic Health Record |
| **eHN** | eHealth Network |
| **eID** | Electronic Identification |
| **eIDAS** | Electronic Identification, Authentication and Trust Services |
| **eP** | ePrescription |
| **EPR** | Electronic Personal Record |
| **ERN** | European Reference Network |
| **EU** | European Union |
| **EUDI Wallet** | European Digital Identity Wallet |
| **FHIR** | Fast Healthcare Interoperability Resources |
| **GA** | Grant Agreement |
| **GDPR** | General Data Protection Regulation |
| **GP** | General Practitioner |
| **HCPO** | Healthcare Provider Organisation |
| **HDR** | Hospital Discharge Report |
| **HL7** | Health Level 7 |
| **HP** | Health professional |
| **HPIN** | Health Professional Information Notice |
| **ICD** | International Classification of Diseases |
| **ICT** | Information and Communication Technologies |
| **ICU** | Intensive Care Unit |
| **IHE** | Integrating the Healthcare Enterprise |
| **ISM** | International Search Mask |
| **ISO** | International Organization for Standardization |
| **LSP** | Large-Scale Pilots |
| **MS** | Member States |
| **NCP** | National Contact Point |
| **NCPeH** | National Contact Point for eHealth |

| | |
|---|---|
| **NHS** | National Health Service |
| **OR** | Operation Ready |
| **PCHR** | Personally Controlled Health Record |
| **PDQm** | Patient Demographics Query for Mobile |
| **PHR** | Personal Health Records |
| **PIN** | Patient Information Notice |
| **PS** | Patient Summary |
| **(Q)EAA** | (Qualified) Electronic Attribute Attestation |
| **QR** | Quick Response |
| **REM** | Registered Electronic Mail |
| **SAML** | Security Assertion Markup Language |
| **SNOMED CT** | Systemized Nomenclature of Medicine – Clinical Terms |
| **SP** | Solution Provider |
| **SSO** | Single Sign On |
| **TCC** | Tele-Critical Care |
| **URI** | Uniform Resource Identifier |
| **WHO** | World Health Organisation |
| **WP** | Work Package |
| **XCPD** | Cross-Community Patient Discovery |

## GENERAL DEFINITIONS

The terminologies and definitions in this document are intended to promote a shared understandability and enhance the readability of this work. These definitions were based on the proposed EHDS regulation, as well as other internationally recognised definitions, such as those provided by WHO, eHealth Network and MyHealth@EU, where applicable and when available. The feedback from partners during the elaboration of this document's preparation was also considered. It is important to note that countries may have variations of these definitions within their own healthcare systems, so the definitions provide here should only be considered within the context of this document. These definitions are not legally binding and serve as a provisional framework to support WP9 ongoing activities and ensure a consistent interpretation. These definitions are specific to this document and may be revised as necessary in light of additional input and evolving requirements for future deliverables.

| Term | Definition | Reference |
|---|---|---|
| **Cross-border eHealth services** | In this document, cross-border eHealth services refer to the services that can be exchanged through the MyHealth@EU infrastructure, which currently (2024) supports the Electronic Prescription and Dispensation, and Patient Summary. The next services planned to become available include: Laboratory Results Report, Medical imaging studies and reports and Hospital Discharge Report. | N.A. |
| **Cross-border healthcare** | "Healthcare provided or prescribed in a Member State other than the Member State of affiliation." | Article 3(e) of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare[1] |
| **Cross-border telemedicine** | Refers the delivery of health care services using Information and Communication Technologies (ICT), where patients and health providers are located in two different countries. In this document, the provision of cross-border telemedicine is analysed in the context of MyHealth@EU and its geographical scope. | Based on the Non-Paper of the Portuguese Presidency: *Removing the Barriers to Cross-border Telehealth Services in the EU*, 2021 |
| **Discharge report** | "Electronic health data related to a healthcare encounter or episode of care and including essential information about admission, treatment and discharge of a natural person." | Annex I of the proposed text of the EHDS regulation[2] |
| **Electronic Dispensation (eD)** | "Information on the supply of a medicinal product to a natural person by a pharmacy based on an electronic prescription." | Annex I of the proposed text of the EHDS regulation[2] |

[1] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare [available here]

[2] Regulation on the European Health Data Space [available here]

| Term | Definition | Reference |
|---|---|---|
| **Electronic Prescription (eP)** | "Electronic health data constituting a prescription for a medicinal product." "A prescription means a prescription for a medicinal product or for a medical device issued by a member of a regulated health profession within the meaning of Article 3(1)(a) of Directive 2005/36/EC who is legally entitled to do so in the Member State in which the prescription is issued." | Annex I of the proposed text of the EHDS regulation[2] and Article 3(k) of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare[1] |
| **European electronic health record exchange format (EEHRxF)** | ''A set of technical specifications, targeted at ensuring the interoperability of electronic health record systems used on the European Union market.'' | European electronic health record exchange format and its connection to the harmonisation provisions in the proposed EHDS regulation[3] |
| **Health professional (HP)** | "A doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC, or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC, or a person considered to be a health professional according to the legislation of the Member State of treatment." | Article 3(f) of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare[1] |
| **Interoperability** | "Ability of organisations as well as software applications or devices from the same manufacturer or different manufacturers, to interact through the processes they support, involving the exchange of information and knowledge, without changing the content of the data, between these organisations, software applications or devices." | Article 2(f) of the proposed text of the EHDS regulation[2]. |
| **Medical test results, including laboratory and other diagnostic results and related reports** | "Electronic health data representing results of studies performed in particular through in vitro diagnostics such as clinical biochemistry, haematology, transfusion medicine, microbiology, immunology and others, and including, where relevant, reports supporting the interpretation of the results." | Annex I of the proposed text of the EHDS regulation[2]. |
| **Medical imaging studies and related imaging reports** | "Electronic health data related to the use of or produced by technologies that are used to view the human body in order to prevent, diagnose, monitor or treat medical conditions." | Annex I of the proposed text of the EHDS regulation[2]. |

[3] Concept Note - European electronic health record exchange format and its connection to the harmonisation provisions in the upcoming European Health Data Space regulation [available here]

| Term | Definition | Reference |
|---|---|---|
| **Member State of affiliation** | "(i) for persons referred to in point (b)(i), the Member State that is competent to grant to the insured person a prior authorisation to receive appropriate treatment outside the Member State of residence according to Regulations (EC) No 883/2004 and (EC) No 987/2009;<br>(ii) for persons referred to in point (b)(ii), the Member State that is competent to grant to the insured person a prior authorisation to receive appropriate treatment in another Member State according to Regulation (EC) No 859/2003 or Regulation (EU) No 1231/2010. If no Member State is competent according to those Regulations, the Member State of affiliation shall be the Member State where the person is insured or has the rights to sickness benefits according to the legislation of that Member State." | Article 3(c) of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare[1] |
| **Member State of treatment** | "The Member State on whose territory healthcare is actually provided to the patient. In the case of telemedicine, healthcare is considered to be provided in the Member State where the healthcare provider is established." | Article 3(d) of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare[1] |
| **MyHealth@EU** | MyHealth@EU is a common EU digital infrastructure designed to ensure secure and efficient connectivity and interoperability among Member States to support cross-border healthcare. Therefore, it enables natural persons to share their personal electronic health data with healthcare providers while traveling abroad, ensuring continuity of care.<br>The participation of Member States in MyHealth@EU is mandatory under the proposed EHDS regulation. Currently (2024), MyHealth@EU supports the exchange of Patient Summary, Prescription and eDispensation. According to the proposed EHDS regulation, MyHealth@EU infrastructure should enable the exchange of priority categories of electronic health data as defined in Article 14, as well as additional categories supported by the European electronic health record exchange format. | Based on the proposed text of the EHDS regulation[2] and MyHealth@EU website[4]. |
| **Patient** | "Any natural person who seeks to receive or receives healthcare in a Member State." | Article 3(h) of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' |

[4] MyHealth@EU - Flyer addressed to patients and health professionals [available here]

| Term | Definition | Reference |
|---|---|---|
| | | rights in cross-border healthcare[1] |
| **Patient Summary (PS)** | "Electronic health data that include significant clinical facts related to an identified person and that are essential for the provision of safe and efficient healthcare to that person. The following information is part of a patient summary:<br>1. Personal details;<br>2. Contact information;<br>3. Information on insurance;<br>4. Allergies;<br>5. Medical alerts;<br>6. Vaccination/prophylaxis information, possibly in the form of a vaccination card;<br>7. Current, resolved, closed or inactive problems including in an international classification coding;<br>8. Textual information related to medical history;<br>9. Medical devices and implants;<br>10. Medical or care procedures;<br>11. Functional status;<br>12. Current and relevant past medicines;<br>13. Social history observations related to health;<br>14. Pregnancy history;<br>15. Patient provided data;<br>16. Observation results pertaining to the health condition;<br>17. Plan of care;<br>18. Information on a rare disease such as details about the impact or characteristics of the disease." | Annex I of the proposed text of the EHDS regulation[2] |
| **Telehealth** | "Delivery of health care services, where patients and providers are separated by distance. It ensures that a person receives healthcare when required, particularly for those people with limited access to care. Telehealth employs Information and Communication Technologies (ICT) for the exchange of information for the diagnosis and treatment of diseases and injuries, research, and evaluation, and for the continuing education of health professionals".<br><br>Telehealth is a broader scope than telemedicine, including "non-clinical services such as health education of the population (including professionals), administrative meetings, and medical education of healthcare professionals." | From Cross-border telehealth practice: policy considerations by WHO[5] and Welcome to the world of telemedicine: Understanding the basics, ISO[6] |
| **Telemedicine** | A subset of telehealth which covers the use of technology to deliver health care services at a distance by health professionals using information and communication | Based on the Regional digital health action plan for the |

[5] Cross-Border Telehealth Practice: Policy Considerations by WHO [available here]

[6] ISO - Welcome to the world of telemedicine: Understanding the basics [website available here]

| Term | Definition | Reference |
|---|---|---|
| | technologies (ICT) for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, among other examples. Telemedicine can take different forms such as provider-to-provider or provider-to-consumer care and can be synchronous or asynchronous. | WHO European Region 2023–2030[7] |
| **Teleconsultation** | A form of remote medical consultation in which health professionals use ICT to provide clinical advice, diagnosis, or treatment to patients or other healthcare providers at a distance. This can include real-time (synchronous) consultations using video or audio links or store-and-forward (asynchronous) methods, where medical data, such as images or patient records, are shared for later review and response. | Based on the consolidated telemedicine implementation guide by WHO[8] and the Italian telemedicine guidelines[9,10]. |
| **Patient – HP teleconsultation** | In this document, it means a teleconsultation between a patient and a health professional. | - |
| **HP-HP teleconsultation** | In this document, it means a teleconsultation between a two or more health professionals. Other terms sometimes are used as such a tele-expertise or teleconference between health professionals. | - |
| **Telemonitoring** | Refers to the use of ICT by health professionals to monitor patients remotely. It involves continuous or regular collection of biomedical parameters, transmission and evaluation of health data to monitor the patient's state remotely. In telemonitoring, the data collection can be automatic or patient-guided (e.g., the patient can manage the data collection and transmission through medical devices). | Based on the consolidated telemedicine implementation guide by WHO[8] and thy Italian Telemedicine Guidelines[9] |

[7] Regional Committee for Europe, 72nd session. (2022). Seventy-second Regional Committee for Europe: Tel Aviv, 12–14 September 2022: Regional digital health action plan for the WHO European Region 2023–2030 [available here]

[8] Consolidated telemedicine implementation guide by WHO [available here]

[9] Indicazioni Nazionali per l'erogazione di prestazioni in telemedicina (National guidelines for the delivery of telemedicine services) [available here]

[10] Telemedicina: Linee di Indirizzo Nazionali (Telemedicine: National Guidelines) [available here]

## SCOPE AND INTERDEPENDENCIES

- **Scope**

The scope of this deliverable includes defining use cases, prioritising key use cases and establishing business requirements for the uptake of telemedicine services within the MyHealth@EU framework. The related technical specifications will be outlined in D9.2 – *Technical specifications on the availability of health data in cross-border telemedicine services*.

- **Interdependencies**

Deliverable 9.2 is dependent on the specifications defined in D9.1, and therefore an interactive process between both was established.

As identified in the Xt-EHR workplan, this work also depends on complimentary Xt-EHR Work Packages (WP), such as 4[11], 5[12], 7[13] and 8[14], and therefore the work was coordinated with the leaders of these WPs.

The work planned for this deliverable also depends on the eHealth Network (eHN) guidelines and MyHealth@EU requirements and specifications, that served as basis for this work. In addition, Article 24 – *Supplementary cross-border digital health services and infrastructures* as defined in the proposed text of the European Health Data Space (EHDS) regulation[2] should also be considered for this work, as well as any other relevant article that may impact this work.

[11] WP4 - Sustainability and cross-border interoperability

[12] WP5 - General and security and logging requirements for EHR systems and System Interfaces

[13] WP7 - New services for EHR systems towards EHDS

[14] WP8 - Certification and labelling framework

# 1. INTRODUCTION

The proposed regulation for the European Health Data Space (EHDS)[2] aims to enhance individuals' access and control over their personal electronic health data while allowing certain clinical data to be reused for public interest, policy development, and scientific research. By creating a health-specific data environment, the EHDS will promote a single market for digital health services and products across the European Union (EU).

For this purpose, the joint action Extended EHR@EU Data Space for Primary Use (Xt-EHR) aims to improve interoperability and data exchange in the EU by preparing important specifications, requirements and guidelines to support the implementing acts under the proposed EHDS regulation. The joint action will promote the adoption of common specifications and requirements so that Electronic Health Record (EHR) software solutions and services can adopt, test and implement common specifications based on the European Electronic Health Record Exchange Format (EEHRxF), impacting the EU single market. The results of this project will impact all stakeholders in the process of digital transformation in healthcare based on a standard-based health information exchange. Through Xt-EHR, the interoperability and cross-border exchange of different types of health data will be fostered by proposing the necessary implementation guidelines for the deployment of new services that will complement the MyHealth@EU initiative.

The work package (WP) responsible for this deliverable, WP9 – *Telemedicine under MyHealth@EU in alignment with EHDS proposal*, focuses on the implementation of cross-border telemedicine services within the MyHealth@EU framework. This initiative aims to lay the foundation to support Article 24, which addresses the supplementary cross-border digital health services and infrastructures under the EHDS regulation[2], enhancing the use of health data and ensuring seamless access to healthcare across countries, with a specific focus on telemedicine and interoperable health records.

As outlined in the proposed text of the EHDS regulation[2], telemedicine has become an increasingly important tool for ensuring patients access to care, reducing inequities and reinforcing the free movement of EU citizens across borders. Furthermore, differing healthcare policies should not pose barriers to the free movement of electronic health data, particularly in the context of cross-border healthcare, including telemedicine services. Moreover, the services to access electronic health data and the telemedicine platforms should ensure that individuals can exercise their rights to healthcare, regardless of their country of affiliation within the EU. To achieve this, these services should support the identification of individuals through any electronic identification and authentication methods recognized under Article 6 of Regulation (EU) No 910/2014[15]. In cross-border healthcare scenarios, identity matching and authentication may present challenges, and Member States (MS) may need to provide supplementary access tokens or codes for individuals seeking care abroad. Therefore, it is crucial to ensure interoperable, cross-border identification and authentication for both individuals and health professionals. According to the proposed text of the EHDS regulation[2], the European Commission (EC) should be empowered to adopt implementing acts for this purpose, including establishing any necessary supplementary mechanisms to guarantee individuals can access their personal electronic health data when receiving healthcare in other MS.

For background information regarding this work, additional information is provided in Annex I –*MyHealth@EU infrastructure and cross-border telemedicine*, which outlines the state of play of cross-border telemedicine services and the MyHealth@EU infrastructure.

[15] Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC [available here]

## 1.1 Objective of the deliverable

This deliverable will provide requirements to support cross-border telemedicine services under the MyHealth@EU infrastructure, by particularly focusing on understanding how MyHealth@EU services can be leveraged to support telemedicine services, such as teleconsultations. This deliverable will present an analysis of the enabling conditions, use cases and business requirements considering the existing guidelines and framework of MyHealth@EU, and the proposed text of the EHDS regulation, which was the current version available at the time of writing this document. Other relevant references will also be analysed, and the expertise of the WP9 participants will be key for this work.

Furthermore, the deliverable is tasked with identifying and defining the priority use cases within telemedicine services, which will serve for developing the business requirements. These use cases will be selected based on their potential impact and relevance to the healthcare objectives of the EU in line with EHDS.

This deliverable will not operate in isolation but will consider the synergies and outputs from other Xt-EHR Work Packages. This includes the integration of electronic identification (eID), which is pivotal for ensuring secure and reliable identification processes across the digital health services under EU. These inclusions are interdependent from the work developed under WP5[12] and WP8[14].

Lastly, the deliverable will significantly contribute to the EHDS, aligning with the strategic goals outlined in Article 24. These contributions aim to strengthen the proposed EHDS by providing guidance on how MyHealth@EU can facilitate cross-border health data exchange, enabling seamless healthcare provision across the EU through telemedicine. This alignment ensures that the deliverable not only addresses immediate telemedicine needs but also integrates with the broader vision of a unified and efficient digital health ecosystem across the European Union.

# 2. METHODOLOGY

This section defines the methodology that was implemented in the production and development of this deliverable, detailing the structured approach and frameworks that must be employed to fulfil the intended goals, which took into consideration the consortium partners opinions, guidance, and approval.

The main objective was to provide clear understanding of the reliability and validity of the findings that were reported in this deliverable. For this purpose, a number of meetings with WP9 partners were scheduled with the objective to discuss and outline the priority use cases, content definition and business requirements to ensure the availability of electronic health data in cross-border telemedicine services, taking into consideration the existing MyHealth@EU infrastructure and the work which is being produced by the other WPs.

## 2.1. Scenarios and use cases identification

As specified in the Grant Agreement (GA) of Xt-EHR, one of the initial objectives of D9.1 was to define the priority use cases. These use cases were identified through a thorough analysis of the interviews, survey, and workshop conducted, as detailed in the following sections. Accordingly, the subsequent sections of this chapter delve into the insights gained from these analyses.

### 2.1.1. Telemedicine experts' interviews

Interviews with telemedicine experts were conducted with the primary goal of identifying and prioritizing key use cases for cross-border telemedicine services, as well as understanding the specific requirements and needs that could influence the adoption of MyHealth@EU services in this context. Additionally, these discussions served as an initial step in raising awareness about this subject.

This methodology ensured a comprehensive approach to gather insightful information to the development of requirements, guidelines and recommendations for the implementation of cross-border telemedicine services under MyHealth@EU, while aligning with the proposed EHDS regulation[2].

The interviews with telemedicine experts were organized into four main sections:

1. **Healthcare Mobility:** This section aimed to gather the interviewees' knowledge regarding cross-border healthcare mobility initiatives in their respective countries. Additionally, objective examples of healthcare mobility initiatives, and their opinions on how cross-border telemedicine within MyHealth@EU could support these initiatives were obtained.
2. **Cross-Border Telemedicine:** This section was developed with the objective to gather insights from interviewees on existing cross-border telemedicine projects in their countries and explore their potential integration within MyHealth@EU. This was also used to identify priority use cases and key requirements for integration of these projects under MyHealth@EU.
3. **Identification of Requirements:** This section aimed to pinpoint enablers and barriers for cross-border telemedicine services within MyHealth@EU. Interviewees were questioned about their views on the main requirements for the successful implementation of cross-border telemedicine services, such as specific regulations, reimbursement rules, data security and privacy, interoperability, data quality, and mechanisms for assessing and guaranteeing the quality of cross-border telemedicine services.
4. **Conclusions**: This final section summed the interview with the final remarks of the participants. Moreover, the participants were questioned regarding their interest in participating in future additional interviews, workshops, meetings, and/or activities related to cross-border telemedicine under MyHealth@EU.

The template developed for the structured analysis of the interviews can be found in Annex II – Structured Interview template of this deliverable, and a summary of the key discussion points and ideas from the interviewees is presented in *Annex III – Telemedicine interview analysis.*

### 2.1.2. Cross-border telemedicine survey

To complement the interviews, a specific survey (*Annex IV – Survey template*) was designed to capture a broader range of responses and enhance the overall knowledge base for this work. This 'Cross-border Telemedicine' survey primary objective was to gather insights from telemedicine professionals and experts regarding priority use cases for cross-border telemedicine within the MyHealth@EU infrastructure. The survey consisted of 23 questions, including both multiple-choice and open-ended formats, with an estimated completion time between 5 to 10 minutes. In order to obtain a structured comprehensive analysis, the survey was divided into four distinct sections:

1. **Healthcare Mobility:** This section was developed with the intent to explore participants views/perspectives on the potential benefits of telemedicine services in patient mobility initiatives, such as seeking specialized care in another country. Participants were queried about their awareness of cross-border healthcare initiatives within their countries, providing a description of those initiatives. Participants were also requested to share their perspectives on how cross-border telemedicine services under MyHealth@EU could support cross-border initiatives.
2. **Cross-border Telemedicine:** This section was elaborated with the objective of identifying initiatives and priority use cases for integration into the MyHealth@EU infrastructure. Participants were questioned about their knowledge of cross-border initiatives in their own or other countries, detailing the types of services offered (e.g., teleconsultation, telemonitoring, teletriage, telerehabilitation), and whether those initiatives were fully implemented or in planning stages. Moreover, participants provided their insights on the added value of cross-border telemedicine, such as expanded access to healthcare, reduced geographic barriers, improved service efficiency, cost savings for patients, and support for rapid diagnosis and treatment. Participants also had the opportunity to provide their views on the potential incorporation of existing telemedicine services into MyHealth@EU, identifying priority use cases for integration, and outlining the main requirements for such integration (e.g., interoperability, legal compliance, data security, technical specifications, performance criteria, training, accessibility, auditing, and compliance).
3. **Identification of possible requirements for Cross-border Telemedicine under MyHealth@EU:** This section is intended to identify requirements to ensure the effectiveness, safety, and accessibility of digital health services across the EU. Participants were questioned regarding their insights on the main enablers and barriers for the successful implementation of telemedicine services within MyHealth@EU. The purpose of this section was the identification of the requirements for a successful implementation of telemedicine services, as well as the major obstacles that should be taken into consideration when establishing such services.
4. **Conclusion:** The final section assessed the final thoughts of the participants regarding the subject at matter, giving them the opportunity to express their potential interest in participating in future activities, such as interviews, workshops, or meetings.

The survey analysis, including the key findings, is presented in *Annex V - Cross-border telemedicine survey analysis.*Annex V - Cross-border telemedicine survey analysis

### 2.1.3. Workshop on telemedicine use cases

A workshop focusing on telemedicine use cases was conducted to gather opinions and insights from consortium partners regarding crucial scenarios to explore within the context of this deliverable. Utilizing the collaborative platform 'Mural', participants had the opportunity to explore different use cases and provide real-time input and collaboration on the value of telemedicine under MyHealth@EU (as shown in *Annex VI – Workshop template*). Participants were requested to assess how telemedicine services could benefit patients, health professionals, and policymakers in each identified use cases.

To facilitate the discussion, two hypothetical scenarios were presented to participants for discussion and analysis:

I. The first scenario described John, a patient suffering from chronic heart failure, who falls ill during a business trip abroad in an EU MS and required urgent care. In the proposed scenario, John sought assistance at the nearest hospital which provided MyHealth@EU services. The intended purpose of this scenario was to assess requirements, benefits, and barriers of establishing telemedicine under MyHealth@EU services, mainly to help and address all the health-related issues regarding patients with cardiovascular pathologies in a cross-borders setting.

II. The second scenario featured Emily, a patient diagnosed with a rare disease, who required specialized care unavailable in her home country due to the lack of an expert clinician. To address this issue, the option of seeking specialized care abroad was proposed to her. Participants were invited to discuss and offer insights on how telemedicine, within the MyHealth@EU framework, could help to overcome such challenges, as represented in this scenario.

A comprehensive description of the scenarios, with an additional analysis from the participants, is presented in *Annex VII - Telemedicine Workshop analysis.*

## 2.2. Use Case Analysis

Building on the previous approaches, the second step was to draft and reach consensus on scenarios and use cases to develop the required patient journey, processes, and business requirements to realise the potential of MyHealth@EU in supporting cross-border telemedicine services in line with the proposed EHDS regulation[2].

Each identified scenarios and use cases were analysed in detail to elucidate its scope, functional steps, and to fully understand the patient journey and its associated processes. This included identifying dependencies or constraints that could impact implementation within the MyHealth@EU infrastructure. The analysis followed an iterative process, with regular partners engagement to validate and refine the requirements, ensuring they accurately reflected the needs of end-users in line with the proposed EHDS regulation[2].

Key reference documents for this analysis included the eHN guidelines, the eHealth Digital Service Infrastructure (eHDSI) requirement catalogue, the proposed EHDS regulation, and the Electronic Identification, Authentication and Trust Services (eIDAS) framework. Additionally, the expertise of the teams responsible for managing MyHealth@EU was instrumental in assessing the feasibility of the proposed ideas.

# 3. TELEMEDICINE UNDER MYHEALTH@EU PROPOSAL

The findings from the workshop, interviews and survey outlined in the previous chapters highlight the strong interest in leveraging MyHealth@EU services to facilitate cross-border telemedicine. Based on the priorities of the EHDS regulation and results from this work, the selected use cases focused in using MyHealth@EU services to support teleconsultations across borders. Additional use cases that were identified and detailed in Annex III – Telemedicine interview analysis, Annex V - Cross-border telemedicine survey analysis and Annex VII - Telemedicine Workshop analysis, represent opportunities that Member States may consider for future developments.

The next subsections will detailed the different process and proposals to enable the use of MyHealth@EU services to support cross-border teleconsultations.

Firstly, the **identification and authentication of patients and health professionals (HP)** in a cross-border setting were deemed as the priority scenario to be analysed in this document, as the necessary initial step to enable the use of MyHealth@EU services to support telemedicine services across borders. This step is crucial, as it establishes the foundation for accessing services, particularly given that the current patient journey within MyHealth@EU typically involves in-person identification, such as presenting a physical ID card to a HP, as well as HP identification and authentication following strong authentication mechanisms. These requirements were introduced in the eHDSI Requirements catalogue version 4.0.0 (Wave 4), with two-factor authentication (2FA) for HP implemented in Wave 5 (version 5.1.1 Operation Ready (OR)). These requirements have been maintained in the version 8.0 of the eHDSI Requirements catalogue [16], which were analysed in this deliverable. The analysis covered both patient-to-HP teleconsultations and HP-to-HP teleconsultation, where in both cases, the participants are located in different countries.

Secondly, the **potential impact on accessing the existing MyHealth@EU services** was evaluated, along with any requirements necessary to enable the key steps required in a teleconsultation, covering the processes before, during and after the teleconsultation encounter.

Finally, the **eHDSI requirement catalogue was reviewed** to identify existing requirements of MyHealth@EU that could be impacted, and to outline the need for any new requirements, if applicable.

Importantly, the solutions proposed in this document are based on the principle of favouring opportunities that have minimal impact on the existing MyHealth@EU infrastructure, in order to reduce the burden on Member States and Central services/Core services while increasing the likelihood of adoption. Therefore, solutions identified as extensions to the current infrastructure were favoured over those that required significant evolution. As per the definitions provided in the X-eHealth project [17], an 'evolution' would involve more significant architectural and procedural changes, demanding more work and analysis. In contrast, an 'extension' would introduce new functionalities with minimum changes by reusing current architecture and procedures inside MyHealth@EU.

[16] eHDSI Requirement Catalogue V8.0 OR [Access restricted to MyHealth@EU members [Available upon sign in here]

[17] X-eHealth Project: Deliverable 7.1- X-eHealth Architecture definition to implement and deploy EEHRxF services [available here]

## 3.1. Use case description

The use case description was developed using the structure outlined in the eHN guidelines, including those for PS[18] and Hospital Discharge Report (HDR)[19], to ensure alignment with the existing framework. Table 1 below presents a high-level description of the purpose, relevance, context, participants, and functional process steps, aiming to facilitate analysis and the potential drafting of guidelines in the future, should adoption occur. The detailed analysis of each step and potential solutions are further developed in sections 3.3.2 and 3.3.3.

**Table 1.** Telemedicine under MyHealth@EU use case description, based on the structure of the eHN guidelines.

| TITLE | TELEMEDICINE UNDER MYHEALTH@EU |
|---|---|
| **PURPOSE** | The priority use cases, defined through the methodology described in section 2, focused on two key scenarios:<br>• a teleconsultation between a patient in his/her country of affiliation (Country-A) and a HP in a different country (Country-B).<br>• a teleconsultation between two HPs, one in Country-A and the other in Country-B, discussing the case of the patient from Country-A.<br>These telemedicine services will be supported by MyHealth@EU infrastructure, and the same principles could be applied by implementers, including MS, for national and regional-level interoperability. This national and regional-level interoperability would ensure that information sharing is not limited to cross-border cases, helping maintain consistency while avoiding fragmentation and duplication of efforts. |
| **RELEVANCE** | The MyHealth@EU services are a crucial part of the proposed EHDS regulation, which emphasizes secure and interoperable health data exchange across the EU. This interoperability is of utmost importance to enhance the availability of health data for cross-border healthcare, facilitating better coordination and collaboration in the Union. MyHealth@EU supports these objectives by ensuring that patient health information is accessible and shareable across borders, thus enabling continuity of care. The sharing of health information should be supported in health encounters both in person and virtually, ensuring seamless and trustworthy access to critical information for the care of citizens in the Union.<br>Additionally, the EHDS regulation promotes the use of standardized health data formats and interoperable systems, which are essential for the seamless operation of cross-border telemedicine services. MyHealth@EU contributes to this by implementing standardized protocols that enable healthcare systems across countries to communicate effectively. Therefore, these services can be extended to support telemedicine services, including teleconsultation. This interoperability is crucial for facilitating efficient teleconsultations and collaboration between HPs in various countries, thereby reducing fragmentation and enhancing the overall efficiency of the European health care systems.<br>This is highly relevant considering that many individuals seek medical assistance from specialists in a country different from their country of residence. As a result, health data from Country-A should be accessible to all European citizens and HP, regardless of location. |

[18]Guideline on electronic exchange of health data under Cross-Border Directive 2011/24/EU for Patient Summary [available here]

[19]Guideline on electronic exchange of health data under Cross-Border Directive 2011/24/EU for Hospital Discharge Reports [available here]

| TITLE | TELEMEDICINE UNDER MYHEALTH@EU |
|---|---|
| | Cross-border telemedicine plays a vital role in the evolving healthcare systems and MyHealth@EU can support clinical decisions by providing HPs with critical information needed for the prevention, diagnosis, treatment, and management of diseases in this context.<br>The ability to access a patient's health data from requests submitted by various entities helps eliminate unnecessary duplicate tests, exams and diagnosis, reducing healthcare costs and easing the burden on patients. However, it remains the responsibility of the receiving health professional to determine which information is clinically relevant. |
| **DOMAIN** | Telemedicine services, teleconsultation |
| **SITUATION** | Cross-border (potential inter-regional or national) |
| **CONTEXT** | As outlined in the proposed text of the EHDS regulation, telemedicine is increasingly essential for ensuring patient access to care, addressing healthcare disparities, and facilitating the free movement of EU citizens across borders. The regulation underscores that varying national healthcare policies should not obstruct the seamless flow of electronic health data, especially in the realm of cross-border healthcare and telemedicine services. For this purpose, it is imperative that electronic health data access services and telemedicine platforms enable individuals to exercise their healthcare rights irrespective of their country of residence within the EU. This possibility is further complemented in Article 24, which addresses the supplementary cross-border digital health services and infrastructures under EHDS, where telemedicine is listed. To support this, these services must accommodate the identification of individuals through any electronic identification methods recognized under Article 6 of Regulation (EU) No 910/2014[15].<br>Therefore, MyHealth@EU plays a pivotal role in ensuring secure and interoperable health data exchange across the EU and the existence of cross-border HP identification and authentication mechanisms, which can be exploited for patients in the context of telemedicine services, including teleconsultation. This proposal does not limit but rather guarantees equitable healthcare whether delivered in person or virtually.<br>At the moment of drafting this deliverable, the current services available within MyHealth@EU include Patient Summary and ePrescription/eDispensation, which provide a foundation for seamless health information exchange across EU. In the near future, this will be expanded with additional services, including Discharge Reports, Medical test results, including laboratory and other diagnostic results and related reports, and Medical Imaging studies and related imaging reports. These planned services will enhance the cross-border sharing of health data, including in the telemedicine domain.<br>• Use cases in scope:<br>○ **Use case 1 – Teleconsultation between Patient and HP**: in this scenario, a patient from Country-A seeks a teleconsultation with a HP from Country-B, who needs to access data from country-A regarding the patient.<br>○ **Use case 2 – Teleconsultation between two HPs**: this scenario involves a teleconsultation between two HPs, one from Country-A and another from Country-B, where HP-B needs to access data regarding a patient from Country-A.<br>○ **Both use-cases** will consider the creation of a discharge report[20] regarding a teleconsultation encounter performed by a HP in country-B that needs to be sent to a HP in Country-A; |

[20] Discharge Report is defined in the EHDS regulation[2] as a "Electronic health data related to a healthcare encounter or episode of care and including essential information about admission, treatment and discharge of a natural person."

| TITLE | TELEMEDICINE UNDER MYHEALTH@EU |
|---|---|
| | • Scenarios that can be considered in the future:<br>  ○ Telemonitoring |
| **INFORMATION** | Current MyHealth@EU services: Patient Summary, ePrescription/eDispensation.<br>Planned MyHealth@EU services: Laboratory Result Report, Discharge Reports, Imaging study manifest, Imaging report, Metadata on imaging studies and reports used for search and retrieval. |
| **PARTICIPANTS** | Citizen / Patient<br>Health professional in patient's country of origin/affiliation (Country-A)<br>Health professional in country of treatment and care (Country-B) |
| **FUNCTIONAL PROCESS STEPS** | The following steps provide a summarized overview of the process for the selected use cases. The reader is advised to consult the more detailed description available in sections 3.3.2, 3.3.3 and 3.3.4, to better understand the different solutions and requirements necessary to accomplish these steps. These steps serve as a basis to analyse the different use cases, including the identification and authentication steps necessary for sharing health data across borders, however they do not capture all possible variables.<br>***Use case 1: Teleconsultation between Patient and HP***[21]<br>• ***Scheduling phase:***<br>1. The patient in Country-A requests a teleconsultation with a HP of a Healthcare Provider Organisation (HCPO) in Country-B.<br>2. The HCPO-B schedules the teleconsultation appointment with a HP from Country-B.<br>3. HCPO-B requests the patient's International Search Mask (ISM) attributes, provides instructions, Patient Information Notice (PIN) document and request validation for data sharing, as applicable.<br>4. The patient provides ISM attributes and acknowledges the PIN.<br>5. HCPO-B stores ISM information to be shared with HP-B.<br>6. HCPO-B provides the patient access to the teleconsultation platform and the patient can access and use the teleconsultation platform.<br>• ***Pre-teleconsultation phase (before the teleconsultation begins)***[22]:<br>7. The HP-B is identified and authenticated using its usual platform to access MyHealth@EU services.<br>8. HP-B inserts the patient's ISM attributes using its existing platform and selects an option informing that the encounter is in the context of a teleconsultation[23].<br>9. NCP-B sends this request and ISM information to NCP-A.<br>10. NCP-A forwards the request to the National Infrastructure-A for patient identification and authentication.<br>11. National Infrastructure-A sends the request for the identification and authentication to the patient using the mechanism defined by Country-A. |

[21] Use case 1 has been thoroughly detailed to align with the process description provided in Section 3.3.2, which was structured based on a patient journey flowchart, outlining each step specific to this use case.

[22] The identification and authentication of the patient may also occur days before the teleconsultation in situations where the HP-B needs to access the information in advance. This is further analysed in the subsequent sections.

[23] The NCPeH will need to recognize that this request occurs in the context of teleconsultation, necessitating an additional step for remote identification and authentication of the patient, as in-person verification by HP-B is not possible. This new step is essential for verifying the patient's identity in a remote context to mitigate risks such as impersonation. This is discussed further in section 3.3.3.

12. After receiving this request, the patient identifies and authenticates himself/herself using a strong two-factor mechanism as defined by the Country-A[24].
13. Once validated by the National Infrastructure, NCP-A matches the ISM attributes for patient search and confirms the authentication to NCP-B.
14. NCP-B notifies the National Infrastructure-B of the successful patient's identification and authentication.
15. The National Infrastructure-B confirms the successful patient's identification and authentication to HP-B.
16. Afterwards, HP-B request access to the relevant clinical documents, by entering data according to the ISM attributes (e.g., defined for PS, eP, Imag., Lab.) through its standard platform to access MyHealth@EU services[25].
17. NCP-B receives the HP-B request to access patient's information and sends it to NCP-A.
18. NCP-A receives the NCP-B request to access patient's information and sends it to National Infrastructure-A.
19. National Infrastructure-A receives the request to provide the patient's data and sends it to NCP-A in the friendly-A format.
20. NCP-A receives the friendly-A and converts it into a Pivot format to send to NCP-B.
21. NCP-B receives the Pivot format, translates it into friendly-B format and sends it to National Infrastructure-B.
22. National Infrastructure-B receives the friendly-B format and converts it into Country-B's local format to send to the HP-B.
23. HP-B can access MyHealth@EU services displayed in his/her usual platform and starts the teleconsultation.
    - ***End of the teleconsultation***[26]***.***

***Use case 2: Teleconsultation between two HPs***[27]

1. HPs provides information to the patient on how personal health data in the priority categories of personal electronic health data will be collected and processed in the context of a cross-border teleconsultation.
2. The HP in Country-A has a scheduled teleconsultation with a HP in Country-B regarding a patient from Country-A[28].
3. The HP-B is identified and authenticated through his/her usual platform to access MyHealth@EU services.
4. HPs check patient consent to access their health data (if applicable)[29].
5. HP-B queries Country-A for a list of personal health data of that patient, based on the query parameters, similar to the steps presented above regarding the patient and document search.
6. Country-A provides a list of the personal health data available for the patient matching query parameters if validation by NCP-A was successful.

[24] This step is important to check the patient's identity to avoid possible risks, such as impersonation, in a remote context.

[25] Regarding the ISM attributes, some systems may request all data for both patient and document search steps simultaneously or in a stepwise manner; however, access to the relevant documents is only granted after completing all validation processes.

[26] For information on sharing teleconsultation-related information, refer to section below "Both use cases – Sharing information regarding the priority data categories as defined in article 14 of the proposed EHDS regulation back to citizen's country of affiliation as a discharge report".

[27] Use case 2 was developed in alignment with the eHN guidelines; therefore, the steps may not be as detailed as those outlined in use case 1.

[28] The teleconsultation platform is selected and managed by the HCPO / HPs, who need to ensure that proper secure access exist to allow for this HP-HP teleconsultation. The steps in the use case 2 are only analyzing the access of patient-A information by HP-B.

[29] The process to access patient-A's data in this context is further detailed in section 3.3.2.2, where different solutions are explored considering possible consent-based mechanisms or a prompt for patient identification and authentication similar to the one described for use case 1.

7. HP-B selects all or subsets of reports and requests them from Country-A.
8. The set of personal health data is electronically transferred from the Country-A to the HP-B in a secure way through MyHealth@EU.
9. The personal health data is presented to the HP-B in an understandable way, namely regarding language, structure and vocabularies.

***Both use cases – Sharing information regarding the priority data categories as defined in article 14 of the proposed EHDS regulation back to patient's country of affiliation as a discharge report.***

These reports, which include electronic health data registered during a teleconsultation, should comprehensively cover key aspects of the healthcare encounter or episode of care. This includes essential information about the teleconsultation, treatment, and discharge, ensuring that all relevant details are communicated effectively to support continuity of care in the patient's country of affiliation. The documentation and sharing of the clinical information generated during the teleconsultation encompasses the following steps:

1. The HP-B generates a report based on the clinical information retrieved during the teleconsultation.
2. HP-B request NCP-B to send this report to the patient's country of affiliation.
3. NCP-B receives, translates and transcodes the document and sends it to NCP-A.
4. NCP-A receives, translates and transcodes the report and sends it to the National Infrastructure-A.
5. National infrastructure-A stores this report in the relevant EHR system(s).

## 3.2. Patient Journey

A patient journey was developed to better understand the incorporation of MyHealth@EU services in the context of a teleconsultation that was scheduled by a citizen (patient) from Country-A with a HP from Country-B.

This patient journey flowchart helps to provide a clear and comprehensive understanding of the core processes involved in a teleconsultation and how MyHealth@EU infrastructure can be leveraged to support cross-border teleconsultation services. The patient journey flowchart focuses on validated and well-established steps, offering a foundational overview to foster discussion and agreement on the most viable solutions. Some processes and proposals are not included in this initial flowchart, as they are detailed in subsequent chapters of this document and will also be further explored in Deliverable 9.2 – *Technical specifications on the availability of health data in cross-border telemedicine services*.

The flowchart represented in **Figure 1** is divided into four primary phases: i) Scheduling (section **Phase I – Scheduling**), ii) Pre-teleconsultation (section **Phase II – Pre-teleconsultation**), iii) Teleconsultation, and iv) Post-Teleconsultation (section **Phase III and IV – Teleconsultation and Post-teleconsultation**). Each phase involves interactions between different entities and systems across both countries A and B. The process uses several technological infrastructures, including national infrastructures, NCPeH, and the MyHealth@EU central services. It is important to note that the flowchart specifically focuses on the patient identification and authentication process just before the teleconsultation begins.

The flowchart is divided into 7 layers:

- **The patient from country-A (patient-A)**
  - This layer describes the activities that will require an active participation of the patient to enable MyHealth@EU services in a teleconsultation context. It includes different steps, including the identification and authentication of the patient to ensure the correct individual is verified and authorized to share his/her personal health data, avoiding possible unauthorised access.

- **National/Regional infrastructure from country-A and -B**
  - Refers to all the technological and administrative processes that take place within each infrastructure of the country before, during, and after the teleconsultation. These infrastructures support data requests and exchange, support authentication processes and coordination between all the entities involved in the process.
  - The activities performed by the national infrastructures also encompass managing the storage of teleconsultation reports in the patient's EHR in country-A, as well as retrieval of relevant information from the EHR systems in country-A. As such, the national infrastructures may include other necessary entities for addressing requests related to the management of the patient's EHR.

- **NCP-A and NCP-B**
  - NCPs serve as intermediaries, facilitating data exchange and communication between Country-A and Country-B through MyHealth@EU. They ensure the secure and standardized sharing of the clinical data through MyHealth@EU services to support teleconsultations.
  - NCPs are responsible for sending and receiving data requests and responses, verifying and matching information, and coordinating with national infrastructures following a HP's request to access services. They also manage internal and external communication and ensure accurate semantic mapping between both countries.

- **Central Services/ Core services**
  - The MyHealth@EU Core Services[30] concern those necessary at EU level for the provision of cross-border exchanges. The Core Services refer to the digital services/artefacts provided centrally by the Solution Provider (SP) to enable the Generic Services (national/NCPeH) deployment and operation, by ensuring trans-European connectivity, access and interoperability required for the implementation of data exchange at a national/NCPeH level.

- **Healthcare Provider Organisation in Country-B (HCPO-B) and HP-B**
  - This layer involves the HP provider organisation in Country-B, responsible for managing the teleconsultation services and coordinating with patients and other entities.
  - The HCPO-B is responsible for activities such as scheduling the teleconsultation and ensuring that the patient can access the teleconsultation platform; receiving and sharing patient information; and facilitating communication and data exchange with Country-A.
  - This layer also includes the activities of the HCPO-B personnel, including HP-B. Moreover, HCPO-B is the provider organization where HP-B is credentialed to provide care.

[30] eHMSEG. eHDSI Service Catalogue, Delivery and Overall Deployment Plan, V2.8, 2018. [Access restricted to MyHealth@EU members - Available here]

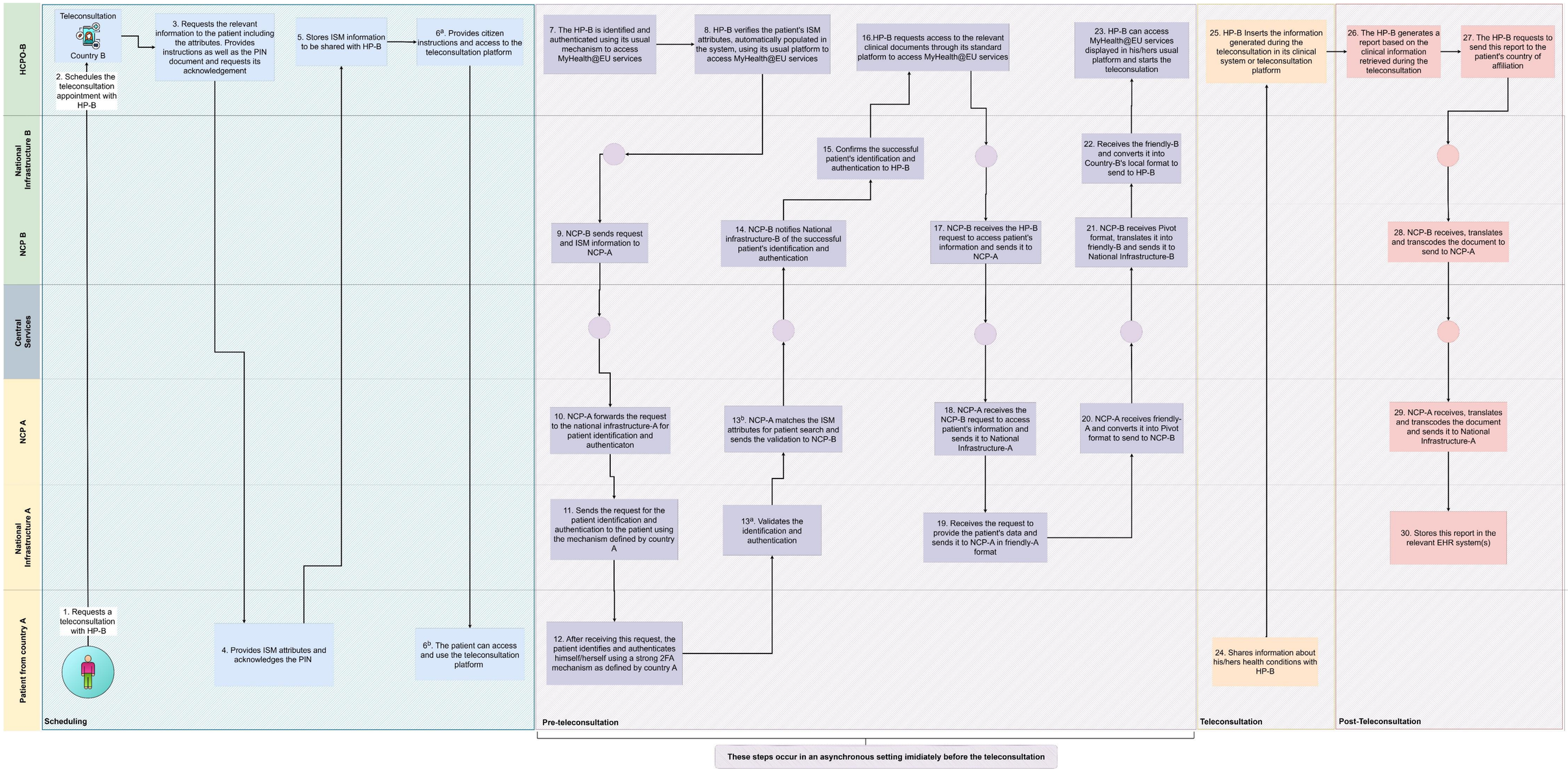


Figure 1. **Example of the patient journey flowchart for use case 1.** The numbering scheme aligns with the steps outlined in sections 3.3.2 and 3.3.4. For example, steps 6a and 6b refer to the same process step, organized by the actors involved.

Acronyms: NCP - National Contact Point; ISM - International Search Mask; HP-B - Health Professional from Country B; PIN - Patient Information Notice; EHR - Electronic Health Record; 2FA - Two-Factor Authentication.

## 3.3. Responsibilities, Processes and Proposals to Enable MyHealth@EU Services in a Cross-Border Teleconsultation

This chapter summarises the main responsibilities, process description and proposals to address the gaps identified, where new mechanisms are required to support the use of MyHealth@EU services in the context of a cross-border teleconsultation. This analysis, as presented in Table 2, primarily focuses on **Use Case 1 – Teleconsultation between Patient and Healthcare Professional**, which is further detailed in Section 3.3.2. It also addresses certain aspects of **Use Case 2 – Teleconsultation between two Healthcare Professionals** (detailed in Section 3.3.3), since they share common elements. Additionally, the processes related to accessing patient data and sharing a report with the findings of a cross-border teleconsultation is also explored in Table 2.

### 3.3.1. General Overview – Process description

For a comprehensive overview of the responsibilities and processes involved in the context of cross-border teleconsultation under MyHealth@EU, Table 2 provides detailed steps required for each actor involved in using MyHealth@EU services in the context of a cross-border teleconsultation. It also includes references to possible proposals to address the gaps identified, where new mechanisms are required. This table references all the actors described in section 3.2 – *Patient Journey*, ensuring a clear and detailed definition of their tasks and responsibilities. Its purpose is to help the reader understand the specific roles each actor plays in enabling secure and efficient cross-border teleconsultations. Additionally, it highlights the interactions between systems and actors, identifying areas where further alignment or development may be necessary to enhance the overall process.

It is important to underscore that the proposals for patient identification and authentication presented in this deliverable and referenced in Table 2 are grounded in the eIDAS Regulation and the emerging European Digital Identity Wallet (EUDI Wallet) [31], which is still under development at the time of writing. The eIDAS framework provides a robust legal and technical foundation for secure digital identification across the EU, ensuring compliance with EU standards for security and interoperability. This makes it an ideal candidate to support secure and interoperable cross-border teleconsultation services under MyHealth@EU.

By leveraging eIDAS, **patient identification and authentication** can be streamlined in remote health encounters. In this case, the process of patient identification and authentication can occur at three distinct moments: i) during the scheduling phase, where it is up to HCPO-B to decide how and whether to implement it; ii) as a requirement to enable access to MyHealth@EU services by HP-B, where the decision on how and if to implement it is up to Member States; and iii) for the patient to access the teleconsultation platform. The latter occurs outside the scope of MyHealth@EU, as these services are accessed via an existing clinical platform, which typically operates independently from the teleconsultation platform. However, it is strongly recommended to ensure robust patient identification and authentication to access the teleconsultation platform.

Moreover, it is also important to consider in the future additional scenarios, where legal representatives, such as caregivers, are involved in a cross-border teleconsultation. The existing mechanisms that enable identification and authentication in this context must be taken into account.

Importantly, eIDAS 1 allows the public sector service providers to connect to an existing eIDAS-Node in order to deliver online services that facilitate the identification of citizens and businesses from other Member States[32]. These services include eGovernment platforms that allow individuals to file taxes, access benefits, and engage with public authorities. For instance, the region Lombardia of Italy, has already in place a webpage (refer to *Annex VIII – Example of eIDAS use for public* service), in which a foreign citizen can login using his/her national eIDAS login system by selecting the flag

[31] European Digital Identity Wallet Architecture and Reference Framework [available here]

[32] eID – Public Service Providers [website available here]

of that country, which automatically redirects to that's country authentication system[33]. The European Commission's webpage on eID – Private Service Providers presents valuable information on how private sector entities can integrate eID solutions to enable secure cross-border electronic identification. It highlights the benefits of using eIDAS for businesses, including streamlined access to services and compliance with EU regulations. eIDAS also promotes the voluntary reuse of governmental eIDs by the private sector, with each Member State remaining free to set the conditions for this reuse. eIDAS 2 introduces the EUDI Wallet[31] that can also support the operation of eIDAS mechanisms by the private sector. Therefore, it is also recommended that the teleconsultation platform provided by HCPO-B is compliant with existing eIDAS mechanisms.

The POTENTIAL project[34] is testing the EUDI Wallet for an eHealth use case, particularly the eP service in the context of MyHealth@EU. While initial work focuses on proximity flows, remote flows are the next step. In a remote flow scenario, citizens could use the EUDI Wallet to scan a QR code displayed by a relying party. This process could help to simplify, during the scheduling phase, the collection of necessary attributes during the scheduling phase while ensuring proper identification and authentication of patients in cross-border settings. Additionally, the EUDI Wallet leverages the mdoc standard as defined in ISO/IEC 18013-5[35] to create (Qualified) Electronic Attribute Attestations ((Q)EAA) for the attributes specified in the ISM. As the POTENTIAL project progresses, its findings and technological advancements will be integrated into deliverable D9.2, ensuring that proposed solutions remain updated and aligned with the latest developments.

To enable access to MyHealth@EU services, the process of remote identifying and authenticating the citizen is introduced. This process can be enhanced or fulfilled by obtaining the citizen's consent to share his/her health-related data through MyHealth@EU, facilitating the cross-border teleconsultation. It is recommended that both scenarios utilize existing eIDAS-compliant mechanisms. Several options can support the patient and authentication process, but data reconciliation is managed at the level of the national infrastructure of country-A. For instance, when NCP-A receives a request for patient identification and authentication from NCP-B, it forwards the request to the national infrastructure of country-A. Each Member State has the autonomy to determine how to communicate the request to the citizen, provided it employs an eIDAS-compliant mechanism, or a two-factor authentication process as allowed in MyHealth@EU. For instance, the citizen might receive instructions via a text message or email, or the country might implement a system similar to bank payment notifications, where the citizen is notified about a pending identification and authentication request. The EUDI Wallet could for example be reused for this purpose, as citizens can used it to manage the different services offered under the eIDAS umbrella. Other national eHealth apps may also be reused for this purpose, as some of these are also able to connect to eIDAS-compliant authentication mechanisms.

Three main approaches might be adopted by Member States to enable the use of MyHealth@EU services to support a cross-border teleconsultation, depending on the use case (if patient-HP teleconsultation or HP-HP teleconsultation):

- Coordinated Patient Participation: The patient actively participates in the authentication process to grant HP-B access to their health information. It aligns with existing eGOV mechanisms, where access to services trigger a request for identification and authentication, ensuring system security and integrity.
- Pre-Authorized Consent: Patients can electronically sign a consent form under the eIDAS framework, granting access to their data before the teleconsultation. This approach eliminates the need for real-time authentication and ensures compliance with General Data Protection Regulation (GDPR)[36] by using informed consent models like those in European Reference Networks (ERNs). The consent must be clear, revocable, and limited to necessary data, with audit trails ensuring transparency and accountability. It is still pending analysis whether the patient only needs to provide consent once for all subsequent teleconsultations or if they must

[33] eIDAS login of Lombardia Region, Italy [website available here]

[34] POTENTIAL Project (For European Digital Identity) [website available here]

[35] ISO/IEC 18013-5, Personal identification [available here]

[36] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) [available here]

give it individually for each teleconsultation and HP. This will depend on the legal assessment at the EU level and from each Member State and is further addressed in Section 3.3.2.2.

- Country-Specific Consent Management: Country-A could manage consent through MyHealth@EU services, allowing NCP-A to verify consent when requested by NCP-B for teleconsultation. This approach bypasses real-time patient authentication, streamlining cross-border healthcare interactions while adhering to data protection and privacy standards.

Clear **instructions** on how to use MyHealth@EU services to support cross-border teleconsultations should be made available for citizens, HPs, and HCPOs. These instructions should detail the specific requirements of each Member States (e.g., the attributes necessary for patient identification and document search), along with the procedures for patient identification and authentication. The instructions could be made available through an EU-wide central webpage or portal, or through country-specific webpages. If the latter approach is chosen, a centralized public repository should be established to ensure streamlined access to information across Member States. For example, the existing MyHealth@EU webpage[37] could be updated to include access to such instructions, as well as the Patient Information Notice (PIN).

**Table 2. Summary of responsibilities, processes and proposals divided by actors to enable MyHealth@EU services in a cross-border teleconsultation**

| Entry | Responsibilities | Processes & proposals |
|---|---|---|
| **HCPO-B** | | |
| **HCPO-B-1** | Schedules the teleconsultation appointment. | **1.** HCPO-B receives a teleconsultation request by a patient via a platform, app, phone, or videoconferencing system.<br>**2.** Confirms the availability of HP-B and suitable timeslot.<br>**3.** Communicates the appointment details (date, time, platform access) to the patient via the same channel.<br>**4.** Updates the teleconsultation schedule in the clinical system to ensure availability. |
| **HCPO-B-2** | Recognizes the existence of MyHealth@EU services. | **General observations:** HCPO-B should be informed of the existence of MyHealth@EU services to understand that they can be used to support cross-border teleconsultation. Generally, the dissemination of the MyHealth@EU services is done by Country-B.<br>**1.** Disseminate information about MyHealth@EU services to HCPO-B staff.<br>**2.** Train HCPO-B staff on how MyHealth@EU services can support cross-border teleconsultations.<br>**3.** Provide a repository of materials (e.g., guides, Frequently Asked Questions, etc.) for reference. |
| **HCPO-B-3** | Accesses the instructions of the patient's country of affiliation to understand the requirements of MyHealth@EU to use the existing services in the context | **1.** Access the source of instructions.<br>• Instructions could be made available to HCPO through 2 possible means:<br>○ **EU-central webpage / portal:** Unified platform provided by MyHealth@EU. |

[37] Electronic cross-border health services [website available here]

| Entry | Responsibilities | Processes & proposals |
|---|---|---|
| | of a cross-border teleconsultation. | ○ **National-specific webpages:** Portal or webpage managed by the patient's country of affiliation.<br><br>• **General observations:**<br>○ If this is done centrally, it would be ideal to have an option to select the country or region and instantly view the corresponding information.<br>○ In the case of national-specific webpages, a central public repository should be established to facilitate easier access to information by country.<br>**2.** Navigate to the relevant section:<br>○ Use filters or a search function to select the patient's country or region (if applicable).<br>○ Instantly view the MyHealth@EU requirements for cross-border teleconsultation.<br>**3.** Verify the instructions provided, ensuring the following details are covered:<br>○ **Required information for MyHealth@EU services:** identify necessary ISM attributes, PIN-B (if applicable), and other data.<br>○ **Identification and authentication process:** Understand how patients will receive and respond to requests for identification and authentication.<br>○ **Activation of MyHealth@EU services:** Learn the steps for patients to activate the services, if required. |
| **HCPO-B-4** | Provides the instructions to the patient | **1.** Extract relevant instructions from entry **HCPO-B-3**.<br>**2.** Translate or adapt the instructions to the patient's preferred language, if applicable.<br>**3.** Share the instructions via the mechanisms selected by the HCPO-B, as detailed in entry **HCPO-B-1**, as it does not contain any confidential or sensitive data.<br>**4.** Confirm that the patient has received and understood the instructions by requesting acknowledgment. |
| **HCPO-B-5** | Provides PIN document to the patient and requests its acknowledgement | **1.** HCPO-B should access PIN-B through the current implementation as provided by country-B.<br>**2.** This information could be sent through the mechanisms mentioned in entry **HCPO-B-1**, as it does not contain any confidential or sensitive data.<br>**3.** Ideally, it should be conveyed in a way that acknowledgment by the patient could be recorded (e.g., electronic signature via eIDAS framework or acknowledgement checkbox).<br>**4.** Verify that acknowledgment has been recorded before receiving information on ISM attributes, in order to |

| Entry | Responsibilities | Processes & proposals |
|---|---|---|
| | | comply with General Data Protection Regulation (GDPR)[36] rules. |
| **HCPO-B-6** | Requests the relevant information to the patient, including the ISM attributes based on the instructions of country-A | • **General observation:** Three proposals are outlined for obtaining the ISM attributes; however, it is the responsibility of the HCPO-B to decide on the specific approach to be adopted for their implementation.<br>• The proposals for obtaining the ISM attributes are summarized below and are further explained in greater detail in entry **Patient-A-26**.<br>○ **HCPO-B specific platform:**<br>▪ HCPO-B provides the patient with a link or access to a hospital platform where they can submit their ISM attributes.<br>▪ The platform includes clear instructions based on Country-A's requirements for the ISM attributes.<br>○ **Registered Electronic Email (REM):**<br>▪ HCPO-B sends a formal request to the patient via REM, a secure email system, specifying the required ISM attributes.<br>▪ The email includes detailed instructions on what information is needed and how to format the response.<br>▪ Once the patient replies, HCPO-B receives the email and verifies the ISM attributes<br>○ **Future proposal – EUDI Wallet:**<br>▪ HCPO-B generates a QR code using an eIDAS-compliant mechanism for the remote flow. Note: The way HCPO-B will provide this QR code to the patient will follow the recommendations from the Large-Scale Pilots[31] currently testing the EUDI Wallet.<br>▪ The patient scans the QR code using his/her EUDI Wallet.<br>▪ The EUDI Wallet app prompts the patient to confirm and share the requested ISM attributes securely.<br>▪ The app generates an (Qualified) Electronic Attribute Attestations ((Q)EAA) containing the verified ISM attributes and sends it to the relying party, HCPO-B.<br>▪ The HCPO-B validates the electronic attestation and stores the ISM attributes for use in subsequent processes. |
| **HCPO-B-7** | Stores the ISM attributes and makes them automatically available to the clinical system in use to access MyHealth@EU services | 1. **Ensure system compatibility:**<br>• The system used to capture ISM attributes must be interoperable with the clinical system used by HP-B for accessing MyHealth@EU services. |

| Entry | Responsibilities | Processes & proposals |
|---|---|---|
| | | • Validation checks must be included to ensure data consistency and reduce errors during input.<br>**2. Enable automatic population of attributes:**<br>• The system should be configured to automatically populate ISM attributes into the clinical system when required, preferably without manual intervention of HP-B. |
| **HCPO-B-8** | Provides a mean for the patient to access and use the teleconsultation platform | **1.** HCPO-B must share access details with the patient, including login instructions and authentication steps.<br>**2.** Provides technical support to the patient if they encounter difficulties accessing the platform.<br>• **General observations:** It is recommended that the teleconsultation platform can connect to country-A's eIDAS identification and authentication to ensure the correct identification of the patient.<br>Currently, eIDAS 1 already allows public systems to connect to eIDAS-compliant mechanisms, meaning that a specific webpage allows to select the country that leads to that country authentication page. However, this is not always available for the private sector. The EUDI Wallet can be the available mechanism for such situations, reusing the remote flow, currently under development. |
| **HP-B** | | |
| **HP-B-9** | Accesses patient's clinical documents | **1.** To access the patient's clinical documents, the HP-B must be identified and authenticated through its usual mechanism to access MyHealth@EU services.<br>**2.** After authenticating, the HP-B validates the patient's ISM attributes, automatically populated in the system, using its usual platform to access MyHealth@EU services.<br>**3.** If all requirements are met, HP-B will be able to consult the request documents. |
| **HP-B-10** | Generates a report based on the clinical information retrieved during the teleconsultation | **1.** HP-B documents the findings and recommendations from the teleconsultation in the clinical system or teleconsultation platform.<br>**2.** If requested by the patient, the HP-B must send this report back to the patient's country of affiliation using the MyHealth@EU infrastructure. |
| **National infrastructure of Country-B (Country of Treatment)** | | |
| **National Infrastructure-B-11** | Ensures HCPO / HP / Citizens are aware of MyHealth@EU services can be used to support cross-border teleconsultation | **1.** Facilitates awareness and dissemination initiatives for MyHealth@EU, specifically targeted at HCPOs, HPs, and citizens.<br>**2.** Makes available instructions on how to use MyHealth@EU services to support cross-border teleconsultations, as detailed in HCPO-B-3.<br>**3.** Ensures and enables its use for cross-border teleconsultation. It also includes adapting new |

| Entry | Responsibilities | Processes & proposals |
|---|---|---|
| | | mechanisms to support cross-border teleconsultation, such as mediating the patient's identification and authentication requests and outputs between NCP-B and HP-B |
| **NCP-B** | | |
| **NCP-B-12** | Mediates the patient's identification and authentication request within the scope of MyHealth@EU services access | **1.** Upon receiving the HP-B request for accessing the patient's clinical documents, the NCP-B must send the received ISM attributes to NCP-A for validation.<br>**2.** Once receiving the successful patient's identification and authentication, NCP-B must notify it to National Infrastructure-B. |
| **NCP-B-13** | Mediates the HP-B requests to access to the patient's clinical documents | **1.** NCP-B receives the HP-B request to access the patient's information and sends it to NCP-A.<br>**2.** Once the access is confirmed, NCP-B receives the patient's clinical documents in Pivot format, translates it into friendly-B and sends it to HP-B. |
| **NCP-B-14** | Mediates the sharing of the report of the teleconsultation | **1.** Upon receiving the request to send the teleconsultation report back to the patient's country of affiliation, the NPC-B must translate and transcode the document and sent it to NCP-A. |
| **MyHealth@EU Central Services** | | |
| **MyHealth@EU-15** | Ensures the proper conditions to enable transactions between NCP-A and NCP-B | • The MyHealth@EU Core Services[30] concern those necessary at EU level for the provision of cross-border exchanges. The Core Services refer to the digital services/artefacts provided centrally by the Solution Provider (SP) to enable the Generic Services (national/NCPeH) deployment and operation, by ensuring trans-European connectivity, access and interoperability required for the implementation of data exchange at a national/NCPeH level. |
| **MyHealth@EU-16** | Provides the necessary services for enabling the sharing of a report regarding the main outcomes of the teleconsultation | |
| **NCP-A** | | |
| **NCP-A-17** | Mediates the patient's identification and authentication requests within the scope of MyHealth@EU services access | **1.** Upon receiving the NCP-B request for patient identification and authentication and respective ISM attributes, NCP-A forwards the request to the national infrastructure-A.<br>**2.** After receiving the validation for the identification and authentication from national infrastructure-A, NCP-A matches the ISM attributes for patient search, and if successful, sends the validation to NCP-B. |
| **NCP-A-18** | Mediates the HP-B access to the patient's clinical documents | **1.** NCP-A receives the NCP-B request to access the patient's information and sends it to National Infrastructure-A.<br>**2.** Once friendly-A is provided by National Infrastructure-A, NCP-A converts it into Pivot format and sends it to NCP-B. |

| Entry | Responsibilities | Processes & proposals |
|---|---|---|
| **NCP-A-19** | Mediates the sharing of the report of the teleconsultation | **1.** Receives the teleconsultation document from NCP-B, translates and transcodes it and sends it to National Infrastructure-A. |
| **National infrastructure of Country-A (Country of affiliation)** | | |
| **National Infrastructure-A-20** | Provides public instructions on how use MyHealth@EU services to support cross-border teleconsultation | • As mentioned in **HCPO-B-3**, two possibilities may exist to share the instructions:<br>  ○ **Central-based solution:** in this case, country-A must provide the EC/MyHealth@EU with instructions outlining their specific requirements for using MyHealth@EU in this context. These instructions should include details on ISM attributes, patient identification and authentication procedures, and consent requirements, if applicable. Any updates or changes will require a formal request to update.<br>  ○ **National-based solution:** Country-A must make available a specific public webpage, portal or app where citizens / HCPO / HP can access these instructions.<br>• Multilanguage support must be ensured, and information must be available at least in the country-A official language(s) and English. |
| **National Infrastructure-A-21** | Mediates the patient's identification and authentication | **1. Request from NCP-A to National Infrastructure-A**<br>• Upon receiving a request from NCP-A for patient identification and authentication, the National Infrastructure-A forwards this request to the patient.<br>• The patient completes the process using an eIDAS-compliant or other strong two-factor authentication mechanism, as defined by country-A.<br>**2. Validation by National Infrastructure-A**<br>• After the patient completes the identification and authentication, National Infrastructure-A validates the process.<br>• If successful, National Infrastructure-A informs NCP-A.<br>**Mechanisms for Identification and Authentication**<br>• **Patient awareness:** patient must be informed of the mechanism to be used for identification and authentication and/or consent steps by HCPO-B.<br>**Communication Methods:**<br>• National Infrastructure-A will decide on the mechanism to forward the request to the patient.<br>• These methods may involve:<br>  ○ Text messages<br>  ○ Emails<br>  ○ Notifications similar to bank payment alerts |

| Entry | Responsibilities | Processes & proposals |
|---|---|---|
| | | • Several possibilities may be adopted by Member States, but Member States are encouraged to adopt eIDAS-compliant systems to validate the identification and authentication.<br>**Possible options for Communication and Authentication in Country-A:**<br>**1. Request via Text Message of Email:**<br>i. National Infrastructure-A uses a database to identify the patient's telephone number or email based on the ISM attributes sent by NCP-A.<br>ii. The national Infrastructure-A sends to the patient a text message or email with the instructions for completing the process of identification and authentication process. Note: This text may also include a One-Time Token that the patient should use in a specific platform where the patient is registered to validate the identification and authentication step. The message may direct the patient to a portal utilizing eIDAS mechanisms, similar to those used for eGov services.<br>**2. Request via an officially recognized app:**<br>i. The patient receives a notification in an app officially recognized by country-A, such as a national eHealth app or EUDI Wallet.<br>ii. The app allows the patient to approve or reject this request or redirects the patient to an eIDAS-compliant webpage to complete the identification and authentication step.<br>**3. Request via the EUDI Wallet (remote flow):**<br>i. The patient receives a QR code to scan with their EUDI Wallet.<br>ii. The wallet prompts the patient to approve the attributes to be shared.<br>Note: the method to send this QR code is being defined in the ongoing Large-Scale Pilots, such as the POTENTIAL project.<br>**Completion of the Process by the Patient**<br>The patient may complete the authentication process through:<br>• Approving or rejecting a request in a specific app or portal after passing a valid identification and authentication process.<br>• Inserting a one-time token in a specific app or portal using registered credentials.<br>• Using eIDAS authentication services if redirected to a specific portal or app for this process. |

| Entry | Responsibilities | Processes & proposals |
|---|---|---|
| | | • Scanning a QR code with their EUDI Wallet and approving the attributes to be shared through MyHealth@EU. |
| **National Infrastructure-A-22** | Verifies whether patient-A has granted consent to enable the sharing their data via MyHealth@EU | • Consent may be required by country-A, and therefore the National Infrastructure-A must check if consent has been granted by patient-A.<br>• Member States may decide to impose one or more of the following requirements:<br>  ○ Coordinated Patient Participation: the patient must actively participate in the authentication process to grant HP-B access to their health information. It aligns with existing eGOV mechanisms, where access to services trigger a request for identification and authentication, ensuring system security and integrity.<br>  ○ Pre-Authorized Consent: Patients can electronically sign a consent form under the eIDAS framework, granting access to their data before teleconsultation. This approach eliminates the need for real-time authentication and ensures compliance with GDPR[36] by using informed consent models like those in European Reference Networks (ERNs). The consent must be clear, revocable, and limited to necessary data, with audit trials ensuring transparency and accountability. This consent should be obtained by HCPO-B.<br>  ○ Country-Specific Consent Management: Country-A may manage consent through MyHealth@EU services, allowing NCP-A to verify consent when requested by NCP-B for teleconsultation. This approach may bypass real-time patient authentication, streamlining cross-border healthcare interactions while adhering to data protection and privacy standards. This would require a specific consent management platform by Country-A, where patients can opt-in or opt-out.<br>• A notification mechanism can also be introduced to allow patients to track who accessed their data and when in line with Article 9 *Right to obtain information on accessing data* of the proposed EHDS regulation. This would serve as a safeguard, enabling patients to identify and report any potential unauthorized access. |
| **National Infrastructure-A-23** | Mediates the HP-B access to the patient's clinical documents | • National Infrastructure-A receives the NCP-A request to provide the patient's data and sends it to NCP-A in friendly-A format. |

| Entry | Responsibilities | Processes & proposals |
|---|---|---|
| **National Infrastructure-A-24** | Mediates the sharing of the report of the teleconsultation | • Stores the report received from NCP-A in the relevant EHR system(s).<br>**General requirements**:<br>• The current development for sharing the discharge report may be reused for this purpose.<br>• The elements covered under the scope of Article 14 – *Priority categories of personal electronic health data for primary use*, as outlined in the EHDS regulation, should be included and documented in this report. |
| **Patient-A** | | |
| **Patient-A-25** | Requests a teleconsultation with HP-B, reviews the instructions provided by HCPO-B, acknowledges PIN-B and provides the ISM attributes as well as consent (if applicable) | • The patient must request a teleconsultation with HP-B through one of the mechanisms provided by HCPO-B mentioned in entry **HCPO-B-3**.<br>• As outlined in entry **HCPO-B-6**, the patient reviews the instructions provided by HCPO-B to understand the next steps.<br>• The patient then provides their ISM attributes as proposed in entry **HCPO-B-6** and acknowledges the PIN-B document as part of the process. |
| | | • During this step, the patient may be required to provide signed consent, if applicable. In that case, the process would proceed as follow:<br>1. **Acknowledgement of consent request**: upon receiving a consent request from HCPO-B, the patient must review and acknowledge the PIN document delivered as explained in entry **HCPO-B-6**.<br>2. **Providing consent for data sharing**:<br>• Depending on the defined method, the patient must either:<br>○ **Electronically sign a consent form**, authorizing the sharing of their data in specified context. The electronic signature must be compliant with eIDAS. Or,<br>○ **Provides consent**, using the dedicated platform provided by Country-A to review and provide their consent for data sharing within the specified context.<br>It is still pending analysis whether patient consent needs to be provided once or multiple times for subsequent teleconsultations. This theme and related GDPR[36] considerations are further explored in detail under Section 3.3.2.2.<br>If this step is required, this should be clearly detailed in the instructions mentioned in entry **HCPO-B-4**. |

| Entry | Responsibilities | Processes & proposals |
|---|---|---|
| **Patient-A-26** | Identifies and authenticates themselves using the designated mechanism | The identification and authentication of the patient may occur in different moments:<br>• **During the scheduling phase**, if requested by the HCPO-B or while using the EUDI Wallet.<br>• **During the request from HP-B to access** the MyHealth@EU services.<br>• **During the teleconsultation**, when logging into the teleconsultation platform.<br>1. **During the scheduling phase**, if requested by the HCPO-B or while using the EUDI Wallet<br>• The process by which HCPO-B captures patient information may require an identification and authentication step, particularly to ensure correct identification in remote scenarios or to verify the identity of the patient providing the ISM attributes or consent. However, it is important to note that during the scheduling phase, certain information may be provided by a third party or a legal representative, such as a caregiver, at the patient's request. Therefore, flexibility must be allowed for such cases.<br>• As referenced above in entry **HCPO-B-6**, the EUDI Wallet may be used to send the requested ISM attributes to HCPO-B. This would involve patient identification and authentication during the use of the app.<br>2. **During the request from HP-B to access the MyHealth@EU services,** if Country-A requires the identification and authentication of the patient, then the following applies:<br>• The various options that country-A may provide to patients are described in entry **National Infrastructure-A-22**, and summarized below:<br>a. Approving or rejecting a request in a specific app or portal after passing a valid identification and authentication process.<br>b. Inserting a one-time token in a specific app or portal using registered credentials.<br>c. Using eIDAS authentication service if redirected to a specific portal or app for this process.<br>d. Scanning a QR code with their EUDI Wallet and approving the attributes to be shared through MyHealth@EU.<br>3. **During the teleconsultation**, when logging into the teleconsultation platform:<br>• Before being granted access to the teleconsultation session, patients must identify or authenticate |

| Entry | Responsibilities | Processes & proposals |
|---|---|---|
| | | themselves. The teleconsultation platform must employ different mechanisms for this purpose, with eIDAS-compliant methods being strongly encouraged. For example, as previously mentioned, eIDAS nodes can be reused for this purpose. For example:<br>○ Patients would select the country from which they wish to authenticate, be directed to that country's official authentication system, complete the authentication process, and then be redirected back to the teleconsultation platform.<br>○ Alternatively, the remote flow currently in development for the EUDI Wallet could be leveraged, allowing patients to scan a QR code to complete the authentication process.<br>Note: this process will occur outside of MyHealth@EU infrastructure, as it is assumed that the HP-B will use his/her existing platform to access MyHealth@EU services to support the teleconsultation. |

The following sections provide a comprehensive overview of the processes and mechanisms supporting cross-border teleconsultation services under MyHealth@EU.

The first, detailed in **Section 3.3.2**, examines the process of a patient's journey when a patient from Country-A initiates a teleconsultation with a healthcare provider in Country-B. It outlines each step of the process, from scheduling to post-consultation, emphasizing the role of MyHealth@EU in facilitating the secure exchange of health information across borders.

The second use case, discussed in **Section 3.3.3**, explores how MyHealth@EU can support teleconsultations between two healthcare professionals from different countries, where HP-B needs to access information from patient-A. This section highlights the key steps and requirements for secure identification, authentication, and consent, focusing on the specific context of professional collaboration while referencing shared elements with the patient–health professional use case. This section also reuses concepts covered in Section 3.3.2, when applicable, due to existence of common elements.

Finally, **section 3.3.2.4 and 3.3.4** explores the feasibility of sharing a report summarising the main outcomes of the teleconsultation with the patient's country of affiliation (Country-A). This analysis is based on the priority data categories outlined in Article 14 of the proposed EHDS regulation and builds upon the planned implementation of sharing the Hospital Discharge Report via MyHealth@EU.

By examining these use cases, the subsequent sections aim to provide a clear understanding of the responsibilities, and processes described in Table 2 to enable the use of MyHealth@EU services to support cross-border teleconsultation services, as well as the proposed solutions to address identified challenges.

Key proposals are highlighted in **blue boxes**, which will be further explored under D9.2 – *Technical specifications on the availability of health data in cross-border telemedicine services* work.

### 3.3.2. MyHealth@EU services for a Patient – Health Professional Teleconsultation

This section outlines the detailed process of the patient's journey when a patient from Country-A (patient-A) requests a teleconsultation service from HCPO-B, supported by the cross-border exchange of health information through MyHealth@EU. The patient journey is broken down into four key phases: i) Scheduling (section 3.3.2.2), ii) Pre-teleconsultation (section 3.3.2.3), iii) Teleconsultation (section 3.3.2.4), and iv) Post-Teleconsultation (section 3.3.2.4). Each phase represents a crucial step in the interaction between the patient, health professionals, and supporting systems.

These phases cover the entire process, from initial scheduling to the final steps of the teleconsultation and follow-up procedures related to sending a report from the teleconsultation to the patient's country of affiliation after the teleconsultation. Each phase is aligned with the existing and planned services under MyHealth@EU, including Patient Summary, ePrescription/eDispensation, and future services such as Discharge Reports; Medical test results, including laboratory and other diagnostic results and related reports; and Medical Imaging studies and related imaging reports.

This comprehensive patient journey ensures that health professionals in different countries have access to the necessary patient's clinical data, thereby supporting accurate diagnosis, treatment, and care coordination. By enabling the seamless exchange of health information across borders, this cross-border data exchange process helps to minimize inefficiencies such as duplicate testing and promotes continuity of care for patients, regardless of their location.

#### *3.3.2.1. Process Description*

The detailed steps and process description of each main phase of the patient journey flowchart are described below, discussing new requirements and potential solutions to enable MyHealth@EU services within the teleconsultation context. Please note that the titles of the steps described in the following sections may be more extensive than those in **Figure 1**.

#### *3.3.2.2. Phase I – Scheduling*

Scheduling is the first phase of the patient journey. This phase encapsulates all the necessary steps for the patient from Country-A to book a teleconsultation with a HP in Country-B. The interdepended steps involved in the scheduling phase are consolidated to provide a clearer description of the sequential process, aligning with the journey outlined in **Figure 1**. A summary of the responsibilities, processes and proposals for each actor involved in the scheduling phase can be found in Table 2.

**1.The patient in Country-A requests a teleconsultation with a HP of a Healthcare Provider Organisation (HCPO) in country-B.**

The patient in country-A initiates a request for a teleconsultation service with a HCPO in Country-B, to start the process of booking an appointment with a HP in Country-B. This request must be done through one of the mechanisms provided by HCPO-B, as mentioned in entry HCPO-B-3 from Table 2.

**2. The HCPO-B schedules the teleconsultation appointment with a HP from Country-B**
**3. HCPO-B requests the patient's International Search Mask (ISM) attributes, provides instructions, the Patient Information Notice (PIN) document, and request validation for data sharing, as applicable.**
**4. The patient provides ISM attributes and acknowledges the PIN.**

Upon receiving a teleconsultation request from the Patient via a platform, app, phone, or videoconferencing system, HCPO-B schedules the teleconsultation appointment with a HP from Country-B. This entails confirming the date and time for the teleconsultation appointment with the patient.

The following steps outline the essential components for patient identification and authentication necessary to enable the use of MyHealth@EU services in the context of a cross-border teleconsultation, addressing the use of the

International Search Mask (ISM) attributes, as defined in MyHealth@EU, to search the patient and the documents following a requested by the HP-B. In this step, the provision of the Patient Information Notice (PIN)[38] document should also be considered, since HCPO-B is already requesting personal data from the patient, which will be used to enable MyHealth@EU services. The PIN, elaborated by Country-B in accordance with its legal framework, should be provided to the patient at this moment to ensure transparency and compliance with data protection regulations.

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| **P1** | To understand and meet these requirements, HCPO-B must consult the instructions provided by the patient's country of affiliation. These instructions outline the necessary steps to use MyHealth@EU services within the context of cross-border teleconsultation. Access to these instructions could be provided through either a centralized EU-wide platform or national-specific webpages managed by the patient's country of affiliation.<br><br>If a centralized platform is used, it would ideally offer the option to select a country or region and instantly display the relevant information. In the case of national-specific webpages, a central public repository should be established to facilitate easier access to information by country.<br><br>Users could navigate the relevant sections using filters or a search function. The instructions would include details such as the necessary ISM attributes, the PIN document (if applicable), and other essential data. They would also cover the identification and authentication process, ensuring patients understand how to respond to identification and authentication or consent request. Furthermore, they would explain the steps required for patients to activate MyHealth@EU services if needed. |

### I. Reuse of ISM attributes as defined by country-A for MyHealth@EU

In the current MyHealth@EU workflow, Country-A determines how patients are identified for each service by defining the specific traits that unequivocally identifies them in compliance with its national legislation. The ISM is an important mechanism that enables the patient identification step by requiring specific attributes for the NCP-A to perform patient and document searches. Currently, to access the services, the HP-B first selects the patient's country of affiliation. Subsequently, one or more patient search forms are displayed, which detail the information needed to access the services. The process typically involves the patient presenting their ID card to the HP in Country-B. The specific attributes for this step vary by country but generally include a minimal set of information. Then, NCP-B communicates the patient's information to NCP-A, which then validates this information based on its national infrastructure. This validation step relies on the national infrastructure and data management procedure in place at the national level.

The work of the POTENTIAL project[34], which consists of testing the EUDI Wallet for the eHealth use case, more specifically eP access within MyHealth@EU will also be explored within WP9[39] together with WP5[12]. The EUDI Wallet could potentially allow patients to remotely access cross-border healthcare services, facilitating identification, provision of ISM attributes, and access to data. At the time of writing, POTENTIAL was focused on defining the proximity flow, with the remote flow being the next step.

In the remote scenario flow, patients may be given the option to use the EUDI Wallet to scan a quick response (QR) code displayed by the relying party, which requests specific attributes – in this case, by HCPO-B. This approach simplifies the process of gathering the necessary attributes and ensures the proper identification and authentication of the patient while they remain in Country-A.

[38] PIN model template [Access restricted to MyHealth@EU members - Available here]

[39] WP9 – *Telemedicine under MyHealth@EU in alignment with EHDS proposal*.

For both cases, the mdoc standard as defined in ISO/IEC 18013-5[40] will likely be used to create the (Qualified) Electronic Attribute Attestation ((Q)EAA) for the attributes specified in the ISM.

As the POTENTIAL project evolves, its discoveries and technological advances will be integrated into D9.2 to ensure that updated solutions are proposed.

**P2**

As a proposal, for cross-border teleconsultations, it is recommended to reuse the ISM attributes from Country-A, which are already implemented in MyHealth@EU. This approach would minimize the impact on the existing infrastructure and facilitate integration of teleconsultation services.

For this purpose, the HCPO-B must request the necessary patient information for the ISM, as specified by patient's country of affiliation. The ISM attributes may include the patient ID or National Health Service (NHS) card number, which are crucial for verifying patient identity in the subsequent steps. Consequently, it is essential for HCPO-B personnel to be familiar with the specific attribute's requirements of each country. This knowledge is crucial during the scheduling phase to ensure that all required information is collected, allowing the HP-B to access the MyHealth@EU services effectively.

It is important to note that the identification and authentication process during the scheduling phase occurs outside of MyHealth@EU services. Nevertheless, three approaches for obtaining ISM attributes are recommended, although it is **the responsibility of HCPO-B to decide** which approach to implement:

- **HCPO-B-specific platform** where patients can submit their ISM attributes. This platform would provide clear instructions based on Country-A's ISM attribute requirements.
- **Registered Electronic Mail (REM)**, where HCPO-B sends a formal request to the patient via a secure email system. This email would specify the required ISM attributes and include detailed instructions on formatting the response. Once the patient replies, HCPO-B would verify the ISM attributes.
- **European Digital Identity Wallet (EUDI Wallet):** In this method, HCPO-B generates a QR code using an eIDAS-compliant mechanism. The patient scans the QR code using their EUDI Wallet app, which prompts them to confirm and securely share the requested ISM attributes. The app generates an (Qualified) Electronic Attribute Attestations ((Q)EAA) containing the verified ISM attributes and sends it to HCPO-B. HCPO-B then validates this attestation and stores the ISM attributes for subsequent processes.

After receiving the ISM attributes, HCPO-B must validate them against the requirements to ensure compliance and accuracy. This process ensures that cross-border teleconsultations are carried out efficiently while maintaining the integrity and security of patient data.

The obtained ISM attributes are to be stored in HCPO-B, enabling automatic population into HP-B's usual clinical system during subsequent processes, whenever HP-B needs to access the patient's information.

[40] ISO/IEC 18013-5:2021 Personal Identification [available under purchase here]

### II. PIN documents in Cross-border telemedicine

The PIN[38] is an essential document designed to ensure that patients are fully informed about the type of data that is being exchanged for the eHealth cross-border services and how their health data is processed and shared within the MyHealth@EU framework. It provides essential details about data usage, processing and patient rights, in line with legal standards such as the GDPR[36] and other legal dispositions. The PIN model comprises 3 main parts:

i. General information about MyHealth@EU services, outlining how patient data is collected and used across the EU (mandatory);
ii. Member State-Specific Information, providing details on how each MS handles data, the legal basis for processing, and additional local regulations (mandatory);
iii. Link to Detailed Information, entailing comprehensive details specific to each MS, facilitating access to country-specific data processing and privacy practices (Not Mandatory).

The PIN document is also expected to be aligned according to the dispositions of the proposed EHDS regulation.

Each NCPeH assumes responsibility as the data controller for the collection, storage, transfer, and other data processing activities in the patient's medical record. Personal data must only be accessed by authorized and identifiable health professionals involved in the patient's treatment or in the provision of medications, under professional confidentiality, in the country of treatment. Their medical data ought to be used solely for the purpose of providing medical treatment or dispensing medication.

If the patient does not allow their personal data being processed within MyHealth@EU, their data will not be available to be shared between countries. The responsibility for managing patient consent lies within the national infrastructure of Country-A, and this process currently varies according to each country's specific requirements. Under the proposed EHDS regulation, regarding the primary use, the "opt-out" mechanism remains voluntary for Member States to implement. However, to enhance harmonization, the regulation removes the distinction between national and cross-border opt-outs.

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| **P3** | In the context of cross-border teleconsultation, at the moment of drafting this deliverable, mechanisms for delivering the PIN-B to the patient are still under discussion, given that the patient is not physically present to receive the document prior to the teleconsultation. Alignment with MyHealth@EU practices is important; therefore, it is crucial to establish a method for the patient to acknowledge the reception of the PIN. It is important to underscore that, at the time of this deliverable's elaboration, the mechanism for providing PIN-B to users has been extensively discussed within the MyHealth@EU Legal Work Group[41]. However, a standardized method for presenting the PIN to users has not yet been established.<br><br>One proposed solution involves sending the PIN document by email or other secure online transmissions mechanism during the scheduling phase, considering that HCPO-B will request patient data at this phase. This allows the patient to review what information will be shared through MyHealth@EU services.<br><br>In the case of an email is used as communication channel with the patient, it is crucial to ensure that the email address belongs to the intended recipient. To guarantee this, a verification mechanism should be implemented, such as using Registered Electronic Mail (REM)[42]. REM provides enhanced security and reliability by ensuring that messages are delivered with a high degree of assurance to the intended recipient in a secure way, guaranteeing privacy.<br><br>The PIN document could be acknowledged by the patient through various methods, such as responding to an email or selecting a checkbox in an online prompt, similar to how terms and conditions are typically |

[41] MyHealth@EU Legal Working Group Minutes [Access restricted to MyHealth@EU members - Available here]

[42] Electronic Signatures and Infrastructures (ESI); Registered Electronic Mail (REM) Services; Part 1: Framework and architecture [available here]

confirmed. This process would ensure that the patient has read and understood the document. However, this mechanism is typically defined by the HCPO.

### III. Health Professional Information Notice (HPIN)

The HPIN informs the health professional about how they can access and use patient data, describing the type of data that HP can access, under what circumstances, and the protections in place to prevent unauthorized use. This document describes the responsibilities of HPs under GDPR[36] and national laws, emphasizing the importance of compliance with data protection regulations.

However, each Member State should provide this information and preferably make it available in a joint repository. It has been proposed by the MyHealth@EU Legal Work Group that the HPIN be adopted in the same manner as the PIN. Nevertheless, HPIN is optional, and the countries implementing it are allowed to do it so as they wish.

The content of the HPIN includes the three components of the PIN mentioned above: general information on how the patient´s data can be collected and used across EU by a HP, details on data sharing and access permissions and specific provisions, and directs to comprehensive details concerning each MS.

### IV. Patient validation for the sharing of data

In the context of cross-border teleconsultations, it is often necessary for HP-B to access and review the patient's health data some time (even days or weeks) before the teleconsultation takes place. This pre-consultation review allows HP-B to prepare thoroughly by understanding the patient's medical history, current health status, and any specific concerns that need addressing during the session. However, in the cross-border teleconsultation context, this preparation poses challenges, particularly in terms of accessing the patient's health data without requiring real-time coordination with the patient. In many cases, the patient may not be available at the time of access, which causes difficulties in this process. This raises the question of how to organize the procedure to ensure HP-B has the necessary information without relying on the patient's active involvement.

A significant concern is related to the security and privacy of the patient's data. Should access to health data be tied strictly to a scheduled consultation, or can non-coordinated reviews by HP-B be permitted? While scheduling ensures that both the patient and HP-B are timely aligned, it may not always be practical. Allowing non-coordinated access – where HP-B reviews the patient's clinical data independently of an immediate action from patient – could streamline the preparation process but introduces potential security and legal concerns.

To balance the need for thorough preparation by HP-B with patient's rights privacy and data protection access must be tightly controlled. Only authorized HPs should have access to the data, with strict confidentiality agreements and prior patient consent. Exploring mechanisms that allow for secure access without real-time patient involvement may improve operational efficiency while ensuring compliance with legal and ethical standards.

In the context of cross-border teleconsultations, it is essential to ensure compliance with GDPR[36] principles while balancing the need for effective healthcare provision. The GDPR provides two potential legal bases for accessing patient data prior to a teleconsultation:

1. **Explicit Consent (Articles 6(1)(a) and 9(2)(a))[36]:** The patient can provide consent during the scheduling phase, allowing HP-B to access the required data in advance. This consent must be informed, specific, revocable, and cover the period and purpose of the data use.
2. **Medical Treatment (Article 9(2)(h))[36]:** If access to the data is necessary for treatment, health data processing may occur without continuous patient involvement, provided appropriate safeguards are in place.

To comply with GDPR's principles, particularly data minimization (Article 5(1)(c)) and purpose limitation (Article 5(1)(b)), only the minimum necessary data should be accessed, and appropriate access controls should ensure that

HP-B only views the relevant information. Security measures, such as encryption and audit logs, should also be implemented to meet the requirements exploited in Article 32[36].

Taking into account these legal frameworks, a consent management system could be developed to allow patients to pre-authorize access to their data, specifying the time period for this access and retaining the ability to revoke it. This system would align with the proposed EHDS regulation, which seeks to provide secure, interoperable access to health data across Member States.

**Several possibilities were identified, which will be further explored in *D9.2 – Technical specifications on the availability of health data in cross-border telemedicine services.* The three possibilities identified are as follows:**

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| **P4** | Consent to access the patient's clinical data may be required by Country-A, necessitating that National Infrastructure-A verifies whether the patient has granted consent. In this situation, Member States may decide to impose one or more of the following requirements to manage patient consent for cross-border teleconsultation:<br>○ Coordinated Patient Participation: Patients may be required to actively participate in the authentication process to grant HP-B access to their health information. In this case, the prior consultation of the patient's health data should be scheduled, ensuring the patient is fully aware of this activity to allow HP-B access to their health information. This approach aligns with current identification and authentication services, which are typically triggered when the citizens seek access to a specific service, such as using an electronic government (eGOV) mechanism to verify their identity on a health portal. This ensures adherence to security protocols and maintains the integrity of the system.<br>○ Pre-Authorized Consent: An alternative approach to address the challenge of accessing patient data ahead of a teleconsultation involves the HCPO-B providing the patient with a **consent form**. This form, **signed electronically** using the current **eIDAS framework**, would authorize access to the patient's data without requiring real-time authentication, a process that may be impractical in this phase. A consent form, for instance modelled after the informed consent used in ERNs[43], would be a practical approach to secure prior consent for cross-border teleconsultation. The ERN forms ensure patients are fully informed about the collection and use of their data, the professionals who will access it, and their rights under GDPR[36], including confidentiality, security, and the ability to withdraw consent without impacting their care. Therefore, the consent form provided in the scheduling phase of the teleconsultation should be clear, specific, and revocable, ensuring the patient understands who will access their data and for what purpose. Compliance with data minimization and security is crucial, meaning that only necessary data should be shared, and audit trails must be maintained to log when and by whom data is accessed, in line with GDPR's Article 30[36], ensuring both transparency and accountability.<br>○ Country-Specific Consent Management: Another possibility is for **Country-A to manage a specific consent process**, where patients can authorise the use of MyHealth@EU services for cross-border telemedicine services. In this case, NCP-A could verify whether consent was granted when a request is made by NCP-B in the context of a teleconsultation, eliminating the need for direct identification and authentication of the patient in this context. This would facilitate smoother cross-border healthcare interactions while maintaining compliance with data protection and privacy requirements.<br><br>In all cases, particularly for the latter two options, a notification mechanism could be introduced to allow patients to track who accessed their data and when in line with Article 9 *Right to obtain information on* |

[43] European Commission. *Informed consent form for European Reference Networks (ERN).* [available here]

*accessing data* of the proposed EHDS regulation. This would serve as a safeguard, enabling patients to identify and report any potential unauthorized access. Several countries already have similar mechanisms at the national level, which could be adapted for cross-border scenarios. When an HP-B accesses the patient's data from Country-A without the immediate coordination or verification process, a notification should be sent to the patient, informing him/her that his/her health data has been accessed. This notification system would ensure transparency and reinforce trust in the system's security.

It remains to be ascertained whether identification and authentication is always required, even in options 2 and 3. This is a decision that lies with the Member States, as they determine the legal framework for teleconsultation within their jurisdictions.

Furthermore, it is still to be analysed whether the patient only needs to provide consent once for all subsequent teleconsultations, or if exclusive consent is required for each teleconsultation and HP involved. This decision will depend on the legal assessment at both the EU and Member State level. According to the GDPR articles mentioned above, in situations where a teleconsultation service is performed within an established care relationship (i.e., HP-B has already had a first contact with the patient and received consent for data access), further access to health data could be uncoordinated with the patient. This would support continuity of care, allowing HP-B to access necessary data without requiring repeated patient authentication. However, if no prior interaction has taken place, explicit consent from the patient is required before HP-B can access the data. This consent may be provided in advance, for example, during the confirmation of the teleconsultation at the scheduling stage, to streamline the process.

Deliverable D9.2 will continue to explore which legal and technical solutions are viable for implementing this process in MyHealth@EU. This exploration will be done in coordination with MyHealth@EU and eHN to ensure a harmonized approach across MS, while retaining flexibility for national decisions.

From the meetings, workshops and discussions raised under the development of this deliverable, multiple solutions remain under discussion, and consensus has yet to be reached among participating countries. Importantly, a balanced flexibility will be essential to accommodate the needs of countries to adapt MyHealth@EU services for teleconsultations, considering their existing national infrastructures and specific contexts. This adaptability will ensure that the integration of teleconsultation services aligns effectively with each country's unique requirements and systems. However, the work in D9.2 will provide a clearer path forward, considering both the legal and technical feasibility of different approaches, ensuring a flexible and compliant system for cross-border teleconsultation services.

**5.HCPO-B stores ISM information to be shared with HP-B.**
**6.HCPO-B provides patients access to the teleconsultation platform and the patient can access and use the teleconsultation platform (if step 4 occurs).**

The HCPO in Country-B stores the patient's ISM information for sharing with HP-B, ensuring that ISM attributes are seamlessly available to the clinical system used to access MyHealth@EU services. This guarantees that all necessary details are readily accessible during the teleconsultation. To achieve this, the system capturing ISM attributes must be interoperable with the clinical system used by HP-B for accessing MyHealth@EU services. Ideally, the system should be configured to automatically populate ISM attributes into the clinical system as needed, minimizing or eliminating the need for manual intervention by HP-B.

HCPO-B will provide the patient with clear and easy-to-follow instructions, including links, apps, or other tools required to access the teleconsultation platform. Access details, such as login credentials and authentication steps, will be shared with the patient, along with technical support to address any difficulties they may encounter.

It is recommended that the teleconsultation platform is capable of connecting to Country-A's eIDAS identification and authentication system to ensure accurate patient identification. Currently, eIDAS1 enables public systems to connect

to eIDAS-compliant mechanisms, typically through a dedicated webpage where users can select their country and be redirected to their national authentication page. However, this capability is not always extended to private sector systems. In such cases, the EUDI Wallet can serve as a viable mechanism, leveraging the remote flow currently under development in the Large-Scale Pilots.

By ensuring that all preconditions are met, HCPO-B enables HP-B to fully utilize MyHealth@EU services. Additionally, the information provided by HCPO-B allows the patient to seamlessly access the platform and actively participate in the teleconsultation.

The teleconsultation platform, managed by HCPO-B, is maintained to ensure its quality, security, and suitability for teleconsultation purposes. In accordance with the general principles of MyHealth@EU, the laws and regulations of Country-B apply, as the teleconsultation occurs within its jurisdiction. This ensures compliance with local legal and clinical standards, avoiding any ambiguity regarding jurisdiction in cross-border healthcare services.

With the scheduling phase now complete, the process advances to the next stage: pre-teleconsultation.

#### *3.3.2.3. Phase II – Pre-teleconsultation*

This phase encloses all the actions performed immediately before the start of the teleconsultation. This phase includes the identification and authentication processes of both the patient and the HP-B, as well as the HP-B access to the patient's clinical data through MyHealth@EU services.

During the pre-teleconsultation, it is crucial to ensure that HP-B has access to the previously collected ISM attributes and an interface through which MyHealth@EU services can be accessed. Ensuring that the HP-B works in an institution that has the MyHealth@EU services operational should be a pre-condition, or alternatively, verified during the scheduling phase. The existing portals and platforms currently used by HPs to access MyHealth@EU services can be leveraged for the HP to access the information needed for the teleconsultation, minimizing adding additional steps to the current routine of HPs. Therefore, this approach maintains the HP's familiarity with the tools they regularly use, which are generally used to check information during the teleconsultation.

**The access to MyHealth@EU services should considered the following exceptions:**

- Patient consent not granted: if a consent is not given by the patient (when applicable) or it cannot be recorded in Country-A or -B (if applicable), the use case is terminated.
- Patient consent cannot be checked: If NCP-A cannot check that patient consent has been given (where applicable), a notification is sent to NCP-B informing that MyHealth@EU services cannot be accessed.
- HP-B intends to access an unavailable service in country-A: The HP-B informs of this situation to the patient. The use case is terminated.

If pre-conditions outline above are met, the following steps take place in an asynchronous manner:

**7.The HP-B is identified and authenticated using its usual platform to access MyHealth@EU services.**

In HCPO-B, the HP-B authenticates and identifies himself/herself according to the process within country-B to access the MyHealth@EU services.

HPs and HCPOs administrative data are stored in registries, repositories, or databases within national domains, where most of the data processing occurs. In this case, NCP-B is responsible for ensuring this identification and authentication as currently defined in the MyHealth@EU framework.

Then, the authentication is transmitted according to the current algorithms to the NCP-B, which validates the identification and authentication of the HP-B. No impact is expected in this step to enable MyHealth@EU services in the cross-border teleconsultation.

**8. HP-B verifies the patient's attributes provided automatically by the system/platform (obtained during the scheduling phase) and selects an option informing that the encounter is in the context of a teleconsultation.**

**9. NCP-B sends the request and the ISM information to NCP-A.**

**10. NCP-A forwards the request to the national infrastructure-A for patient identification and authentication.**

**11. National infrastructure-A sends the request for the identification and authentication to the patient using the mechanism defined by Country-A.**

In HCPO-B, the HP-B reviews the patient's attributes, which were automatically provided by the system/platform during the scheduling phase and selects the option indicating that the encounter is for a teleconsultation.

**P5**

In HCPO-B, the system automatically inserts the patient-related ISM attributes, which were provided during the scheduling phase, without requiring action from the HP-B. The HP-B only needs to check if data is correct and indicate that the search is for a teleconsultation context.

Indicating that the request is for teleconsultation is essential for the NCPeH, as it requires an additional step for remote patient identification and authentication, as in-person verification by HP-B is not possible. This could be implemented as a checkbox that HP-B must select to enable MyHealth@EU services specifically for teleconsultation.

Regarding the ISM attributes, currently some systems may request all data for both patient and document search steps simultaneously or in a stepwise manner; however, access to the relevant documents is only granted after completing all validation processes.

With the introduction of new services in MyHealth@EU, it would be beneficial for the HP to have the ability to select all relevant clinical documents in a single step, such as specific laboratory result reports, medical images and reports, and a Patient Summary. Currently, each service access requires separate searches by NCPeH, including patient and document search. Therefore, this new option should be carefully analysed for its feasibility concerning current NCPeH data processing procedures and in accordance with the specific requirements of MyHealth@EU participating countries for data access, all while ensuring a user-friendly experience for HP.

Upon receiving this information from Country-B's national infrastructure, the NCP-B would proceed with the necessary identification step signalling to NCP-A the intent to search for the patient specifically for teleconsultation purposes.

NCP-A, in turn, receives this request to verify the patient's attributes, as well as sending a request for identification and authentication through the national infrastructure of the patient's country of affiliation, ensuring a secure and reliable verification process.

**P6**

In alignment with the proposed EHDS regulation, this step introduces a new mechanism for NCP-A to signal those additional actions are required for remote patient identification and authentication. This will trigger a prompt for the patient to complete these steps, ensuring that their identity is verified before proceeding. Further details on this process will be discussed below.

**12. After receiving the request from the national infrastructure-A, the patient identifies and authenticates himself/herself using a strong two-factor mechanism as defined by the Country-A.**

**13. Once validated by the National Infrastructure, NCP-A matches the ISM attributes for patient search and confirms the authentication to NCP-B.**

**14. NCP-B notifies the National Infrastructure-B of the successful patient's identification and authentication.**

**15. The National Infrastructure-B confirms the successful patient's identification and authentication to HP-B.**

According to current MyHealth@EU requirements, for the identification and authentication of the patient during a healthcare encounter, the patient must provide the HP-B with a trustworthy document with a photo that identifies him/her.

In a cross-border teleconsultation context, this is not possible, as such, discussions with the consortium and eIDAS experts were conducted in order to obtain feedback and proposals for a mechanism to solve this issue. From these discussions, some proposals were provided which are detailed below.

According to the MyHealth@EU framework, a two-factor authentication mechanism is defined for the identification and authentication of HPs by country-B, and this level of trust must be validated in the Country-B. Therefore, a similar standard should be established for the remote identification and authentication of patients, as outlined in the proposed EHDS regulation and in line with the eIDAS regulation. Currently several Large-Scale Pilots[31] are deploying the use of the EUDI Wallet for such process as mentioned previously, however this technology is still under development.

In this context, eIDAS-compliant solutions were explored and incorporated into this work to provide a practical and secure approach for patient authentication. These mechanisms ensure adherence to established regulatory frameworks and enable interoperability with existing systems. Examples include using national eID systems for authentication, one-time tokens for access, or portals integrated with eIDAS nodes.

**P7**

To better understand the patient identification and authentication process in the context of cross-border teleconsultations, it is important to understand that there are **three key moments when identification and authentication may occur**, as detailed in Table 2:

1. **During the scheduling phase, if requested by the HCPO-B or when using the EUDI Wallet:**
    - In this phase, the HCPO-B may need to capture patient information, which could require identification and authentication, particularly for verifying the identity of the patient or the legal representative (e.g., a caregiver). This ensures correct identification, especially in remote settings.
    - The EUDI Wallet could be used to facilitate the process by sending the necessary ISM attributes to HCPO-B. This would involve authentication during the use of the app, allowing the patient to securely share their data.
2. **During the request from HP-B to access the MyHealth@EU services:**
    - If Country-A requires patient identification and authentication, several mechanisms may be employed. These, include:
        - Approving or rejecting a request in a specific app or portal after passing a valid identification and authentication process.
        - Inserting a one-time token in an app or portal using registered credentials.
        - Using the eIDAS authentication service, if redirected to a specific portal or app.
        - Scanning a QR code with the EUDI Wallet and approving the attributes to be shared through MyHealth@EU.

3. **During the teleconsultation, when logging into the teleconsultation platform:**
    - Before being granted access to the teleconsultation session, patients may be required to identify and authenticate themselves. Member States can implement various mechanisms for this purpose or leverage existing ones, with eIDAS-compliant methods being strongly recommended.
    - As a general principle**, HCPO-B will have the flexibility to decide how this can be implemented**, considering the technical and legal frameworks available.

**For the patient identification and authentication for enabling access to MyHealth@EU services (point two above)**, two solutions were provided by an eIDAS expert, as detailed in *Annex IX – Identification and Authentication Proposal against an online service in Country-A* and *Annex X –Patient Identification and Authentication Proposal against an online service in Country-B*. After careful consideration and discussion, **the solution that involves reconciling the patient identification and authentication process within the infrastructure of Country-A was chosen**, based on consensus among participants. This decision was also influenced by the findings from the HEALTHeID project[44], which tested a similar scenario, and the following conclusions were reached:

1. Country-A's infrastructure can manage the identification and authentication process more efficiently, ensuring that patient data is accurately verified before being shared with HP-B.
2. Country-A's existing identification and authentication systems can be leveraged, which may already be compliant with eIDAS standards. This reduces the need for additional infrastructure or processes in Country-B.
3. By centralizing the authentication process in Country-A, the security and privacy of patient data can be better managed, as Country-A will have full control over its data handling and verification processes.
4. This approach aligns with the broader goals of the MyHealth@EU framework, ensuring that cross-border teleconsultations are secure and interoperable across Member States.

While an alternative solution, involving reconciliation in Country-B (see *Annex X –Patient Identification and Authentication Proposal against an online service in Country-B*), was explored, it was deemed less feasible due to complexities and scalability challenges, especially as cross-border teleconsultation volumes increase. The Country-A reconciliation approach is considered more practical for managing the patient's identification process while maintaining security, compliance, and operational efficiency.

Taking all of this into consideration, the solution presented below leverages the one described in Annex IX, where the approach involves reconciling the process of patient identification and authentication within the infrastructure of Country-A.

These solutions should be developed taking into account the national readiness, existing systems and EU based solutions, while also prioritizing user-friendly approaches. Favouring familiar options for patients, such as state-recognized authentication apps or platforms, may facilitate adoption. Moreover, alternatives approaches should also be explored to support patients with lower digital literacy.

[44] eHN update on technical implementation and Member States participation in the HEALTHeID Transfer-a-thon [available here]

- **Proposed Solutions for Authentication via Country-A**

To support secure and interoperable mechanisms for patient identification and authentication in cross-border teleconsultation services under MyHealth@EU, it is encouraged to leverage the eIDAS framework. The eIDAS Regulation provides a legal and technical foundation for secure digital identification across the EU, ensuring compliance with EU standards for security and interoperability. Many Member States have already implemented or are aligned with eIDAS for various purposes, making it an ideal infrastructure for this scope.

Importantly, eIDAS enables public sector service providers to connect to an existing eIDAS Node to deliver online services for identifying citizens from other Member States. For instance, as detailed in Annex VIII – Example of eIDAS use for public service, the Lombardy region of Italy has a platform where foreign citizens can authenticate using their national eIDAS login system by selecting their country's flag, which redirects them to the appropriate authentication system. Additionally, as a proposal for the future, as mentioned in section 3.3, eIDAS 2 introduces the EUDI Wallet, which will support the operation of eIDAS mechanisms including the private sector services.

Other important point to raise, is how to properly notify the patient of the identification and authentication request. Given that the patient is authenticated via Country-A's national eIDAS infrastructure or eGOV services, outside of MyHealth@EU services, Country-A must establish a notification system to inform the patient of the authentication request. This may include solutions such as:

- **SMS:** Sending secure links or one-time tokens for authentication.
- **Email:** Providing instructions via REM to initiate the process.
- **Push Notifications**: Similar to bank payment alerts, these notifications would be sent to the patient's EUDI Wallet or another recognized app.

Independently of the solution adopted, the patient must be made aware of the instructions that detail the necessary steps to complete this process.

By adopting these measures, Country-A ensures a secure, streamlined, and patient-friendly approach to identification, authentication, and consent, in line with the EHDS Regulation, MyHealth@EU, and eIDAS regulations.

- **Identification and Authentication Process Overview**
  1. **HP-B** authenticates against a Country-B service according to the eHDSI requirements.
  2. **HP-B** performs a standard patient search against Country-A, following the data requirements specified by Country-A's ISM[45].
  3. Before releasing the *patientIdentifier*, a unique identifier that ensure accurate patient matching, Country-A needs to authenticate the patient;
  4. A technical solution is implemented to request the patient to authenticate against a Country-A service, using their own national eGOV services or other eIDAS-compliant mechanisms, with this process occurring outside the MyHealth@EU services. The process entails the following steps from the side of the patient:
     a. After receiving an active notification from National Infrastructure-A to identify and authenticate, the patient must log into their national eGOV service or eIDAS-enabled eID system through a device connected to the internet.
     b. The patient will then provide the requested attributes (e.g., name, health ID, etc…) to complete the process.

[45] For example, in the case of PS and eP, the IHE XCPD (Integrating the Healthcare Enterprise Cross-Community Patient Discovery) is the standard in use for this search. For FHIR-based systems, Patient Demographics Query for Mobile (PDQm) standard is applied.

5. The outcome of the patient authentication is sent to the **MyHealth@EU Country-A services** (OpenNCP or National Connector).
6. **National Infrastructure-A** processes the authentication results and validates the identification and authentication of the patient according to the data received. Once confirmed, **National Infrastructure-A** forwards the validated information, including the *patientIdentifier*, to **NCP-A**.
7. **NCP-A** processes the information from **National Infrastructure-A** to verify the patient's identity and ensure that the *patientIdentifier* has been authenticated in line with the data received. NCP-A then matches the ISM attributes (e.g., personal and medical identifiers) for the patient search, comparing them against national databases to confirm data consistency and accuracy.
    a. **If the patient search is validated:** **NCP-A** sends the successful validation, along with the *patientIdentifier*, to **NCP-B**, allowing the Document Search to be initiated as requested by **HP-B**.
    b. **If the patient search is not validated:** **NCP-A** sends an error message to **NCP-B**, reporting the failure to identify the patient. **NCP-B** will then inform **HP-B** of the issue, and the validation process may need to be repeated.
8. Upon successful validation, **NCP-A** closes the **transaction**[45] as required by country-B, having confirmed that the *patientIdentifier* has been authenticated and is consistent with Country-A's records.
9. **NCP-B** receives confirmation that the patient has been successfully identified and authenticated, and forwards this information, including the *patientIdentifier*, to **National Infrastructure-B**.
10. **National Infrastructure-B** sends the final confirmation of the patient's identification and authentication to **HP-B**, allowing further transactions to proceed as part of the **usual MyHealth@EU flow**.

**16. Afterwards, HP-B requests access to the relevant clinical document through its standard platform to access MyHealth@EU services.**

**17. NCP-B receives the HP-B request to access patient's information and sends it to NCP-A.**

**18. NCP-A receives the NCP-B request to access patient's information and sends it to National Infrastructure-A.**

**19. National Infrastructure-A receives the request to provide the patient data and sends it to NCP-A in friendly-A format.**

**20. NCP-A receives friendly-A and converts it into a Pivot format to send to NCP-B.**

**21. NCP-B receives the Pivot format, translates it into friendly-B format and sends it to National Infrastructure-B.**

**22. National Infrastructure-B receives the friendly-B format and converts it into Country-B's local format to send to the HP-B.**

**23. HP-B can access MyHealth@EU services displayed in his/hers usual platform and starts the teleconsultation.**

Upon receiving the information that the patient is identified and authenticated, the HP-B searches for the necessary patient data, such as PS, eP, Medical test results, including laboratory and other diagnostic results and related reports; and Medical Imaging studies and related imaging reports. This step is conducted for the HP-B to gather all relevant information necessary for the teleconsultation.

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| P8 | The above-described process adheres to the standard flow and requirements of MyHealth@EU. However, it may be necessary to revisit the flow to avoid triggering several requests to the patient for identification and authentication to consult each service – ideally the same identification and authentication process should allow the access of several services as long as the security and privacy safeguards are in place – for example, most eIDAS-compliant One-Time-Token have a short span of time for identification and authentication to avoid security risks. Overall, to enhance efficiency there should be a **recommendation to avoid multiple identification and authentication requests to the patient**, simplifying the workflow for both patient's and HPs.<br><br>Alternative solutions to the re-identification and authentication issue are also addressed in step 3 of the scheduling phase, which encompasses 3 solutions for the patient consent to access data.<br><br>Another key issue in the document search process is that, in the current setup, HP may need to re-enter the patient's ISM attributes for each document search, which can be impractical. As of the creation of this deliverable, MyHealth@EU offers only two services (eP/eD and PS). With the addition of new domains, it would be beneficial from the user's perspective to streamline document retrieval for HPs. Ideally, a single search should provide a comprehensive list of available documents or HP-B could select all relevant clinical documents in a single step by inserting all relevant ISM attributes. As mentioned above, this possibility will likely impact the current procedures of MyHealth@EU and NCPeH flows to allow for the **simultaneous consultation of various documents.** |

In the current MyHealth@EU process, electronic health data from Country-A is firstly converted from its local format into a standardized Friendly-A format by the National Infrastructure-A. This format reflects the structure and semantics of the national document but is aligned with international standards. The data is then passed to NCP-A, where it is further transformed into a Pivot format, a common intermediary format that ensures semantic interoperability across countries. The pivot document is more technical and follows a strict schema with predefined value sets, allowing for consistent data mapping between different national formats, while the friendly document adapts the national format to align with the pivot without altering the original meaning[46].

Upon receipt, NCP-B translates the Pivot into Friendly-B format, which is then transferred to the National Infrastructure-B. The National Infrastructure-B converts the Friendly-B format into the local format of Country-B. Finally, the data is delivered to the National Infrastructure-B or its corresponding portal in the appropriate local format.

Throughout this process, the document transitions between various formats, data structures, and languages. These transformations ensure the use of common formats, vocabularies, and translations, enabling seamless data exchange across borders, ensuring that Country-B receives the document in a standardized and fully compatible form.

These steps allow for the HP-B to access MyHealth@EU services to retrieve the provided information to start the teleconsultation with all the necessary data available. At this stage, the pre-teleconsultation phase is terminated and process flow transitions into the teleconsultation itself.

[46] MyHealth@EU Glossary [Access restricted to MyHealth@EU members - available here]

#### *3.3.2.4. Phase III and IV – Teleconsultation and Post-teleconsultation*

To streamline the process description and ensure a coherent flow of information, the sections pertaining to the teleconsultation and post-teleconsultation phases have been merged. This integration reflects the close relationship between these phases, as the outcomes and data generated during the teleconsultation significantly impact the subsequent steps of information sharing and updating patient records. However, to maintain a clear, distinct view of each phase, these sections remain separated in the patient journey flowchart.

**24. Patient-A shares information about his/her health conditions with HP-B.**

**25. HP-B inserts the information generated during the teleconsultation in its clinical platform or teleconsultation platform, as applicable.**

**26.The HP-B generates a report based on the clinical information retrieved during the teleconsultation.**

During a teleconsultation, the HP-B engages in a real-time discussion with the patient, which often leads to the generation of new medical information[47]. This information typically falls under the priority data categories outlined in Article 14 of the proposed EHDS regulation[2], such as diagnoses, treatment plans and ePrescriptions, among other examples. These findings, including new diagnoses or changes to the patient's treatment or medication plan, are crucial for safeguarding patient safety and ensuring continuity of care. The HP-B is responsible for documenting this information and sharing it with the patient's country of affiliation (Country-A), upon patient's request or by HP-B recommendation. This ensures that the patient's General Practitioner (GP) or other healthcare providers in Country-A have access to the necessary data to continue the patient's care.

**P9**

For documenting information generated during teleconsultations, the HP-B should use their usual clinical systems or teleconsultation platforms, preferably compatible with the EEHRxF. Using familiar systems simplifies adaptation, minimizes retraining, and provides flexibility for MS, allowing them to maintain existing national systems while ensuring compliance with cross-border health data exchange requirements.

The proposed EHDS regulation defines discharge reports as "*Electronic health data related to a healthcare encounter or episode of care and including essential information about admission, treatment and discharge of a natural person*." In this context, teleconsultation reports can be aligned with discharge reports, as they similarly document critical medical outcomes observed during a healthcare encounter. MyHealth@EU's planned introduction of the Hospital Discharge Report (HDR) service provides a suitable framework for teleconsultation reports, streamlining cross-border data exchange.

The categories deemed relevant for teleconsultation reports were identified in a workshop with the WP9 participants, where the EHDS priority data categories and eHN guidelines were analysed. Participants went through the eHN HDR core dataset (Annex XI – *Hospital Discharge Report Core Dataset from eHN guidelines*), and debated which categories are applicable to the cross-border teleconsultation context. The conclusions of this workshop informed the proposal for teleconsultation documents to include key information like diagnoses, treatment plans, and other priority data.

In this workshop, participants analysed the HDR Core Dataset from the eHN and evaluated which attributes would be useful to insert in the document generated from the teleconsultation. In the context of cross-border teleconsultation, the following categories from the eHN HDR were identified as essential:

- **Diagnostic Summary:** This data element pertains to all problems/diagnoses that affect care during the inpatient case or are important for ensuring continuity of care.

[47] Some teleconsultations may not necessarily require a report; however, if the patient requests it or the HP deems it necessary, a report with relevant information from the teleconsultation should be generated and sent to the patient's country of affiliation.

- **Significant Observation Results:** Results from significant functional, diagnostic, and imaging examinations that are necessary to maintain continuity of care. These results include key findings that have implications for ongoing treatment and patient management.
- **Objective Findings:** A synthesis of significant functional, diagnostic, and imaging examination results, which offer a detailed overview of objective clinical findings crucial for patient care continuity.
- **Medication Summary:** A detailed summary of medications prescribed during the patient's care, which is vital for informing future treatment and ensuring patient safety.
- **Other Recommendations:** Additional advice provided after discharge, which may include various recommendations, such as suggesting a hip replacement, reducing the number of cigarettes smoked, stopping smoking entirely, increasing physical exercise, and other lifestyle changes. Multiple recommendations can be made, depending on the patient's condition and needs.

These categories ensure that the document generated from the teleconsultation is comprehensive and supports effective cross-border healthcare delivery by addressing key elements required for continuity of care.

The datasets exchanged between countries should also align with the forthcoming recommendations from Work Packages 5[12], 6[48], and 7[49] of the joint action Xt-EHR, which are under development.

From a technical perspective, compliance with standards such as Health Level 7 Fast Healthcare Interoperability Resources (FHIR)[50] ensures interoperability, while the use of terminologies like Systemized Nomenclature of Medicine – Clinical Terms (SNOMED CT)[51] facilitates consistent data sharing across borders.

Although not all teleconsultations may require sending the report back to country-A, a mechanism should be available to enable this, based on the patient's wishes and HP-B's recommendations, in line with the rights of natural persons as established under the proposed EHDS regulation to access and make use of their personal electronic health data regardless of the Member State.

**27. HP-B requests NCP-B to send this report to the patient's country of affiliation.**

**28. NCP-B receives, translates and transcodes the document to send to NCP-A.**

**29. NCP-A receives, translates and transcodes the document and sends it to the National Infrastructure-A.**

**30. National infrastructure-A stores this report in the relevant EHR system(s).**

The proposed mechanism for sharing teleconsultation documents closely follows the structure currently defined for the future implementation of the discharge reports within the MyHealth@EU framework. This ensures secure cross-border data exchange while maintaining data integrity and enabling healthcare providers in Country-A to access the necessary information. In some MS, the document may be automatically shared with the patient's GP or stored in a national EHR system. In others, it may be added to personal health records (PHR) or personally controlled health record (PCHR) systems.

[48] WP6 - *Electronic Prescriptions and Patient Summary towards EHDS.*

[49] WP7 - *New services for EHR systems towards EHDS.*

[50] Fast Healthcare Interoperability Resources (FHIR) [website available here]

[51] Systemized Nomenclature of Medicine – Clinical Terms (SNOMED CT) [website available here]

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| P10 | As outlined in the steps above, once the teleconsultation concludes, the HP-B generates a report detailing the relevant observations from this healthcare encounter.<br><br>The mechanism being developed for the future service to exchange Hospital Discharge Reports (HDR) via MyHealth@EU may also be adapted to facilitate this exchange. At the time this deliverable was prepared, the new HDR service within MyHealth@EU was still under development, and details on how Country-A will receive and store this information were still under discussion. This will be continually evaluated in D9.2, as a similar mechanism is anticipated for this context. Nevertheless, certain foundational principles should be followed to implement this capability effectively.<br><br>This process must ensure compliance with the proposed EHDS regulation, MyHealth@EU standards, and eHN guidelines for HDR19, as well as the work being developed by WPs 5[12], 6[48] and 7[13], as mentioned above. This alignment is critical to ensure consistency, standardization, and compliance with European regulations and standards.<br><br>This report is expected to be prepared for cross-border transmission by the national infrastructure in country-B, that will translate and transcode the data into a format that aligns with MyHealth@EU standards and is compatible with other Member States' systems. The translation ensures the document is in the correct language, while the transcoding maps the data into standardized coding systems, such as SNOMED CT or international classification of diseases (ICD), ensuring semantic consistency.<br><br>Next, the document is securely transmitted across borders through MyHealth@EU infrastructure to Country-A. MyHealth@EU ensures that the document is encrypted and transferred safely, maintaining data confidentiality and integrity during the process. Once the document reaches Country-A, it undergoes another round of transcoding and translation to adapt the data to the national language and healthcare standards. This ensures that the priority data categories are accurately reflected in the national format.<br><br>Finally, if previous authorization is conceded by the patient, the document may be stored in its EHR, in the national infrastructure of Country-A. It may be integrated into the patient's EHR or shared with relevant healthcare providers, such as the patient's GP, to ensure continuity of care. In countries where national EHR systems are established, the data may be stored there automatically. In others, the information may be placed in PHR or PCHR systems, based on the local regulatory framework and healthcare infrastructure.<br><br>Given the varying readiness of Member States, it may be beneficial to initially allow the exchange of non-structured or semi-structured formats for teleconsultation-related documents, enabling gradual adoption while the joint action Xt-EHR continues to refine the standards and processes for the EEHRxF. |

### 3.3.3. MyHealth@EU services for a Health Professional – Health Professional Teleconsultation

This scenario involves a consultation between two HPs, one from Country-A and another from Country-B, regarding a patient from Country-A. In the context of cross-border telemedicine, for safe and effective healthcare provision, there must be requirements established on the necessary procedures for HP to access the patient's health data. Secure identification and authentication of the HP are crucial to ensure that only authorized individuals access the patient's data.

#### *3.3.3.1. Process Description*

This chapter explores how MyHealth@EU could support cross-border teleconsultations between two HPs, highlighting the established processes and requirements for secure identification, authentication, and consent. Please note that several steps are applicable to both use cases, and therefore the process description has been simplified to highlighted key steps in this specific context.

- **Identification and authentication of the HPs**

All countries involved in the MyHealth@EU framework participate in a well-established circle of trust, based on shared policies for data protection, privacy, and confidentiality. This trust circle ensures that HPs data are handled securely across borders. Key to this framework is the unique and secure identification and authentication of each HP by their respective national infrastructures. This process guarantees that only authorized professionals can perform specific healthcare actions, in compliance with national and EU regulations.

As part of this security framework, national health authorities are required to confirm that all HPs are authenticated using a two-factor authentication process. This level of verification is essential to uphold the integrity and safety of cross-border healthcare interactions.

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| **P11** | In the specific use case of teleconsultation between HPs from different countries, the existing MyHealth@EU identification and authentication processes can be reused. This means the current procedures for verifying the identities of HPs will be applied, ensuring the continuity of security and trust when HPs collaborate across borders. This seamless reuse of existing infrastructure eliminates the need for any additional authentication processes, facilitating smooth and efficient healthcare consultations between professionals from different countries. As detailed in section 3.3.2.2 (Phase I – Scheduling), the ISM attributes should also be obtained beforehand so that HP-B can proceed with the request to access patient's-A health-related information. |

- **Access to the patient's data**

A critical issue arises when HP-B needs to access patient's health data during a teleconsultation with HP-A, especially in cases where patient is not physically present or actively involved. To ensure seamless cross-border healthcare collaboration, a mechanism for sharing patient data without requiring real-time patient authentication is essential.

In such teleconsultations, re-authenticating the patient (if required) each time data is accessed is not necessary under GDPR. If during the scheduling phase the patient provides the consent for their data to be accessed in the context of the teleconsultation, this consent authorizes HP-B to access their information during consultations with other professionals. The consent must clearly cover the scope of data sharing and interactions with other HPs.

According to GDPR Article 9(2)(h)[36], HPs are permitted to share patient data with each other for treatment purposes, provided appropriate safeguards are in place. This structure allows for secure data sharing in teleconsultations without the need for repeated patient authentication, streamlining the process while maintaining compliance with privacy regulations.

As such, a mechanism must be in place to obtain patient consent for access to their data in this context.

**P12**

One solution to avoid repeated authentication processes is to request the patient's electronically signed consent for data access during the scheduling phase, as proposed in section 3.3.2.2 (Phase I – Scheduling) of the Patient journey. This approach allows HPs to access the patient's data later, during the teleconsultation, without needing to synchronize with the patient in real-time, avoiding the impractical challenges of coordinating time availability between the patient and the HPs.

The solution mentioned above involves establishing a specific mechanism for obtaining patient consent. This mechanism can be achieved through an **electronically signed consent form**, leveraging the eIDAS framework, or through a **new consent management platform in Country-A**. Such mechanisms would require the patient to provide upfront consent in accordance with GDPR requirements for a cross-border teleconsultation involving an HP registered and recognized by their respective country, specifically HP-A in Country-A and HP-B in Country-B.

It may also be necessary to introduce an option where HP-B can confirm that they have obtained a signed consent form from patient. This confirmation would allow HP-B to certify to NCP-B that valid consent was acquired, enabling access to patient data through the MyHealth@EU infrastructure, or this could also be check with NCP-A if the consent is managed at the country-A level.

In accordance with the rules of Country-B, NCP-B could either validate the electronic signature via the eIDAS node or accept the consent based on a trust circle, where HP-B assumes responsibility for obtaining the form in compliance with GDPR and EHDS regulations.

The implementation of such a mechanism could require changes to existing infrastructure, as there is no uniform system in place for managing these processes at the national or regional level of some MS. Therefore, integrating such solutions into the MyHealth@EU framework would represent a significant enhancement to facilitate secure and efficient teleconsultations across borders.

- **Additional considerations**

To keep the patient informed about access to their data and to prevent possible issues that may arise from the uninformed access, a **notification mechanism** could be introduced to allow patients to track who accessed their data and at which moment. This would serve as a safeguard, allowing patients to identify and report any potential unauthorized accesses.

### 3.3.4. Sharing of the information generated during the teleconsultation back to the patient's country of affiliation

As proposed in the section 3.3.2.4 (Phase IV – Post-Teleconsultation) of the Patient Journey, the information generated during the teleconsultation between two HPs can be highly valuable for inclusion in the patient's EHR. The data that falls under essential categories such as diagnoses, treatment plans, and ePrescriptions, as described in Article 14 of the EHDS regulation, should be documented and sent to the patient's EHR. This ensures that the findings from the teleconsultation – whether they involve new diagnoses or updates to treatment – are properly documented.

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| P13 | The mechanism proposed in section 3.3.2.4 (*Phase IV – Post-Teleconsultation*) for sharing teleconsultation documents closely follows the structure currently defined for the future implementation of discharge reports within the MyHealth@EU framework. This guarantees secure cross-border data exchange, preserving data integrity while enabling healthcare providers in Country-A to access the necessary information. In some Member States, this document may be automatically shared with the patient's GP or stored in a national EHR system, while in others, it may be added to PHR or PCHR systems. These varying scenarios are currently being discussed in collaboration with the eHealth Network and the MyHealth@EU communities to ensure alignment with national processes.<br><br>As explained above (blue boxes P9 and P10), this report can be securely transmitted through the MyHealth@EU infrastructure to Country-A. MyHealth@EU ensures that the document is encrypted and transferred safely, maintaining data confidentiality and integrity throughout the process. Once it reaches Country-A, the document undergoes another round of transcoding and translation to adapt it to the national healthcare standards and language. This step ensures that priority data categories are accurately reflected in the national format. With the patient's prior consent, the document may then be stored in their EHR within the national infrastructure of Country-A, where it may be shared with relevant healthcare providers, such as the GP, to ensure continuity of care. |

The alignment with the eHN and the MyHealth@EU communities ensures that this entire process integrates seamlessly with existing national workflows, adhering to the proposed EHDS regulation, MyHealth@EU standards, and the eHN guidelines for hospital discharge reports.

This step marks the conclusion of the HP-HP teleconsultation use case.

## 3.4. Analysis of eHDSI requirements to support cross-border teleconsultation

In MyHealth@EU, eHDSI requirements relate to the critical criteria and functional requirements that govern the infrastructure's operation and implementation for cross-border health data sharing. These requirements ensure that the system functions properly and is consistent with the objectives of interoperability, data security, and compliance with EU legislation such as the proposed EHDS.

The eHDSI Requirement Catalogue V8.0 OR[16] was used to assess the existing requirements necessary to support cross-border telemedicine services, with special focus on teleconsultations. For this purpose, each requirement was carefully reviewed to evaluate its relevance and the potential impact in the proposed telemedicine use cases. While essential requirements currently applied under MyHealth@EU remain relevant, the introduction of cross-border telemedicine services necessitates updates to these requirements to ensure a seamless integration.

Given the evolving nature of telemedicine and the dispositions in the proposed EHDS regulation, it is crucial to adapt the existing framework to accommodate new functionalities and processes. The following section outlines the specific impact of each requirement within the proposed cross-border telemedicine process. A comprehensive summary of the changes and their implications is provided in *Annex XII – Preliminary analysis of MyHealth@EU eHDSI Requirements*, which highlights the adjustments needed to align with telemedicine service delivery.

### 3.4.1. Summary of relevant requirements to support cross-border telemedicine services

Most requirements will remain applicable in the cross-border telemedicine context where MyHealth@EU services are leveraged. However, specific requirements will need to be updated to accommodate telemedicine, along with the introduction of potential new requirements, as exploited in Table 3. For clarity and traceability, the original numbering of these requirements will be maintained throughout the analysis and the original text will be shown in italic.

**Table 3.** New and updated requirements to support cross-border telemedicine services under the MyHealth@EU infrastructure.

| Type of amendment | Requirements to support cross-border telemedicine services |
|---|---|
| **Updated Requirements** | 02. Ensure Patient Identification |
| | 03. Create and apply policies and procedures to ensure trust between countries |
| | 04. Ensure lawful processing of personal and health data |
| | 06. Make ePrescription available to HP |
| | 07. Handle Dispensation of medicine and Substitution |
| | 10. Ensure high quality information (structured, equivalent, understandable) is exchanged between countries |
| **New Requirements** | A. Make Discharge Report available to HP<br>A.01. Create the MyHealth@EU Discharge Report content<br>A.02. Transcode, translate and exchange cross-border the Discharge Report<br>A.03. Inform Country of affiliation about the Discharge Report<br>A.04 Display the Discharge Report to the Health Professional |

#### 3.4.1.1. Updated requirements

**02. Ensure Patient Identification.**

*The patient must be uniquely and securely identified at national level (by the National infrastructure in the Country of affiliation). The HP in the Country of treatment must verify by the available means the identity of the patient.*

***02.01. Uniquely identify the Patient***

***02.01.01. Identification and authentication of a patient with demographic data or demographic data and eID***

*The HP in the Country of treatment must ensure that the patient is who pretends to be, and has a trustworthy document with photo and demographic data (used for identification in the country of treatment).*

Contrarily to MyHealth@EU scenario, in telemedicine services, the patient is not able to identify himself/herself to the HP using a physical trustworthy document with photo and demographic data, or request the patient to access on his/hers mobile phone in order to verify the eID generated. The latter will be enabled with the future use of the EUDI Wallet. However, according to the previous analysis, a novel preposition on the requirement is needed for the HP to verify the patient identification. For instance, new functional requirements will be needed:

- The patient in the Country of affiliation (Country-A) must have access to a remote, eIDAS-compliant mechanism that enables them to securely identify and authenticate themselves, upon request by the national infrastructure of the Country of affiliation. This request is initiated by the HP of Country of treatment (Country-B) as part of cross-border telemedicine services.
- Authentication of the patient with the national infrastructure's identity providers is needed when connecting to the system.

- The NCPeH of the Country of treatment must send a request to the NCPeH of the patient's Country of affiliation, prompting the citizen to undergo identification and authentication remotely.
- The identification and authentication of a patient takes place in the National Infrastructure of the Country of affiliation and uses the attributes as established in the International Search Mask and (if applicable) additional attributes regarding the use of eIDAS framework.

Considering a trustworthy environment, the HP will be able to introduce the patient's attributes as defined for the ISM for the patient search step, to start the identification process with the Country of affiliation. This process aims to guarantee the correct verification of the identification of the patient to ensure that MyHealth@EU services can be used as requested. After the request of the identification of the patient by the HP, if validated by the Country of affiliation, the HP receives the confirmation of the validation of the identification of the patient.

Consequently, it is proposed a trustworthy and safe remote identification of the patient by the HP exclusively in a remote teleconsultation.

Within the MyHealth@EU environment, the HP must be able to rely on the authentication of the patient by the Country of affiliation. To establish trust, certain security requirements must be met, such as those defined in the eIDAS framework. Therefore, the level of trust should be based on the authentication and the quality of attributes and must encompass all relevant factors that drive these qualities, which are necessary to provide the essential assurance level of the electronic authentication. The relying party has to place sufficient confidence in the authentication and attribute assertions which will be set up by the country according to any binding agreement signed by the NCPeHs.

***03. Create and apply policies and procedures to ensure trust between countries***

***03.04. Education, training and awareness of the cross-border services***

*The NCPeHs must ensure that their staff, external service providers and health professionals involved in the provision of the cross-border services within MyHealth@EU are trained and have enough information to support both national and foreign patients. Training activities must be planned and implemented for this purpose.*

The training required for the stakeholders involved in a teleconsultation within MyHealth@EU infrastructure must be provided in a timely and targeted manner. Given the possible scenarios in telemedicine services, it is imperative to guarantee adequate training to the health professionals from both countries, external service providers and staff involved. This will entail providing adequate educational materials explaining on how to use the information systems, and the differences among the Member States approaches to consent management, among other.

As mentioned above, instructions should also be provided for users, such as HP and patients, so they are aware of how MyHealth@EU services can be used for cross-border teleconsultations.

***04. Ensure lawful processing of personal and health data***

*NCPeHs must ensure their compliance with the data protection provisions at European and National level, by providing the following minimum requirements:*

- *Identify the applicable legal basis for processing personal and health data within MyHealth@EU.*
- *Identify the controller(s) and the processor(s) of the personal and health data processed within MyHealth@EU.*
- *Inform patients about their rights as concerns the protection of their personal and health data processed through the MyHealth@EU provided services.*

Currently, HP-B can only access patient information via MyHealth@EU when the patient is physically present with them. The introduction of cross-border telemedicine services may impact this requirement, to ensure the possibility of access to patient data in telemedicine settings where health encounters occur remotely. To support teleconsultation and other forms of cross-border telemedicine, it is crucial to adapt the requirement to allow HP-B to lawfully access patient data even when the consultation is not conducted in person.

This adaptation must account for scenarios where patient and HP-B are not in a coordinated, real-time setting (i.e., the patient and HP-B are not interacting simultaneously when data is accessed). Such cases require the introduction of secure, asynchronous access to patient information, ensuring that access is compliant with the EU's data protection laws while preserving patient rights and confidentiality. Similarly, principles must also be applied for the scenario of a HP-HP teleconsultation to discuss a specific clinical case from a patient.

Moreover, new mechanisms for obtaining prior patient consent remotely must be integrated into MyHealth@EU to accommodate teleconsultation, ensuring that HP-B can access necessary health data at any time while maintaining data integrity, traceability, and security. This may involve leveraging the eIDAS framework for secure patient authentication and authorization, allowing more flexible and lawful access to health data in cross-border telemedicine scenarios**.**

It is crucial to assess each of these mechanisms, which may imply more than one solution. Nonetheless, it is encouraged that the selection of the solutions discussed in previous sections (for patient identification and authentication, as well as consent) are harmonized across MS to foster seamless systems and user-friendly, requiring less need for users to adapt to multiple procedures while also respecting legal requirements. Importantly, the selection of the preferred mechanisms will also impact requirement *02. Ensure Patient Identification*.

***06. Make ePrescription available to HP***

*NCPeH of Country of affiliation must make available the ePrescription clinical document (independently of the format), according to the data set defined by the eHN eP Guidelines.*

*NCPeH of Country of treatment is responsible for ensuring the traceability of the information included in the eP received from NCPeH of Country of affiliation.*

Teleconsultation between a patient and a HP may result in the HP-B issuing an eP for that patient. In this case, the Country of treatment must make available the eP clinical document for the patient, that can be dispensed in the Country of affiliation, being this prescription emitted in the context of cross-border telemedicine services.

***07. Handle Dispensation of medicine and Substitution***

*The dispensation is performed according to the legislation in the Country of treatment. The NCPeH of the Country of treatment must send the information about the dispensation to the NCPeH of the Country of affiliation. The information must reflect the actually dispensed medicine in the MyHealth@EU semantic format.*

*NCPeH of Country of affiliation must confirm to NCPeH of Country of treatment, the reception of the information about the dispensation.*

Similar to as observed in the previous requirement, the same is applicable here. Any eP exchanged through MyHealth@EU shall be accompanied by the electronic dispensation. Regarding the telemedicine services, the dispensation notice can occur in the Country of affiliation. In this case, the Country of affiliation must send the information about the dispensation to the NCPeH of the Country of treatment, being confirmed posteriorly by the Country of treatment after reception. This ensures the prescription cycle is completed and prevents the risk of the same eP being reused inappropriately.

Moreover, the general principles of the eDispensation are also applicable to the teleconsultation context, which is performed according to the legislation in the Country where dispensation occurs.

***10. Ensure high quality information (structured, equivalent, understandable) is exchanged between countries***

*The NCPeHs must ensure the high quality of the health data being exchanged within the MyHealth@EU clinical documents (qualities of the content of the clinical documents). The following criteria were agreed to define the exchanged data as being of ''high quality'':*

- *The data is structured.*
- *The data is equivalent in the meaning.*
- *The data is understandable by the human actors who will make use of it.*

Following the creation of a discharge report containing the information of the teleconsultation generated by the Country of treatment, this report shall allow the possibility of the use of non-structured fields. Non-structured options permit easier implementation by the MS.

#### 3.4.1.2. New requirements

**A. Discharge report available to Country of Affiliation**

During the teleconsultation, new findings regarding the patient may emerge, and both HP-B and patient may wish for this information to be transmitted back to the patient's Country of affiliation for further continuity of care. In this case, a new requirement must be formulated to allow for the exchange of a discharge report relatively to the teleconsultation itself. The content of this teleconsultation report must contain all relevant information from the teleconsultation with patient or between two HPs, providing a relevant document to complement the existing EHR information in the Country of affiliation.

The eHN Guideline regarding the exchange of Hospital Discharge Reports (HDR) was published in November 2023[19], and the implementation of the HDR service is under development. The specific requirements for implementing this exchange within the MyHealth@EU framework have not yet been fully defined. In addition, WP7[13] is currently working on defining the requirements and specifications of discharge reports for the future implementing acts under the EHDS regulation.

The proposed EHDS regulation defines discharge reports as a priority data category, broadening their scope beyond just hospital settings to encompass other healthcare encounters. Therefore, when the requirements for the exchange of discharge reports are incorporated in the eHDSI requirements catalogue, the telemedicine use case should be integrated expanding the type of reports exchanged. As outlined above, the majority of data elements specified in the eHN guideline for HDR are also relevant in the context of cross-border teleconsultations. These elements can be effectively leveraged to support the exchange of critical health information in this setting.

As mentioned above, given the varying readiness of Member States to share this new report, it may be practical to initially permit non-structured or semi-structured formats. This approach will provide the necessary flexibility for countries to begin implementing these new services for EU patients.

This new requirement should not differentiate between in-person and remote health encounters, ensuring its applicability in cross-border telemedicine services. As a result, the following requirements are anticipated to be introduced, which should be aligned with the future requirements for HDR and the WP7[13] work for discharge reports:

**A. Make Discharge Report available to HP**

- Both NCPeH of Country of affiliation and NCPeH of Country of treatment must ensure that semantic interoperability is achieved, and the clinical documents can be exchanged cross-border.
- Independently of the format and type of health encounter (in person and/or remote), NCPeH of Country of treatment must make available the discharge report, structured according to the data set defined by applicable documents (e.g., eHN guidelines, EHDS implementing acts).
- NCPeH of Country of treatment must make available the discharge report only to authenticated and authorized HP (*Note: other possibilities may exist, which are currently being discussed for the HDR service, and therefore this should be aligned*).

- The information in the discharge report must reflect the actual health encounter findings in the MyHealth@EU semantic format.
- NCPeH of Country of treatment is responsible for the content of the discharge report sent to NCPeH of Country of affiliation.
- NCPeH of Country of affiliation is responsible for ensuring the traceability of the information included in the discharge report received from NCPeH of Country of treatment.
- NCPeH of Country of affiliation is responsible to present to their HP (or other according to HDR definition), the discharge report received from the NCPeH of Country of treatment.
- NCPeH of Country of affiliation must confirm to NCPeH of Country of treatment, the reception of the information included in the discharge report.

This requirement may include the following sub-requirements:

**A.01. Create the MyHealth@EU Discharge Report content**

**A.02. Transcode, translate and exchange cross-border the Discharge Report**

**A.03. Inform Country of affiliation about the Discharge Report**

**A.04 Display the Discharge Report to the Health Professional**

This final requirement should be consistent with ongoing discussions around the exchange of HDR. The patient's general practitioner or specialist may benefit from having access to this clinical document. The national infrastructure of the Country of affiliation will manage this process. During the cross-border teleconsultation, the HP-B may decide to propose the use of a new medicine or altered the current medication plan. This information should be reported in this report from the cross-border teleconsultation.

The previously updated and new requirements following the eHDSI requirements catalogue correspond to a baseline of the requirements that need to be updated or formulated in order to implement the described teleconsultation services under the MyHealth@EU infrastructure. Specifically, these requirements explored the new adding solutions that might be required to be created for the implementation of teleconsultation services under MyHealth@EU. Further, the deliverables D9.2 (*Technical specifications on the availability of health data in cross-border telemedicine services*) and D9.3 (*Requirements for Large-Scale Uptake of Telemedicine Service*) will continue to explore which technical specifications are viable for implementing this process in MyHealth@EU. Specifically, deliverable D9.2 will detail the technical specification for MyHealth@EU to ensure the availability of health data for telemedicine services, while D9.3 will provide conclusions of the requirements for telemedicine services in order to support the implementation of the EHDS regulation.

# 4. Conclusion and recommendations

The thorough identification and analysis of use cases and requirements regarding the implementation of cross-border telehealth within the MyHealth@EU framework, in advance of the proposed EHDS, underscores the importance of interoperability and seamless cross-border data exchange. These elements are key to improving healthcare accessibility and quality across the EU.

The proposed EHDS regulation[2] includes telemedicine as a potential cross-border digital service through the existing MyHealth@EU infrastructure. Achieving continuity in cross-border healthcare across the EU requires establishing shared practices for patient data exchange among countries. This political commitment to cross-border healthcare access has raised awareness of the need for interoperable eHealth systems, driving initiatives like the EU e-Health Interoperability Framework and pilots for health data exchange.

The insights provided in this deliverable will play a critical role in supporting the future uptake of telemedicine as a supplementary service within MyHealth@EU, ensuring the continuity of care for EU citizens, regardless of their location. Telemedicine can enhance access to specialized healthcare services, particularly for patients in remote areas, and will enable health professionals to collaborate more effectively across borders.

Moving forward, the next phase of development will focus on refining the technical specifications necessary to bring this vision to life. An effort that will be critical in the future expansion of MyHealth@EU and will be the focus of *Deliverable 9.2 – Technical Specifications on the Availability of Health Data in Cross-Border Telemedicine Services*, which will explore how existing components of MyHealth@EU can be leveraged to support cross-border telemedicine services.

Maintaining strong coordination amongst stakeholders, such as medical professionals, technological specialists, government agencies, and patient advocacy groups, is essential as we set out on this path. This will help overcome the challenges involved in providing healthcare across borders and realize the full potential of cross-border telemedicine to enhance patient outcomes and revolutionize the delivery of healthcare in Europe by pooling our combined knowledge and dedication.

## 4.1. Next steps for Deliverable 9.2

Deliverable 9.2 will delve deeper into the technical and legal aspects of the proposed solutions and mechanisms outlined in this deliverable. Key focus areas include:

1. **Patient Involvement in Identification and Authentication**: It may be necessary for the identification and authentication processes to occur in a timely coordinated manner between HP and patient, with active patient participation. This could be achieved through mechanisms similar to those used in eGOV services for identity verification and authentication, ensuring adherence to security protocols.
2. **Consent Forms for Data Access**: An alternative approach could involve healthcare providers issuing electronic consent forms under the eIDAS framework, enabling data access without requiring real-time authentication. These forms would provide clear, revocable consent, ensuring that the patient understands who will access their data and for what purpose. Its applicability to additional teleconsultations should also be assessed and compliance with GDPR and data minimization principles is crucial to ensure security and transparency.
3. **Country-Managed Consent Process**: Country-A could manage a consent process where patients authorize cross-border telemedicine services in advance. This could eliminate or complement the need for real-time identification and authentication at the time of the teleconsultation. Such an approach would streamline cross-border healthcare while maintaining compliance with data protection laws.

In all scenarios, particularly for the latter two options, introducing a **notification mechanism** for patients to track who accessed their data and when is essential. This would serve as a safeguard, allowing patients to monitor data access and report any potential unauthorized use. Several countries already employ similar mechanisms at the national level, which could be adapted for cross-border applications.

Such mechanisms can draw inspiration from the projects, mechanisms, and services detailed in the sections below, including the ERNs, and the secure consent frameworks these initiatives employ. These existing solutions provide valuable models for ensuring transparency, security, and patient-centred care in cross-border telemedicine services.

### 4.1.1. Consent form based on the European Reference Networks (ERNs)

The ERNs[79] are virtual networks that bring together health professionals across Europe to tackle rare and complex diseases. ERNs utilize telemedicine tools to facilitate cross-border collaboration and provide patients with access to expert consultations. MyHealth@EU can benefit from the structured consent processes already employed by ERNs, ensuring that patient data is securely shared and that patients are fully informed about data access and their rights to withdraw consent.

A standardized, transparent consent form modelled after ERNs would ensure patient autonomy in cross-border telemedicine services, offering clear information on data use, patient rights, and contact details for further inquiries. This model, combined with strict adherence to GDPR, would create a secure framework for data sharing in telemedicine.

### 4.1.2. Patient identification and authentication for telemedicine services under MyHealth@EU

Ensuring the secure and reliable identification of patients and health professionals is critical for cross-border telemedicine services. Patient identification and authentication mechanisms should be robust and interoperable between different countries' healthcare systems. The existing two-factor authentication protocols, used for securely identifying HP in their local systems, must be reinforced across borders under MyHealth@EU.

The EUDI Wallet[78,] currently under testing, could provide a standardized, interoperable solution for cross-border patient authentication. Patients could use this digital identity to authenticate themselves on healthcare websites or platforms in other EU countries through QR codes or direct attribute sharing with clinical systems, streamlining the process for accessing healthcare services across borders.

### 4.1.3. Expansion of Cross-border healthcare mobility through MyHealth@EU

MyHealth@EU holds the potential to significantly expand and enhance existing cross-border healthcare services across Europe, particularly in relation to healthcare mobility and telemedicine. One key framework already in place, which MyHealth@EU can build upon, is the S2 document[52], a recognized EU mechanism that facilitates cross-border access to healthcare services, enabling patients to seek planned treatment in other Member States. This foundation offers an ideal starting point for implementing telemedicine services that transcend national borders, allowing patients to access specialized care in other countries without physically traveling.

As telemedicine grows in importance, particularly for remote consultations and follow-up treatments, MyHealth@EU can play a central role in ensuring patients are not restricted by borders when seeking the best available care. By

[52] EU standard forms for social security rights [available here]

incorporating frameworks like the S2 document, MyHealth@EU will be able to support a more integrated, efficient, and patient-centred approach to healthcare delivery across the EU.

### 4.1.4. Legal and security considerations

Under GDPR, data processing for healthcare purposes (Article 9(2)(h)) permits sharing health data across borders, provided the necessary safeguards are in place. Cross-border telemedicine services under MyHealth@EU should adhere to data minimization principles, ensuring that only the essential data required for the consultation or treatment is shared. Additionally, the platform must maintain an audit trail, recording who accessed the data and when, ensuring accountability and transparency.

The implementation of secure digital health platforms, encrypted data transmission, and regular audits will be essential to ensure compliance with GDPR's security requirements (Article 32) and to protect patient data from unauthorized access during cross-border telemedicine services. This will promote trust in MyHealth@EU, encouraging wider adoption of its services.

# ANNEXES

## Annex I –MyHealth@EU infrastructure and cross-border telemedicine

The following text provide additional information regarding the state of play of cross-border telemedicine services and the MyHealth@EU infrastructure, supporting the work and objectives of WP9[39].

## MyHealth@EU

MyHealth@EU is an infrastructure for primary use which allows the cross-border exchange of electronic health data, formed by the combination of national contact points for eHealth (NCPeH), and the central platform for digital health. This voluntary infrastructure was established as part of the actions provided for in Article 14 of Directive 2011/24/EU[1]. Through MyHealth@EU, participating countries started to provide patients with the possibility to share their electronic health data with healthcare providers when travelling abroad. In other words, MyHealth@EU emerges as a common infrastructure for the countries to ensure healthcare connectivity and interoperability in an efficient and secure way.

According to Article 23 of the proposed EHDS regulation[2], the Commission shall establish a central platform for digital health to provide services to support and facilitate the exchange of electronic health data between NCPeH of the MS, in this case the MyHealth@EU infrastructure. Each NCPeH shall enable the exchange of the personal electronic health data referred in Article 14 with all other NCPeHs, and this exchange shall be based on the EEHRxF.

In agreement with Article 23 of the proposed EHDS regulation[2], MS may provide through MyHealth@EU supplementary services that facilitate telemedicine services, with a view to achieve a high level of trust and security, enhancing continuity of care and ensuring access to safe and high-quality healthcare. Telemedicine services shall seek to ensure interoperability of MyHealth@EU with technological systems established at international level for the exchange of electronic health data.

## Cross-border Telemedicine

The COVID-19 pandemic exposed the inadequacies and vulnerabilities of delivering healthcare within the eHealth practices, mechanisms, and infrastructures of each country. Telemedicine emerged as a critical service, proving to be an essential need for delivering healthcare remotely to patients during this challenging period. Since then, telemedicine has witnessed consistent global growth at an accelerated pace. In this direction, several initiatives related to the development of telemedicine were launched both internationally and at European level. In addition, telemedicine solutions allow patients in developing countries to collaborate remotely with other clinicians based in more developed nations, promoting the democratization on healthcare[53].

A notable initiative in the context of telemedicine growth in Europe is the Regional Digital Health Action Plan 2023-2030, introduced by the World Health Organisation (WHO) Regional Committee for Europe in 2022[7]. According to this digital health plan, four strategic priorities are identified to enhance digital health. Among these priorities, it is highlighted the enhancement of countries capacities to better govern health digital transformation, and the building of networks and promotion of health knowledge exchange. Regarding the defined priorities, **telemedicine** services are defined as a subset of telehealth which covers the use of technology to deliver health care services at a distance by health professionals using ICT for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, among other examples. Telemedicine can take different forms such as provider-to-provider or provider-to-consumer care and can be synchronous or asynchronous[7]. Telemedicine appears as a potential mechanism to

[53] Saliba, V., Legido-Quigley, H., Hallik, R., Aaviksoo, A., Car, J., & McKee, M. (2012). Telemedicine across borders: a systematic review of factors that hinder or support im plementation. International journal of medical informatics, 81(12), 793-809 [available here]

facilitate knowledge exchange among health professionals from different countries, as well as an important service for evolution of digital health. Further evidence on the growing interest in cross-border telemedicine can be demonstrated by the joint work between the WHO, World Trade Organisation and World Bank that produced a report entitled of "Cross-Border Telehealth Practice: Policy Considerations". This report explores the role that cross-border telehealth plays in a global healthcare delivery, addressing regulatory, ethical, and quality assurance challenges. The document aims to provide guidance for policymakers, healthcare providers, and stakeholders involved in implementing cross-border telehealth services. This report was open to public feedback until April 25th, 2024[54]. In addition, the American Telemedicine Association refers that telehealth is expected to become structurally integrated into national healthcare systems, mentioning its potential to enhance care among the population. Regarding this vision, it is identified as possible barriers the regulatory, fiscal and connectivity to address the access and interoperability of healthcare[55].

From the formalized definition of telemedicine, the transmission of medical data and information through different platforms including text, sound, images or other forms required for the diagnosis or treatment of patients, led to a wide variety of services. Telemedicine services can be delivered through two primary methods: i) store-and-forward and ii) real-time[56]. In the store-and-forward approach, health data is gathered and shared at different times, meaning there is no need for both the patient and healthcare provider to be available simultaneously. In contrast, real-time telemedicine involves live interaction between both parties, allowing them to communicate instantly, even though they are in separate locations[56].

Telemedicine introduces several challenges, especially in cross-border scenarios, such as interoperability concerns, communication difficulties between platforms and healthcare providers, differing policies and practices, lack of reimbursement frameworks, and social or semantic barriers. However, telemedicine also offers numerous benefits that can extend to cross-border healthcare, such as providing access to specialized health professionals for patients in rural areas, reducing waiting times and queues, addressing mobility limitations, and shortening response times. Additionally, it can help manage non-urgent cases more effectively, easing the strain on emergency services.

Telemedicine can be applied to several services including teleconsultation, telepathology, teleradiology, tele-critical care (TCC) and telemonitoring. Each of these services are described below including specific studies conducted on the field and their barriers and enablers.

A study conducted by Khan *et al.* demonstrated the importance of international collaboration between low and high-resources settings for the treatments of patients. With the patient consent, and using **teleconsultation** with anonymised data exchange, a Nigerian clinician responsible for patient care engaged in collaborative consultations with physicians at Queen's Hospital (England). This collaboration aimed to obtain assistance in diagnosing the patient with a complex medical history. The patient exhibited a positive response to the proposed treatment after the diagnosis and surgical intervention. These collaborative types of frameworks have the potential to serve as a model for global health management, effectively addressing escalating healthcare demands while optimizing time and cost efficiency by obviating the necessity for patient and physician to travel[57]. Furthermore, this type of mutual collaboration also promotes the exchange of expertise and knowledge between the healthcare community.

[54] World Health Organization (WHO). Cross-Border Telehealth Practice: Policy Considerations. 2024 [available here]

[55] The ATA and ATA Action's Vision 2030: The Future of Telehealth in the United States [available here]

[56] Real-Time Versus Store-and-Forward Telehealth Technology. AMD Telemedicine [available here]

[57] Khan, Z., Mlawa, G., Yousif, Y., Afghan, A., Balami, D., Mohammed, M., ... & Ibrahim, M. (2022). The future of cross-continental telemedicine in the management of complicated endocrine patients and its suitability based on a case report. Cureus, 14(2) [available here]

Additionally, the design of such frameworks stands to gain potential advantages if structured with a patient-centred approach, potentially fostering patient empowerment[57].

Another study reported cross-border teleconsultations between American doctors and Mexican patients to perform remote mental health evaluations. The findings indicated that teleconsultation allowed to significantly reduce the evaluation time of the patient. However, physicians reported technical difficulties and a decrease capacity for rapport-building[58].

A recent study conducted with the objective of discerning how EU citizens feel regarding the cross-border exchange of health data has revealed that 26.09% of the participants expressed confidence regarding their electronic health data privacy[59,60]. According to several surveys, patients are willing to speak with their doctors via video call as long as their data security is ensured. However, responders indicated certain limitations, such as data protection, insurance coverage, and the inability to provide emergency care[57].

The prominence of **telepathology** projects stems from the logistical advantage of transferring images across borders compared to transporting biological samples, specialists, or patients. This approach not only improves the distribution of pathologist expertise but also creates significant legal issues. Newer platforms to support telepathology have begun using diagnostic viewers, cloud services, open access platforms, plug-in technology, and even mobile cellular devices. In this case, reference centres can digitally transmit scanned slides and have them evaluated by the pathology department[53,61]. An example includes the *Pathologi Oltre Frontiera* (Italy), that established a virtual laboratory for analysing stained histologic preparations. This initiative aimed to address the need for pathologic diagnoses in underdeveloped regions, aiding clinicians in managing patient care effectively. An example of such case occurred at the Mtendere Mission Hospital (Zambia), where surgery samples were processed for microscopic analysis using whole-slide scans. Through a satellite connection, two independent Italian pathologists conducted thorough reviews of the cases remotely. The final diagnoses were then transmitted to medical personnel in Zambia via Internet[62].

One of the primary strengths offered by this type of telemedicine service is the potential to improve operational efficiency. Telepathology reduces time-consuming process of having manually transport of dedicated glass slides via third-party courier services. However, the adoption of explicit and/or implied consent shall be included during telepathology contract negotiations. The negotiations can present a challenge in countries with high rates of illiteracy and limited use of technologies used to share information across borders. These technological limitations imply the delivery of poor local technical support, possible affecting the quality of data, image screens, monitoring and reports[61].

**Teleradiology** stands as the pioneering service within telemedicine, demonstrating efficacy transcending geographical boundaries. Telemedicine facilitates access to radiological services round-the-clock, a capability typically unavailable, thereby optimizing resource utilization. Given the limited operational hours of conventional radiology services, telemedicine enables continuous access, thus enhancing resource efficiency. Teleradiology constitutes a sustainable network, broadening the radiologists' catchment area to improve the use of their expertise during nocturnal and weekend shifts. Its economic viability has been evaluated, fostering collaborative practices among radiologists[60].

[58] Mishori, R., Hampton, K., Habbach, H., Raker, E., Niyogi, A., & Murphey, D. (2021). "Better than having no evaluation done": a pilot project to conduct remote asylum evaluations for clients in a migrant encampment in Mexico. BMC Health Services Research, 21(1), 508 [available here]

[59] Natsiavas, P., Kakalou, C., Votis, K., Tzovaras, D., & Koutkias, V. (2019). Citizen perspectives on cross-border eHealth data exchange: a European survey. In MEDINFO 2019: Health and Wellbeing e-Networks for All (pp. 719-723). IOS Press [available here]

[60] Hosten, N., Rosenberg, B., & Kram, A. (2021, April). Project report on telemedicine: What we learned about the administration and development of a binational digital infrastructure project. In Healthcare (Vol. 9, No. 4, p. 400). MDPI [available here]

[61] Farahani, N., Riben, M., Evans, A. J., & Pantanowitz, L. (2016). International telepathology: Promises and pitfalls. Pathobiology, 83(2-3), 121-126 [available here]

[62] Pagni, F., Bono, F., Di Bella, C., Faravelli, A., & Cappellini, A. (2011). Virtual surgical pathology in underdeveloped countries: The Zambia Project. Archives of pathology & laboratory medicine, 135(2), 215-219 [available here]

The pathway towards establishing reliable teleradiology begins with understanding security and privacy protection principles, regulations, and legislations. The future of pervasive health care entails ensuring that healthcare services are available to anyone, regardless of location, time constraints or any other limitations. In the near future, the emergence of pioneering pervasive radiology applications is anticipated. This means that the next generation of interconnected cross-domain teleradiology will be characterised as being dynamic, mobile, location independent and available from any geographic location. To develop trusted pervasive eHealth and radiology, the first challenge lies in delineating common principles, rules, and services to establish trust within this ubiquitous environment. The second challenge is to define and create a dynamic, context aware, cross-organisational, and cross-border security infrastructure enabling trusted pervasive radiology and other eHealth services[63].

The Eurasian teleradiology program is an ongoing teleradiology program encompassing Europe and Asia, that aims to support medical centres in interpreting high-resolution computed tomography scans, particularly for the presence of Usual Interstitial Pneumonia in suspected Idiopathic Pulmonary Fibrosis cases. This initiative showcases the feasibility of cross-border teleradiology, emphasizing key success factors such as clearly defined responsibilities, efficient communication channels, structured report templates, and adherence to turnaround times. By leveraging these elements, the program facilitates timely and accurate diagnoses, enhancing patient care and management globally[64].

Regarding examples in the domain of **tele-critical care (TCC)**, telemedicine-based critical care solutions, known as "Tele-ICU", are differentiated into centralised and decentralised systems based respectively on the presence or absence of a remotely located hub of intensive care unit (ICU) personnel who receive patient data and oversee care management. Standalone TCC systems, whether centralised or decentralised, have improved access to critical care in underserved populations, albeit with varying effectiveness due to differences in technology platforms, study methodologies, and patient demographics. To address this, a hybrid program was developed for cross-border communities, combining in-person support with a TCC platform. An independent TCC service line was established at a hospital in the United States (ECRMC), while a case-conference-style, educationally focused TCC model was implemented at Mexican hospitals. This program generated synergistic value, as it enhanced collaborative work between border regions[65].

**Telemonitoring** is a telemedicine service aimed to monitoring the health status of patients at distance. This monitoring service allows for individuals to be continuously follow remotely by health professionals. The primary barrier hindering the widespread adoption of telemonitoring is the inability to conduct certain physical examinations and assess vital signs of the patient remotely. By providing patients with equipment such as weight scales, blood pressure monitor, pulse oximeters, and thermometers, this barrier can be partially addressed. Nevertheless, it may not be able to completely address the inability to conduct a physical examination. In addition, satisfaction from patients may be impacted if a telemedicine visit proves inadequate in addressing their concerns. It is essential to consider this constraint when analysing statistics related to telemedicine usage[57,66,67]. Medical providers recognise the potential of telemonitoring to enhance patient-centred care and cost reduction. Nonetheless, it is acknowledgeable the need for

[63] Hetenyi, S., Goelz, L., Boehmcker, A., & Schorlemmer, C. (2022, May). Quality Assurance of a Cross-Border and Sub-Specialized Teleradiology Service. In Healthcare (Vol. 10, No. 6, p. 1001). MDPI [available here]

[64] Weikert, T., Sommer, G., Tamm, M., Haegler, P., Cyriac, J., Sauter, A. W., ... & Bremerich, J. (2019). Centralized expert HRCT Reading in suspected idiopathic pulmonary fibrosis: Experience from an Eurasian teleradiology program. European journal of radiology, 121, 108719 [available here]

[65] Ramnath, V. R., Hill, L., Schultz, J., Mandel, J., Smith, A., Morris, T., ... & Friedman, L. S. (2021). An in-person and telemedicine "hybrid" system to improve cross-border critical care in COVID-19. Annals of global health, 87(1) [available here]

[66] Vegesna, A., Tran, M., Angelaccio, M., & Arcona, S. (2017). Remote patient monitoring via non-invasive digital technologies: a systematic review. Telemedicine and e-Health, 23(1), 3-17 [available here]

[67] Primer, A. Telehealth and remote patient monitoring for long-term and post-acute care: A Primer and Provider Selection Guide 2013 A program of LeadingAge 2519 Connecticut Ave., NW Washington, DC 20008-1520 [available here]

additional training and organisational support to effectively adopt digital capabilities. Healthcare organisations must be adapted with necessary digital skills and integrated technology-enabled solutions with existing care pathways to reduce burden of adaption and promote adoption. Despite the spread development of novel medical devices able to intergrade telemonitoring solutions, the collaboration and resource-sharing between healthcare institutions can help to overcome barriers posed by underfunding, resource scarcity, and technical infrastructure limitations. Additionally, standardisation of vital parameters presents a limitation for cross-border sharing of information that must be addressed. Additionally, insufficient or disrespected standardisation of measured biomedical parameters and communication protocols used by medical devices and telemedicine systems present a limitation for cross-border sharing of information, which should be addressed and requires further study.

The report from the European Funded Telemedicine Projects revealed that the introduction of Electronic Personal Records (EPR) and telemonitoring technologies could facilitate integration between telemedicine and tele-health services. While these technologies fulfil the criteria of remote access and timely delivery, the effectiveness of the overall services offered is heavily influenced by the accessibility and quality of the input data[68].

Regarding the general barriers in telemedicine services, depending on the context and perspective, these features might act as a dual role, underlining the complexity of cross-border telemedicine initiatives, and the need for nuanced approaches to address the challenged effectively. Differences on the health professional licensing systems between nations appear as one of the principal barriers in the use of cross-border telemedicine[69]. Furthermore, there are regulatory and cultural factors that may impact international cooperation on the implementation of telemedicine services. Regulatory issues include that all parties adhere to applicable laws and international General Data Protection Regulation (GDPR), while cultural issues are determined by the language or limited resources[70].

In this way, based on the described telemedicine services, to establish a functional cross-border telemedicine service, it is imperative to delineate several critical elements. Firstly, a robust structure for the telemedicine network must be defined, encompassing technological infrastructure, communication protocols, and participant roles. Subsequently, a detailed business plan should be developed, outlining objectives, strategies, financial projections, and sustainability measures[60]. The services within telemedicine must be carefully planned, considering the differing goals and requirements of stakeholders on each side of the border. Clear goals, outcomes, and key performance indicators should be established to evaluate the effectiveness and impact of the telemedicine service. Additionally, facilitators, such as supportive policies and technological advancements, and barriers, including regulatory constraints and cultural differences, must be identified to anticipate challenges and opportunities.

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# Annex II – Structured Interview template

**CROSS-BORDER TELEMEDICINE**

**INTERVIEW GUIDE**

**Dear participant,**

Your participation in this interview is highly appreciated. Before you begin, please read the information below, and make sure you understand the terms of this interview.

**Interview purpose**

You have been invited to participate in this interview as you are considered a national telemedicine expert.

This interview aims to identify and collect **priority use cases in cross-border telemedicine services** that could be uptake by the existing **MyHealth@EU** infrastructure from the perspective of professionals who work with telemedicine on a regular basis. In line with the European Health Data Space (EHDS) proposal, this interview is a component of the Xt-EHR joint action and takes place in the framework of Telemedicine under MyHealth@EU.

The results from this interview will be incorporated into the deliverable D9.1 - Guidelines and use cases on the availability of health data in cross-border telemedicine services.

- **Joint Action 09: Xt-EHR - Extended EHR@EU Data Space for Primary Use**

The **Xt-EHR joint action** aims to build the foundations for improving the primary use of electronic health data, as targeted in the proposed EHDS regulation. Xt-EHR will contribute to the development of **technical specifications and guidelines** for the future implementing acts provided for the proposed **EHDS regulation**. These recommendations will be important for laying the foundations for the development of existing cross-border digital health services and making available the basis for sharing and accessing data relating to different health domains such as ePrescription, eDispensation and Patient Summary, Discharge Reports; Medical test results, including laboratory and other diagnostic results and related reports; and Medical Imaging studies and related imaging reports, as well as the development of cross-border services in the field of telemedicine.
**Work Package 9** will focus on developing the **groundwork for the implementation of cross-border telemedicine services under MyHealth@EU**. This will be done by i) Defining use cases and business requirements to be uptake by MyHealth@EU as supplementary services under Article 24 of the EHDS regulation proposal; ii) Preparing requirements and technical specifications on cross-border telemedicine services to achieve interoperability between telemedicine software and taking into consideration the inclusion of the domain into MyHealth@EU infrastructure and iii) Preparing guidelines on large Scale Uptake of Telemedicine Services.

- **MyHealth@EU**

MyHealth@EU services allow Member States citizens to have access to healthcare when traveling to other European countries, under conditions similar to those in their home country without having to worry about the language barrier, by supporting data exchange in a secure and interoperable way.

These services allow healthcare professionals in the destination country to access basic and essential information through the **Patient Summary**, which, in critical situations, will be essential. On the other hand, the **Electronic Prescription and Dispensation** services of MyHealth@EU enable a dispensation in a pharmacy from participating Member State – destination country – without having to present a paper prescription.

**Consent**

The information submitted will be kept on the SharePoint of the joint action which is under the responsibility of the coordinator of the project (National eHealth Authority, Cyprus), however your name or any other information that may identify you individually will not be disclosed on D9.1 deliverable. The data collected will not be used for commercial or other purposes unrelated to the research.
If you have **any questions,** please contact laura.rocha.ext@spms.min-saude.pt (responsible for overall coordination of Cross-border Telemedicine Interviews).

If you choose to take part in this interview, you are granting your consent to processing the following data:

- Contact information: your name, email address, professional role and organisation of employment.
- Answers provided during the interview.

This information will be used to organize the answers provided in the questionnaire to allow its analysis. If further follow-up is needed your contact data will be used to invite you to answer further questions. You may at any time decline to answer such questions and to ask us to stop contacting you.

We will audio or video record the interview and retain the chat in order to transcript the session. The opinion data you provide through this interview will be kept confidential, only accessed within the context of this project. The results from this interview will be published in D9.1, and your name or any other information that may identify you individually will not be disclosed.

**Identification**

Please feel free to share this document with other relevant experts in your country and indicate it in the table below.

| Country | Name | E-mail | Institution Organisation | Professional Role |
|---|---|---|---|---|
| | | | | |

**Interview structure**

## Section I - Healthcare mobility

1. **Are you aware of any cross-border healthcare initiatives within your country, such as patient mobility to another country to receive treatment?**

   Yes/No

1.1. If yes, could you describe such initiatives?

1.2. In your views, could cross-border telemedicine under MyHealth@EU support such services?

## Section II – Cross-border telemedicine

2. **Are you aware of any cross-border telemedicine initiatives in your country or other countries?**

   Yes/ No

2.1. If yes, please describe such initiatives.

2.2. If yes, which services? Are they already implemented or planned?

2.3. If not, have you ever considered the possibility of cross-border telemedicine initiatives?

2.4. Considering the existing telemedicine services in your country, in your opinion could these services be incorporated into MyHealth@EU in the future? What would be the added value?

2.4.1. What should be the priority use cases?

2.4.2. What will be the main requirements for such integration?

## Section III – Identification of possible requirements for cross-border telemedicine services under MyHealth@EU

3. **In your view, what will be the main requirements for a successful implementation of telemedicine services within MyHealth@EU? The idea here is to capture important requirements that should be taken into consideration for setting up such services, including possible enablers and barriers.**

## Section IV – Conclusion

4. **Are you interested in participating in additional interviews regarding this topic?**

Yes / No / Maybe

5. **Would you be interested in participating in future workshops, meetings, or activities regarding cross-border telemedicine under MyHealth@EU?**

Yes / No / Maybe

Thank you for sharing your experiences. If there's anything you'd like to add or question, feel free to do so.

After this interview, we will send by email the summary of the interview for your revision and validation.

## Annex III – Telemedicine interview analysis

To recruit possible interview participants, an email containing the description and objectives of the joint action Xt-EHR, along with the interview proposal, was sent to six telemedicine experts and one telemedicine organisation. Five responses were received from the candidates, in which four of them agreed to take part in the interview.

Four interviews were conducted with experts from Portugal, Belgium, and the Czech Republic. These included a telemedicine expert experienced in managing a national telehealth centre, a neurologist familiar with telemedicine tools, a representative from an international telemedicine association, and a senior expert from the Ministry of Health of an EU-Member State.

From the analysis of the interviews, it is evident that there is a common agreement regarding the role of telemedicine in facilitating remote access to medical services, extending beyond physicians to include various health professionals.

Additionally, interviewees highlighted that important health information about the patient may emerge during the teleconsultation and should be communicated back to the patient's country of affiliation. Initiatives like MyHealth@EU aim to enhance healthcare services by providing comprehensive clinical and digital solutions. Telemonitoring, for example, was stated as a solution to bridge the gap between in-person care and self-care, offering promising outcomes for healthcare improvement. Additionally, for national settings, continuous patient monitoring, particularly in cardiovascular interventions, has become feasible with telemedicine, allowing patients to recover at home while being monitored remotely. Interviewees believe that continuous patient monitoring through telemonitoring would be a good addition to incorporate in cross-border telemedicine under MyHealth@EU.

Based on the analysis of the interviews, a summary of the key discussion points and ideas from all the interviewees was compiled. The main findings are outlined below:

- **Cross-Border Telemedicine:** Cross-border healthcare initiatives are underway, such as cross-border medical collaboration and seeking operation procedures across borders, allowing patients to receive treatment in neighbouring countries. Telemedicine facilitates remote consultations, enabling access to specialist care without the need for travel. Efforts to establish common standards and protocols for telemedicine practices are essential for seamless exchange of patient information and coordination of care across borders. Currently, there are already some telemedicine programs in place that allow for collaboration among health professionals from different countries, facilitated through teleconsultation, enhancing patient care through knowledge sharing and expertise exchange.

- **Identification of Possible Requirements for Cross-Border Telemedicine under MyHealth@EU (Barriers and Enablers):** Integrating telemedicine into cross-border healthcare initiatives offers numerous benefits, including improved access, efficiency, and quality of care for patients. Regulatory frameworks like the ones provided by MyHealth@EU play a crucial role in facilitating this integration by providing a clear framework for quality assurance. However, several key requirements must be addressed, including reimbursement, licensure, interoperability and secure data exchange, streamlined clinical guidelines, certification and accreditation, and professional training and education. Barriers such as insecurity regarding the quality of telehealth services and licensing requirements for healthcare providers practicing across borders need to be overcome to ensure successful implementation of cross-border telemedicine.

In summary, all interviews emphasize the crucial role of telemedicine in enhancing healthcare accessibility and quality, particularly in cross-border scenarios. Each interview discussed the challenges and requirements associated with cross-border telemedicine, such as interoperability, clinical guidelines, certification, and professional training. There was a common consensus regarding the benefits of integrating telemedicine into cross-border healthcare initiatives, including improved access to care, cost savings, and collaboration among health professionals. Importantly, the interviews also highlighted that teleconsultations should be considered equal to in-person health encounters in terms of value and effectiveness. Being that both modalities are to be viewed with the same level of importance and credibility within the healthcare system, and therefore same principles should be applicable.

These common themes underscore the importance of telemedicine in advancing cross-border healthcare and the need for collaborative efforts to address challenges and requirements for its successful implementation.

# Annex IV – Survey template

## Cross-Border Telemedicine

This questionnaire **"Cross-border Telemedicine"** was designed within the scope of the joint action Xt-EHR - *The Extended Electronic Health Record* that aims to build the foundations for improving the primary use of electronic health data, as targeted in the proposed **European Health Data Space (EHDS)** regulation. Xt-EHR will contribute to the development of **technical specifications and guidelines** for the future implementing acts as expected in the proposed EHDS regulation. These recommendations will be important for laying the foundations for the development of existing cross-border digital health services and making available the basis for sharing and accessing data relating to different health domains such as ePrescription, eDispensation and Patient Summary, Laboratory Results, Discharge Reports and Medical Images and Reports, as well as the development of cross-border services in the field of telemedicine, among other activities.

**Work Package 9** will focus on developing the **groundwork for the implementation of cross-border telemedicine services under MyHealth@EU**. This will be done by i) Defining use cases and business requirements to be uptake by MyHealth@EU as supplementary services under Article 24 of the EHDS regulation proposal; ii) Preparing requirements and technical specifications on cross-border telemedicine services to achieve interoperability between telemedicine software and taking into consideration the inclusion of the domain into MyHealth@EU infrastructure and iii) Preparing guidelines on large Scale Uptake of Telemedicine Services.

**MyHealth@EU** services allow Member States citizens to have access to healthcare when traveling to other European countries, under conditions similar to those in their home country without having to worry about the language barrier, by supporting data exchange in a secure and interoperable way.

If you're not familiar with the MyHealth@EU infrastructure you can find more information .

**The results of this questionnaire** will be incorporated into the deliverable D9.1 - *Requirements and use cases on the availability of health data in cross-border telemedicine services*. The information submitted will be kept on the SharePoint of the joint action which is under the responsibility of the coordinator of the project (National eHealth Authority, Cyprus), however your name or any other information that may identify you individually will not be disclosed on D9.1.

### Purpose

The primary objective of this questionnaire is to identify and collect **priority use cases related to cross-border telemedicine services** that could be uptake by the existing **MyHealth@EU** infrastructure from the perspective of professionals who work with telemedicine on a regular basis. In line with the EHDS, this questionnaire is a component of the Xt-EHR joint action and takes place in the framework of telemedicine under MyHealth@EU of WP9.

### Instructions

This survey comprises 23 questions. You'll encounter various question formats:

- Multiple-choice questions: select all applicable options.
- Open-ended responses: provide detailed insights or explanations.

**The estimated completion time is 5-10 minutes.**

**Thank you for your collaboration in completing this questionnaire.**

The data collected will not be used for commercial or other purposes unrelated to the Xt-EHR project. **Data will be analysed for deliverable 9.1 and participants names will not be disclosed in this deliverable.**

The submission of this questionnaire consents to the use of this information for the purpose mentioned above

**General Information**

| | |
|---|---|
| **Name** | * |
| **Email** | * |
| **Position** | * |
| **Country** | * |
| **Institution/Organisation** | * |

***Obligatory fulfilment**

**Section I – Healthcare mobility**

In this section, we aim to explore the possible utility of telemedicine services in patient mobility initiatives across countries, such as patient mobility to receive specialized care in another country.

1. **Are you aware of any cross-border healthcare initiatives within your country, such as patient mobility?**
    - Yes
    - No
    - I don't know

**1.1. If you answered yes in Question 1, could you please describe such initiatives? If possible, please provide useful references or links.**

**1.2. In your view, could cross-border telemedicine services under MyHealth@EU support such services?**

- Yes
- No
- I don't know
- Other:_____

**1.3. If you answered yes, please explain how cross-border telemedicine services under MyHealth@EU could support such services.**

**Section II – Cross-border telemedicine**

In this section, we aim to explore cross-border telemedicine initiatives, as well as identify priority use cases / scenarios that could be incorporated into the MyHealth@EU infrastructure.

**2. Are you aware of any cross-border telemedicine initiatives in your county or other countries?**

- Yes
- No
- I don't know

**2.1. If yes, which services?**

- Teleconsultation
- Telemonitoring
- Teletriage
- Telerehabilitation
- Other:_____

**2.2. If yes, please describe such initiatives. If possible, please provide useful references or links.**

**2.3. Are those initiatives already implemented or planned?**

- Planned
- In pilot / local tests
- Fully implemented
- Other:_____

2.4. Do you see value in the deployment of cross-border telemedicine approaches for your country / region / institution?

- Yes
- No
- I don't know

2.5. **Considering the existing telemedicine services in your country, in your opinion could these services be** incorporated into MyHealth@EU in the future?

- Yes
- No
- I don't know

**2.5.1. What would be the added value?**

- Expand access to health care
- Reduction of geographic barriers
- Improving the efficiency of health services
- Cost Savings for patients
- Support for rapid diagnosis and treatments
- Strengthening cross-border cooperation
- Improving response to emergencies disasters
- Other:____

**2.5.2. Taking into account those telemedicine services, what would be the priority use cases/scenarios to be integrated into MyHealth@EU?**

**2.5.3. What will be the main requirements for such integration?**

- Interoperability requirements
- Legal requirements
- Security and data protection requirements
- Technical requirements
- Performance requirements
- Training and support requirements
- Accessibility requirements
- Audit and compliance requirements
- Other:____

**Section III - Identification of possible requirements for cross-border telemedicine under MyHealth@EU**

In this section, we seek to identify possible requirements for cross-border telemedicine under the MyHealth@EU infrastructure, in order to guarantee the effectiveness, safety and accessibility of digital health services across the European Union.

3. **In your view, what will be the main enablers for a successful implementation of telemedicine services within MyHealth@EU? The idea here is to capture important enablers that should be taken into consideration for setting up such services.**
   - Specific regulation framework
   - Clear and transparent reimbursement rules
   - Data security and privacy
   - A mechanism for identification and authentication of healthcare professionals and healthcare institutions in other nations
   - Guidance for telemedicine services provision in a cross-border context
   - Interoperability, common standards
   - Trust and secure communication infrastructure for telemedicine
   - Data quality
   - Education, training and awareness initiatives
   - Mechanisms for assessing and guaranteeing the quality of cross-border telemedicine services
   - Telemedicine systems as medical devices and their interoperability with EHR systems
   - Common technical specifications, standards, and profiles for the exchange of electronic health data
   - Other: ____

4. **In your view, what will be the main barriers for a successful implementation of telemedicine services within MyHealth@EU? The idea here is to capture important barriers that should be taken into consideration for setting up such services.**
   - Regulatory differences between Member States

- Lack of conditions in the national infrastructure for telemedicine provisioning, particularly for cross-border services
- Lack of interoperability of devices used in telemedicine services
- Lack of certification of telemedicine systems
- Language and cultural barriers
- Differences in clinical protocols and medical guidelines with respect to the use of telemedicine
- Lack of access to technological infrastructure
- Non-existence of mechanisms to ensure that telemedicine services are easy to use, accessible to different groups of persons and health professionals, including citizens with disabilities
- Lack of interoperability with EHR systems at the national/regional/local levels
- Other:_____

**Section IV – Conclusion**

5. **Are you interested in participating in additional interviews regarding this topic**
   - Yes
   - No

6. **Would you be interested in participating in future workshops, meeting or activities regarding cross-border telemedicine under MyHealth@EU?**
   - Yes
   - No

7. **Thank you for sharing your experiences. If there is anything you would like to add or question, feel free to do so.**

# Annex V - Cross-border telemedicine survey analysis

The cross-border telemedicine survey gathered responses from 31 participants representing various positions and institutions across multiple countries. The participants included experts from positions such as CEO, Chief Medical Innovation Officer, EU Policy Advisor, Function Manager, IT Architect, PhD Doctor, Dermatologist, Standards Engineer, Business Development Manager, and General Practitioner. These experts hailed from countries including Austria, Belgium, Czech Republic, Estonia, Hungary, Italy, Nigeria, Spain, and the United States.

The summary of the key findings is presented below.

## I. Section I – Healthcare Mobility

Approximately 51.6% of participants indicated awareness of cross-border healthcare initiatives within their countries (Figure 2). These initiatives include: the cross-border effectiveness of patient summaries, electronic prescriptions, and dispensations; the EU Digital COVID Certificate; social security refunding in hospitals, and cross-border health support provision.

Furthermore, 83.9% of participants indicated that in their point of view, the cross-border telemedicine services could be supported under MyHealth@EU (Figure 3); while the remaining percentage were uncertain or did not have enough information to provide a definitive answer. This high percentage of participants that believe that cross-border telemedicine services could be supported under MyHealth@EU indicates a positive outlook for the integration and development of telemedicine services within MyHealth@EU framework. Despite of this positive indication, it is important to highlight the non-complete representation of all MS of EU within the respondents.

Participants who supported the idea of cross-border telemedicine services under MyHealth@EU outlined the following benefits:

- Improvement of access to specialists, allowing patients to receive care for rare or complex conditions, whose services are not available in their home country;
- Continuity of care for travellers and immigrants within the EU, ensuring continue receiving care from their home country's healthcare providers, and reducing the need for patients to navigate through unfamiliar healthcare systems;
- Patient empowerment and engagement throughout telemedicine services, leading to better health outcomes;
- Support in public health monitoring and response, aiding in cross-border coordination of care during health crises;
- Data integration, allowing doctors to access the patient's full medical history, leading to more informed decision-making and personalized care;
- EU regulations could develop guidelines to facilitate the implementation and interoperability of telemedicine solutions.

No barriers regarding the implementation or guidelines of cross-border telemedicine services were requested in the survey at this stage.

## II. Section II – Cross-border Telemedicine

Regarding telemedicine initiatives, 45.2% of respondents indicated awareness of various services, including: teleconsultation, telemonitoring, teletriage, telerehabilitation, tele-assistance, shared access to patient records, tele-expertise, and prescriptions (Figure 4). Teleconsultation emerged as the most recognized, followed by telemonitoring and telerehabilitation (Figure 5).

Participants highlighted several key telemedicine initiatives, delineating a few examples as follows:

- Telemedicine and telemonitoring services for chronic disease management, allowing a broader application of telemedicine in promoting proactive health management;
- The integration of eHealth platforms within national and cross-border healthcare projects, underscoring the collaborative nature of telemedicine within healthcare framework;
- The use of mobile devices in healthcare delivery, as seen in projects like MobiHealth[71], reflecting the shift towards patient-centred care models;
- Expert consultations for complex diseases, highlighting the role of telemedicine in facilitating access to specialized medical expertise;
- The incorporation of telemedicine within Doctors Without Borders (*Médecins Sans Frontières*), highlighting its transformative role in extending healthcare services to underserved communities globally.

In response to "if these initiatives were already implemented or planned", 50% of respondents indicated that were fully implemented, while 35.7% reported were in pilot or local testing phases (Figure 6). A significant majority (96.8%) expressed a positive outlook towards adopting cross-border telemedicine strategies in their home countries (Figure 7). Additionally, 77.4% expressed confidence in integrating their existing telemedicine services into the MyHealth@EU platform (Figure 8), while the remaining participants did not know. The perceived benefits of the integration of telemedicine within MyHealth@EU, highlighted by the participants, include improving service efficiency, expanding healthcare access, supporting rapid diagnosis and treatments, reducing geographical barriers, strengthening cross-border cooperation, cost-saving for patients, and enhancing emergency response capabilities (as observed in Figure 8).

Delineated priority use cases for telemedicine under MyHealth@EU include teleconsultation and telemonitoring for managing various health concerns, expanding limited healthcare capacity, doctor-to-doctor cross-border consultations, and the cross-border exchange of health data. These use cases underscore the diverse range of healthcare scenarios where MyHealth@EU could be leveraged to support telemedicine services with the aim of improving patient outcomes and healthcare delivery.

### III. Section III – Requirements for Cross-border Telemedicine

Participants identified crucial requirements for integrating telemedicine under MyHealth@EU. The most important enablers identified were (Figure 9):

2. Ensuring interoperability and common standards for effective data exchange across different healthcare systems;
3. Establishing a reliable mechanism for identifying and authenticating health professionals and institutions across national borders – essential for trust and accountability;
4. Protecting patient data from unauthorized access and breaches – crucial for maintaining confidentiality;

[71] MobiHealth [website available here]

5. Providing comprehensive education, training, and awareness programs for health professionals and patients – vital for promoting the understanding and utilization of telemedicine technologies;
6. Standardizing technical specifications and profiles for exchanging electronic health data – enhancing interoperability;
7. Clear and transparent reimbursement rules for telemedicine services – ensuring financial sustainability;
8. Developing a specific regulatory framework for telemedicine – providing clarity on legal and ethical considerations;
9. Maintaining high standards of data quality – essential for accurate diagnosis and treatment;
10. Recognizing telemedicine systems as medical devices and ensuring their interoperability with EHR systems – enhancing their reliability;
11. Providing guidance for telemedicine service provision in a cross-border context – facilitating international collaboration;
12. Establishing mechanisms for assessing and guaranteeing the quality of telemedicine services – ensuring safe and effective care.

Participants also identified several key barriers to the successful implementation of telemedicine services within MyHealth@EU (Figure 10). The most highlighted barriers were:

1. Absence of mutual recognition of prescriptions and reimbursements among countries, which hinders seamless access to healthcare services;
2. Inadequate education and training programs for health professionals, that could possibly disrupt the effective utilization of telemedicine technologies;
3. Limited access to technological infrastructure, including digital infrastructure and necessary devices, which poses a significant barrier;
4. The absence of formal certification mechanisms for telemedicine systems, consequently raising concerns about quality assurance;
5. Ensuring user-friendly and accessible telemedicine services for diverse groups, including those with disabilities, which can be challenging;
6. Language and cultural barriers within the EU present significant obstacles to effective communication and access to services;
7. Insufficient national infrastructure for telemedicine provision impacts accessibility and quality of care;
8. Interoperability issues related to devices and systems, as well as differences in clinical protocols and guidelines across Member States, present challenges to standardized telemedicine practices;
9. Regulatory differences among Member States create complexity and uncertainty regarding compliance with legal requirements.

Elaborating plans to address these concerns are of most importance to the successful implementation of telemedicine services under MyHealth@EU.

## IV. Section IV – Conclusion

In sum, this survey highlights the strong support for integrating telemedicine services within the MyHealth@EU framework, the perceived benefits, and the significant challenges and requirements for the successful implementation. The diverse insights provided by participants emphasize the need for collaborative approaches, technological innovation, cultural sensitivity, and strategic planning to realize the full potential of telemedicine in improving healthcare delivery across Europe.

## Full Analysis

To complement the interviews, a specific survey was designed to capture a broader range of responses and enhance the overall knowledge base for this work (and can be found in Annex IV – Survey template). This 'Cross-border Telemedicine' survey primary objective was to gather insights from telemedicine professionals and experts regarding priority use cases for cross-border telemedicine within the MyHealth@EU infrastructure. The survey consisted of 23 questions, including both multiple-choice and open-ended formats, with an estimated completion time between 5 to 10 minutes. The survey gathered responses from 31 participants representing different roles and institutions across multiple countries, including Austria, Belgium, Czech Republic, Estonia, Hungary, Italy, Nigeria, Spain, and the United States. In order to obtain a structured comprehensive analysis, the survey was divided into four distinct sections:

### I. Section I – Healthcare mobility

Based on the responses from Section 1 of the survey showed inAnnex IV – Survey template, approximately 51.6% of participants indicated that they were aware of cross-border healthcare initiatives within their countries (Figure 2).

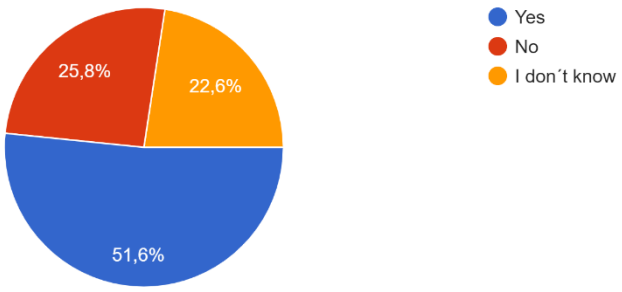



**Figure 2.** Question 1 - Are you aware of any cross-border healthcare initiatives within your country, such as patient mobility?

The initiatives in cross-border healthcare include the cross-border validity of drug prescriptions, the EU Digital COVID Certificate, electronic prescriptions, patient summaries as part of the MyHealth@EU infrastructure development, social security refunding in hospitals, and the availability of cross-border health support provision.

Additionally, as depicted in Figure 3, approximately 83.9% of participants, revealed that in their point of view, cross-border telemedicine services can be supported under MyHealth@EU.

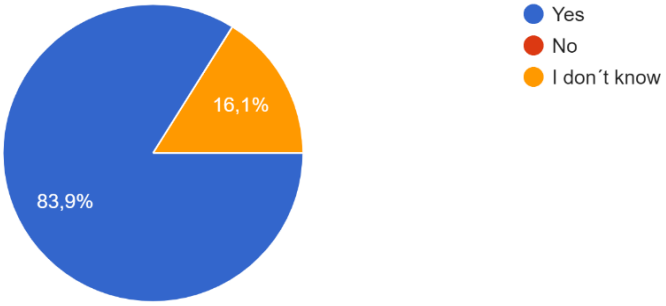



**Figure 3.** Question 1.2 - In your view, could cross-border telemedicine services under MyHealth@EU support such services?

These findings suggest a considerable level of awareness and support for cross-border healthcare initiatives, including telemedicine services, among the participants surveyed. This indicates a positive outlook for the potential integration and development of telemedicine services within the MyHealth@EU framework.

Participants who responded positively outlined various ways in which cross-border telemedicine services could be supported under MyHealth@EU. These include:

- **Improved Access to Specialists:** Patients would have easier access to specialists who may not be available in their home country, particularly beneficial for rare or complex conditions requiring specialized care.
- **Continuity of Care for Travelers and Expats:** Individuals traveling or living abroad within the EU could continue receiving care from their home country's healthcare providers, ensuring continuity of care and reducing the need for patients to navigate unfamiliar healthcare systems.
- **Enhanced Patient Empowerment and Engagement**: MyHealth@EU could empower patients to take an active role in their healthcare by facilitating easier access to services and information, leading to better health outcomes.
- **Support for Public Health Monitoring and Response**: Telemedicine services could aid in monitoring and responding to public health crises by enabling cross-border coordination of care and swift sharing of critical information.
- **Data Integration and Patient Records:** MyHealth@EU could facilitate the integration of patient data across borders, ensuring doctors have access to a patient's full medical history, including the Patient summary and ePrescriptions, regardless of where care is provided, leading to more informed decision-making and personalized care plans.
- **EU regulations:** MyHealth@EU regulatory frameworks could aid in the development of guidelines to facilitate the implementation, integration, and interoperability of telemedicine solutions into existing healthcare systems.

## II. Section II – Cross-border telemedicine

Regarding telemedicine initiatives, as demonstrated by Figure 4, 45.2% of respondents indicated awareness of various telemedicine services.

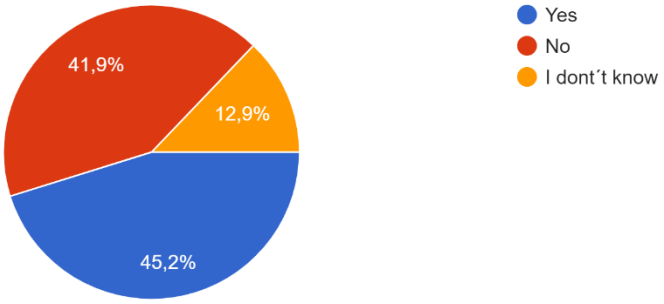



**Figure 4.** Question 2 - Are you aware of any cross-border telemedicine initiatives in your country or other countries?

Such telemedicine initiatives described by the participants include: Teleconsultation, Telemonitoring, Teletriage, Telerehabilitation, Tele-assistance, Shared Access to Patient Records, Tele-expertise, and Prescriptions. As depicted in Figure 5, Teleconsultation emerged as the most recognized, followed by Telemonitoring and Telerehabilitation.

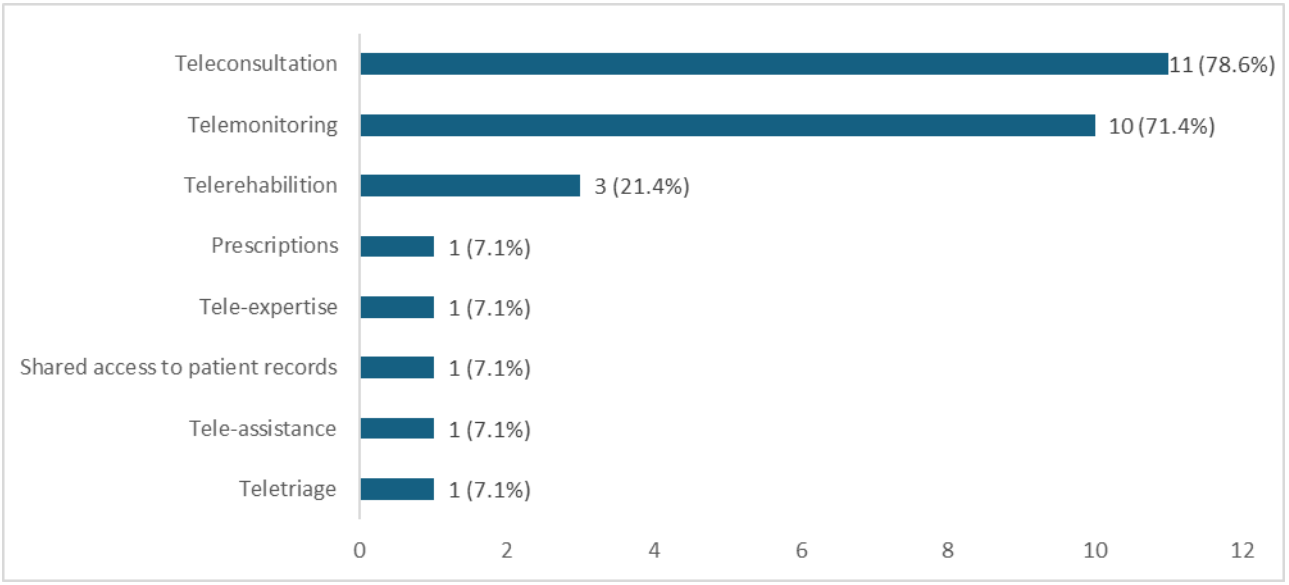



**Figure 5.** Question 2.1 – If yes, which services?

The telemedicine initiatives described by the participants were:

1. **Studies in Chronic Leg Ulcers:** Participants highlighted ongoing studies focusing on chronic leg ulcers, indicating a targeted approach to addressing specific medical conditions through telemedicine. This suggests a growing interest in utilizing telemedicine for specialized medical research and treatment.
2. **Emergency Telemedicine Networks:** The establishment of emergency telemedicine networks between major cities and smaller hospitals' emergency departments demonstrates a strategic effort to improve access to critical healthcare services, especially in remote or underserved areas. This

initiative aims to enhance emergency medical response and support smaller healthcare facilities with expert consultations.

3. **New Digital Model for Italian Integrated Home Care:** The description of a digital model for Italian Integrated Home Care emphasizes the potential benefits of enhanced coordination, improved access to healthcare services, and personalized care plans. However, the identification of barriers such as the digital divide, privacy concerns, and technical challenges highlights the importance of addressing these issues for successful implementation[72].
4. **Telemedicine and Telemonitoring Services for Chronic Disease Management:** Participants mentioned telemedicine and telemonitoring services as integral components of chronic disease management programs. This indicates a broader application of telemedicine beyond acute care, emphasizing its role in promoting proactive health management and long-term patient wellness.
5. **eHealth Platforms:** The integration of eHealth platforms underscores the collaborative nature of telemedicine initiatives within healthcare networks. By connecting various healthcare providers and services, these platforms facilitate comprehensive medical care delivery and streamline communication and data sharing among stakeholders[73,74,75,76].
6. **Use of Mobile Devices in Healthcare Delivery:** The utilization of mobile devices in healthcare delivery, exemplified by projects like MobiHealth[71], signifies the growing adoption of digital technology to enhance accessibility and efficiency in healthcare services. This type of initiatives reflects a shift towards patient-centred care models and emphasizes the importance of leveraging mobile technology to empower patients and improve health outcomes.
7. **Expert Consultations for Complex Diseases:** Expert consultations for complex patient diseases highlight the role of telemedicine in facilitating access to specialized medical expertise, regardless of geographical constraints. These initiatives aim to bridge healthcare gaps by enabling remote consultations and collaboration among healthcare professionals.
8. **Telemedical Integrated German-Polish Children's Cancer Centre:** The initiative to establish a telemedical integrated children's cancer centre across the German-Polish border showcases the potential of telemedicine to transcend national boundaries and improve access to specialized care for paediatric cancer patients. This project emphasizes collaboration between healthcare institutions and the use of telemedicine technology to ensure timely diagnosis, treatment, and ongoing care.
9. **Telemedicine in *Médecins Sans Frontières* (MSF):** The incorporation of telemedicine within *Médecins Sans Frontières* (MSF) highlights its transformative role in extending healthcare services to underserved communities globally. By leveraging digital technology, MSF aims to overcome logistical barriers and connect healthcare professionals worldwide, thereby enhancing access to quality medical care in remote or crisis-affected areas[77].

In summary, the survey responses underscore the diverse applications and initiatives of cross-border telemedicine initiatives, ranging from specialized medical research and emergency response to chronic disease management and global healthcare outreach. However, challenges such as digital divide, privacy

[72] Cascini, F., Gentili, A., Melnyk, A., Beccia, F., Causio, F. A., Solimene, V., ... & Ricciardi, W. (2023). A new digital model for the Italian Integrated Home Care: strengths, barriers, and future implications. Frontiers in Public Health, 11, 1292442 [available here]

[73] eHealth (French Platform) [available here]

[74] Réseau Santé Wallon [website available here]

[75] MaSanté [website available here]

[76] NetDoktor [website available here]

[77] Medecins Sans Frontieres – Telemedicine [website available here]

concerns, and regulatory hurdles need to be addressed to maximize the effectiveness and sustainability of these initiatives.

In response to the outlined initiatives, participants were asked whether these initiatives were already operational or in the planning phase. As illustrated in Figure 6, the survey revealed that 50% of respondents indicated full implementation, while 35.7% reported that the initiatives were undergoing pilot or local testing phases.

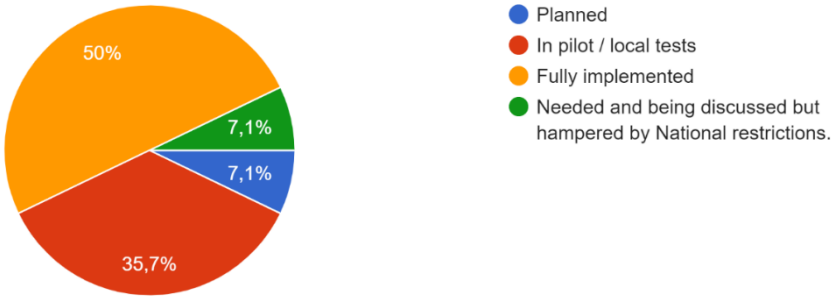



**Figure 6.** Question 2.3 - Are those initiatives already implemented or planned?

Furthermore, as seen in Figure 7, a significant majority, comprising 96.8% of participants, expressed a positive outlook towards the adoption of cross-border telemedicine strategies within their respective countries, regions, or institutions. This overwhelming support underscores the perceived benefits and potential impact of cross-border telemedicine approaches.

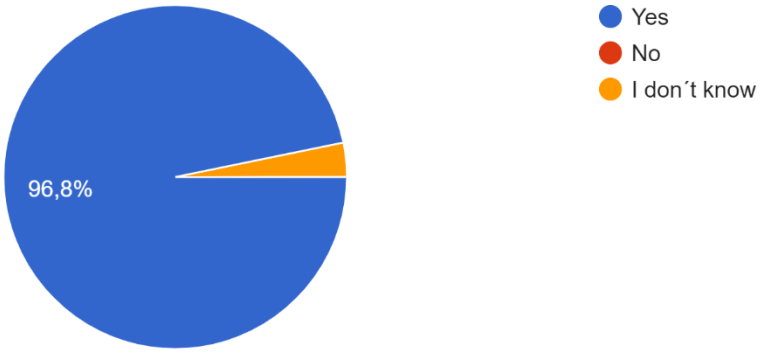



**Figure 7.** Question 2.4 - Do you see value in the deployment of cross-border telemedicine approaches for your country/region/institution?

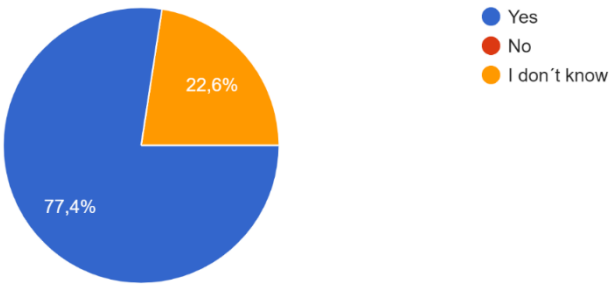



**Figure 8.** Question 2.5 - Considering the existing telemedicine services in your country, in your opinion could these services be incorporated into MyHealth@EU in the future?

Moreover, a substantial portion of respondents, totalling 77.4%, expressed confidence in the possibility of integrating their existing telemedicine services into the MyHealth@EU platform in the future (Figure 8). This reflects a recognition of the value and feasibility of leveraging MyHealth@EU as a platform for consolidating and enhancing telemedicine services on a broader scale.

When participants were asked about the added value of telemedicine under MyHealth@EU, the following results emerged as the most favoured, as depicted on Figure 8.

These selected options highlight the multifaceted benefits that telemedicine integration within MyHealth@EU could offer, ranging from operational efficiencies to improved healthcare accessibility and emergency response capabilities.

Additionally, participants identified priority use cases for telemedicine within the MyHealth@EU framework, participants included:

- Teleconsultation and telemonitoring for managing various health concerns, including allergies, blood type data, eye exams, heart monitoring, glucose levels, blood pressure, chronic, mental health and lifestyle-related diseases, and related preventative measures.
- Expansion of limited healthcare capacity within the country.
- Doctor-to-doctor cross-border consultation for diagnosis and treatment options discussion.

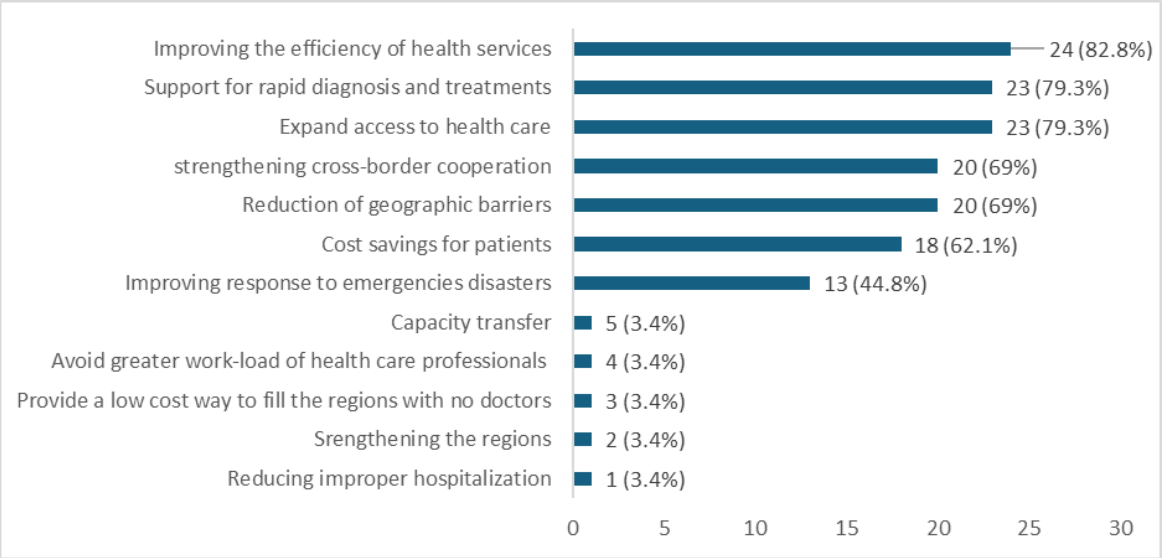



**Figure 8.** Question 2.5.1 - What would be the added value?

- Cross-border exchange of health data, such has the patient summary, prescriptions, lab reports and imaging information.

These priority use cases underscore the diverse range of healthcare scenarios where telemedicine can play a pivotal role in improving patient outcomes, healthcare delivery, and overall system efficiency within the MyHealth@EU framework.

The analysis of the survey data sheds light on the critical requirements identified by respondents regarding the integration of telemedicine within the MyHealth@EU framework. These requirements are outlined below in descending order of importance, as per the preferences of the participants, outlined in Figure 9.

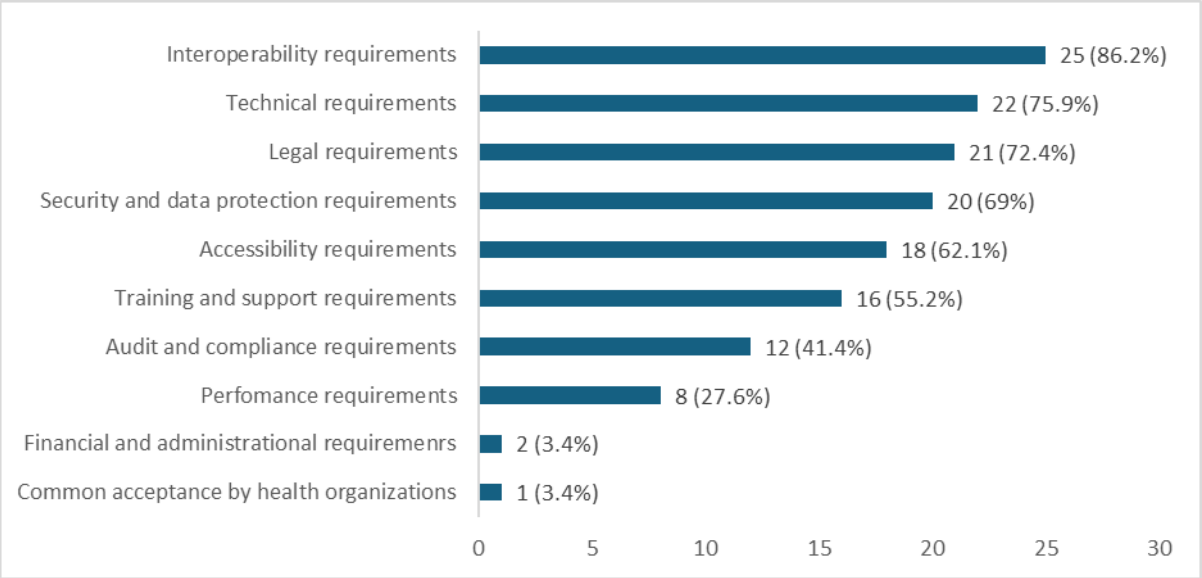



**Figure 9.** Question 2.5.3 - What will be the main requirements for such integration?

From each requirement outlined in the survey, the participants have mentioned:

1. **Interoperability Requirements:** Participants highlighted the need for seamless interoperability between different healthcare systems and technologies to ensure effective data exchange and communication.
2. **Technical Requirements:** This encompasses the technical specifications and capabilities necessary to support telemedicine services effectively, including network infrastructure, software platforms, and hardware devices.
3. **Legal Requirements:** The legal framework governing telemedicine practices, including regulations related to patient privacy, data protection, liability, and licensing requirements for healthcare professionals.
4. **Security Data Protection Requirements:** Ensuring robust security measures to safeguard patient data and protect against unauthorized access or breaches, in compliance with data protection regulations such as GDPR.
5. **Accessibility Requirements:** Addressing issues related to access to telemedicine services for all individuals, including those in remote areas, and ensuring usability across different devices and platforms.
6. **Training and Support Requirements**: Providing adequate training and support for healthcare professionals and patients to effectively use telemedicine technologies and services.
7. **Audit and Compliance Requirements:** Implementing mechanisms for monitoring and auditing telemedicine services to ensure compliance with regulatory standards and quality assurance.
8. **Performance Requirements:** Ensuring reliable performance and scalability of telemedicine systems to accommodate varying levels of usage and demands.
9. **Financial and Administrative Requirements:** Addressing the financial aspects of telemedicine implementation, including funding mechanisms, reimbursement policies, and administrative procedures.

10. **Common Acceptance by Healthcare Services and Providers**: Fostering a consensus among healthcare services and providers regarding the adoption and integration of telemedicine into existing healthcare workflows and practices.

These requirements underscore the need for comprehensive solutions that address technical, legal, security, accessibility, and operational aspects to ensure successful implementation within the MyHealth@EU framework.

### III. Section III – Identification of possible requirements for cross-border telemedicine under MyHealth@EU

Regarding the main enablers for a successful implementation of telemedicine services within MyHealth@EU, participants identified the following factors, listed in order of significance, as depicted on Figure 10:

1. **Interoperability and Common Standards:** Ensuring seamless data exchange and compatibility across different healthcare systems is paramount for effective telemedicine implementation. Common standards facilitate interoperability, enabling healthcare professionals to access and share patient information securely.
2. **Mechanism for Identification and Authentication:** Establishing a reliable mechanism for identifying and authenticating healthcare professionals and institutions across national borders is essential for ensuring trust and accountability in telemedicine interactions.
3. **Data Security and Privacy:** Protecting patient data from unauthorized access, breaches, and misuse is crucial for maintaining confidentiality and trust in telemedicine services. Robust data security measures are necessary to safeguard sensitive health information.
4. **Education, Training, and Awareness Initiatives:** Providing comprehensive education, training, and awareness programs for healthcare professionals and patients is vital for promoting understanding, adoption, and effective utilization of telemedicine technologies and services.
5. **Common Technical Specifications and Standards:** Standardizing technical specifications and profiles for exchanging electronic health data enhances interoperability and facilitates seamless communication between different telemedicine systems and electronic health record (EHR) systems.
6. **Clear and Transparent Reimbursement Rules:** Establishing clear and transparent reimbursement rules for telemedicine services ensures financial sustainability and incentivizes healthcare providers to adopt and deliver high-quality telemedicine care.
7. **Specific Regulation Framework:** Developing a specific regulatory framework for telemedicine services provides clarity and guidance on legal and ethical considerations, ensuring compliance with applicable laws and regulations.
8. **Data Quality:** Maintaining high standards of data quality is essential for accurate diagnosis, treatment, and decision-making in telemedicine. Ensuring data accuracy, completeness, and reliability is crucial for delivering safe and effective telemedicine services.
9. **Telemedicine Systems as Medical Devices:** Recognizing telemedicine systems as medical devices and ensuring their interoperability with EHR systems enhances their reliability, safety, and effectiveness in clinical practice.
10. **Guidance for Telemedicine Services Provision in a Cross-border Context:** Providing guidance and protocols for telemedicine service provision in a cross-border context facilitates international collaboration and enables patients to access telemedicine services across borders seamlessly.

11. **Mechanisms for Assessing and Guaranteeing Quality:** Establishing mechanisms for assessing and guaranteeing the quality of cross-border telemedicine services ensures that patients receive safe, effective, and reliable care regardless of geographical location.

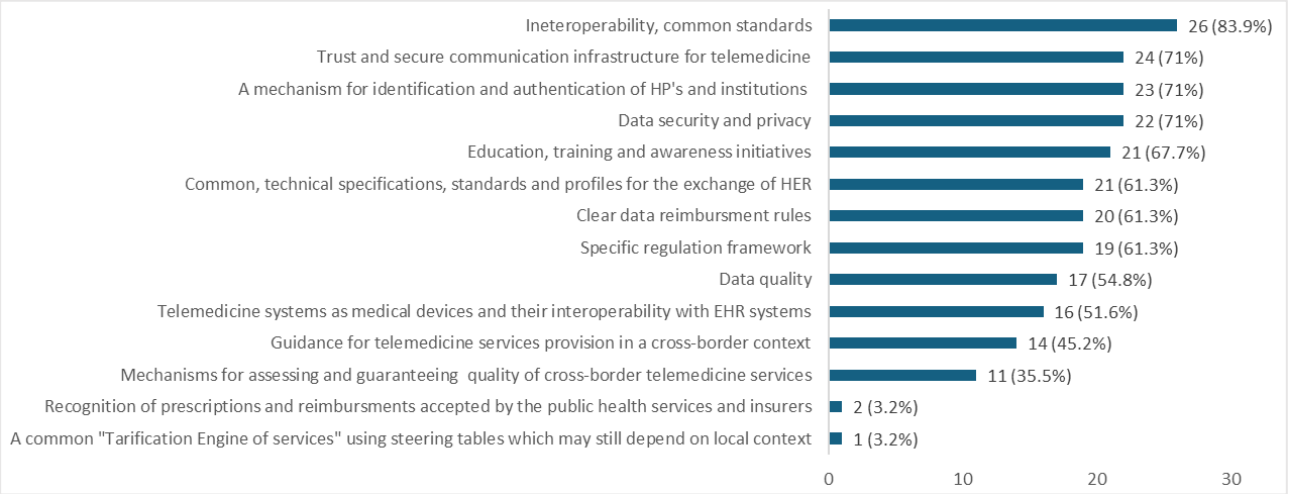



**Figure 10.** Question 3 - In your view, what will be the main enablers for a successful implementation of telemedicine services within MyHealth@EU?

Overall, addressing these key enablers is essential for creating a conducive environment for the successful implementation and adoption of telemedicine services within the MyHealth@EU framework, ultimately improving healthcare accessibility, quality, and outcomes across Europe.

In the survey, respondents identified several key barriers to the successful implementation of telemedicine services within the MyHealth@EU framework. These barriers are ranked below in order of significance based on participant responses:

1. **Lack of Mutual Recognition of Prescriptions and Reimbursements:** Participants highlighted challenges stemming from the absence of mutual recognition among countries regarding prescriptions and reimbursements for medical acts accepted by public health services and insurers. This disparity can hinder seamless access to healthcare services across borders.
2. **Professional Education:** The lack of education and training programs to equip healthcare professionals with the necessary skills and knowledge to effectively utilize telemedicine technologies and practices was identified has a critical barrier to the successful implementation of telemedicine services cross-border.
3. **Limited Access to Technological Infrastructure:** Participants perceive the lack of access to adequate technological infrastructure as a significant barrier. This includes issues related to digital infrastructure, and access to necessary devices and equipment.
4. **Lack of Telemedicine System Certification:** The absence of formal certification mechanisms for telemedicine systems raises concerns about quality assurance and patient safety, potentially impeding widespread adoption and trust in these technologies.
5. **Difficulty in Ensuring User-Friendly and Accessible Telemedicine Services:** Participants highlighted the challenge of ensuring that telemedicine services are easy to use and accessible to diverse groups of patients and healthcare professionals, including patients with disabilities.

6. **Language and Cultural Barriers:** The diversity of languages and cultures within the EU presents a significant challenge for telemedicine implementation, potentially hindering effective communication and access to services.
7. **Inadequate National Infrastructure for Telemedicine Provision:** Insufficient infrastructure at the national level poses a barrier to the widespread provision of telemedicine services, impacting accessibility and quality of care.
8. **Interoperability Issues:** Challenges related to the interoperability of devices and systems used in telemedicine approaches, as well as interoperability with electronic health record (EHR) systems at various levels (national, regional, local), were identified as barriers to seamless integration and data exchange.
9. **Differences in Clinical Protocols and Guidelines:** Discrepancies in clinical protocols and medical guidelines across Member States present challenges for standardized telemedicine practices and interoperability.
10. **Regulatory Differences Between Member States:** Variances in regulatory frameworks and policies among Member States create complexity and uncertainty regarding compliance and legal requirements for the implementation of cross-border telemedicine services.

These barriers underscore the complexity of implementing telemedicine services within a cross-border framework like, highlighting the need for coordinated efforts to address regulatory, technological, educational, and infrastructural challenges to ensure successful implementation and adoption.

### IV. Section IV – Conclusion

As observable on Figure 11, a significant majority of participants, comprising 90.3%, expressed interest in participating in further interviews concerning the implementation of telemedicine services within the MyHealth@EU framework. This high level of interest to engage in deeper discussions and provide additional insights underscores the importance and relevance of the subject matter, as well as the potential value of gathering further perspectives to inform future initiatives and strategies in the field of telemedicine.

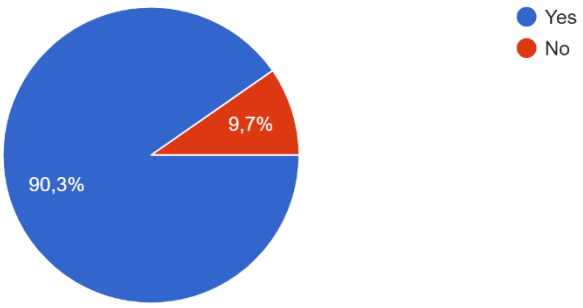



**Figure 11.** Question 5 - Are you interesetd in participating in additional interviews regarding this topic?

The majority of participants, totalling 96.8%, demonstrated interest in engaging in future workshops, meetings, or activities related to cross-border telemedicine within the MyHealth@EU framework (see Figure 12). This high level of interest underscores the strong commitment among respondents to actively

contribute to collaborative efforts aimed at advancing telemedicine initiatives across borders. Their willingness to participate indicates a collective recognition of the importance of fostering cross-border cooperation and innovation in healthcare services, highlighting the potential for meaningful collaboration and knowledge exchange in the area of cross-border telemedicine.

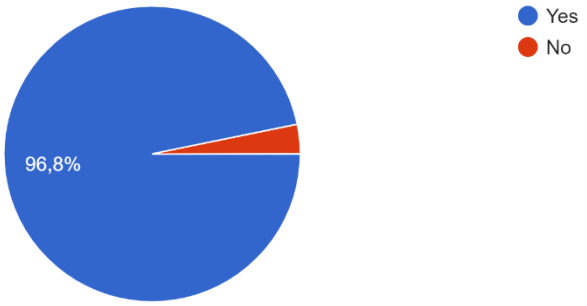



**Figure 12.** Question 6 - Would you be interested in participating in future workshops, meetings, or activities regarding cross-border telemedicine under MyHealth@EU?

The conclusion of the survey reflects diverse perspectives and valuable insights from participants regarding the integration of telemedicine services within the MyHealth@EU framework. In the participants final remarks, the following topics were pointed out:

- **Interest in Integration of NetDoktor Healthcare Network[76]:** One participant expressed interest in integrating the NetDoktor healthcare network into a unified European telemedicine system. This suggests potential opportunities for collaboration and integration with existing healthcare platforms to enhance telemedicine capabilities cross-borders.
- **Focus on AI and Graph Database for Telemedicine Services:** Another participant highlighted the importance of leveraging artificial intelligence (AI) and graph database technologies to enhance telemedicine services. This emphasis on advanced technologies underscores the potential for innovation and efficiency enhancement in healthcare delivery through the integration of cutting-edge technology and methodologies.
- **Consideration of Local Culture and Traditions:** A participant emphasized the significance of considering the culture and traditions of the locality where each telemedicine solution will be deployed. This insight highlights the importance of cultural sensitivity and context-specific approaches to ensure the successful implementation and acceptance of telemedicine services within diverse communities.
- **Reference to Existing Infrastructure and Implementation Guides:** One participant referenced the Austrian EHR infrastructure ELGA and provided information on the "Episode Report Telemonitoring." This example demonstrates the potential for leveraging existing infrastructure and best practices to inform the development and implementation of telemedicine initiatives within the MyHealth@EU framework.
- **Proposal for Splitting Telemedicine Services:** Participants proposed splitting telemedicine services into distinct categories:
    - Data Collection Services: Focused on gathering patient data and transmitting it to a server infrastructure, this component enhances interoperability by channelling data from the server into EHR and MyHealth@EU infrastructures. In addition to medical data, this process encompasses various non-medical services, including device calibration, device maintenance, and technical assistance for patients. These functions are optimally administered by specialized telemonitoring service providers.

- Telemedicine Services: Focused on analysing incoming data and providing medical services using AI tools and software. This segmentation allows for specialization and optimization of telemedicine workflows.

To conclude the survey analysis, it is important to underscore the complexity of considerations involved in the implementation of telemedicine services within a cross-border framework like MyHealth@EU. The diverse insights provided by participants underscore the need for collaborative approaches, technological innovation, cultural sensitivity, and strategic planning to realize the full potential of telemedicine in improving healthcare delivery across Europe.

## Annex VI – Workshop template

MyHealth@EU integrate the Patient Summary and Electronic Prescription and Dispensation (ePrescription/eDispensation) services.

Member States citizens can benefit from healthcare when travelling to other European countries, under conditions similar to those in their home country without having to worry about the language barrier.

These services allow healthcare professionals in the destination country to access basic and essential information through the Patient Summary, which, in critical situations, will be essential. On the other hand, with Electronic Prescription and Dispensation it is possible to obtain medication from a pharmacy in a participating Member State without having to present a paper prescription.

- Extension indicates that a scenario could be introduced with little effort in the MyHealth@EU infrastructure. To add new functionalities on existing NCPeH, by reusing architecture and processes.
- Evolution requires more effort and analysis. To add architectural and process changes to the current framework

For the realization of this workshop, the Mural platform was used to address the following questions:

**Telemedicine Use Cases Under MyHealth@EU**

| **Scenarios** | **Added Value** | | |
|---|---|---|---|
| **Description** | Health Professional | Policy Makers | Patient |
| Jonh has chronic heart failure. He goes abroad on a business meeting and feels sick needing urgent care. He goes to the nearest hospital which has MyHealth@EU services | | | |
| Emily was diagnosed with a rare disease. In her country of origin, there is no specialist doctor available who can accompany her. She could have access to a specialist outside her home country. | | | |

# Annex VII - Telemedicine Workshop analysis

The telemedicine workshop, which included 24 participants from the Xt-EHR joint action, showcased a variety of viewpoints and active engagement, providing valuable implementation insights for telemedicine under MyHealth@EU. Participants analysed two hypothetical scenarios using the Mural platform, offering insights into how telemedicine solutions could aid patients, health professionals, and policymakers in each case.

The workshop was deliberately structured to encourage participants to empathize with the patients in the scenarios. This immersive approach aimed to provide a deeper understanding of the patient experience, promoting a more patient-centred perspective in professional practice. The template of the workshop can be found in Annex VI – Workshop template.

The remaining sections start by a brief description of each scenario, following by the main outputs received during each case by the participants.

## 1. Analysis of John's Case

John's scenario depicts a chronic heart failure patient who falls ill during a business trip abroad and requires urgent care at a hospital providing MyHealth@EU services.

Key insights from the workshop emphasised the integration of telemonitoring data into the Patient Summary (PS). Participants noted that the PS should indicate if the patient is under a telemonitoring program and if so, it should provide the last 24 hours of heart monitoring data to offer real-time insights for timely medical interventions. In the interviews mentioned above, it was also discussed that prescribed telemonitoring programs should be prioritized over patient self-management plans, as they offer more structured and clinically supervised data. In addition, relevant information may happen that should be transmitted back to patient's country of affiliation. In this context, the proposed EHDS regulation designates discharge reports as a priority data category in Article 14, which could be leveraged as well.

The identification of doctors and hospitals was also a critical point of discussion. Participants highlighted the necessity for doctors in Country-B to access laboratory results reports and imaging data from the National Contact Point (NCP) of Country-A. Moreover, healthcare providers in Country-B should automatically see the PS from MyHealth@EU services, ensuring immediate access to critical information.

Participants pointed out that leveraging existing telemonitoring apps could facilitate data sharing. In this aspect, some components from PATHeDs'[78] MyHealth@EU translation services could be reused to help translating telemonitoring data to ensure it is comprehensible and usable in the context. The PATHeD project sought to create a service that enables patients to access their Patient Summary through an app and present it to health professionals in English or other languages, utilizing the existing MyHealth@EU infrastructure. Additionally, the workshop underscored the need for a robust system to identify the doctor responsible for medication adjustments, to ensure accountability and accurate record-keeping.

The potential for telemedicine to enhance specialized care and collaboration was also discussed. Telemedicine can improve communication and knowledge sharing between specialists, which is particularly beneficial in post-operative care for heart surgeries. To address current gaps in MyHealth@EU infrastructure, participants suggested linking MyHealth@EU with eCAN's teleconsultation services, providing an all-inclusive telemedicine solution.

[78] International action PATHeD. [available here]

The workshop participants also considered the role of Artificial Intelligence (AI) tools in facilitating and enhancing telemedicine. AI can improve data collection and analysis, increasing the efficiency and accuracy of patient care.

Lastly, participants highlighted that, in line with the proposed EHDS regulation, there should be a way to retrieve data collected during teleconsultation to store in the patient's EHR system(s). One participant suggested that AI could also help categorizing and managing data collected via telemedicine to support policymakers in their roles.

**2. Analysis of Emily's Case**

Emily's scenario involves a patient diagnosed with a rare disease, seeking specialized care not available in her home country.

The workshop responses emphasised the importance of leveraging the European Reference Networks (ERNs)[79]. This network provides support on rare diseases across Europe, ensuring discussion between healthcare providers. Furthermore, the ERNs include information about available specialists for specific rare diseases, facilitating referrals and consultations. The ERNs promote virtual discussion across specialists in Europe. In this virtual meetings, cases of patients affected by rare, low-prevalence and complex diseases are discussed, in order to provide advice and an appropriate diagnosis and treatment options. Leveraging existing ERNs mechanisms would greatly assist in creating a network of specialists available for telemedicine consultations, which would allow patients like Emily to receive specialized care without extensive travel.

The workshop highlighted the importance of robust doctor authentication and identification mechanisms. The systems used in the ERNs for doctor authentication and handling patient consent could also be leveraged for this work, as it ensures that only authorized health professionals can access and share sensitive data of the patient, preserving both patient trust and data integrity in cross-border healthcare. Therefore, these mechanisms could serve as a potential base for the solutions to be developed to support cross-border telemedicine under MyHealth@EU.

At the workshop, participants also suggested the use of the MyHealth@EU to support the ERN platform in the process of sharing relevant health data among specialists, streamlining the process within the framework of MyHealth@EU. Adapting ERNs authentication and identification mechanisms for telemedicine consultations could also ensure secure and efficient service delivery.

**3. Summary of the telemedicine workshop**

The workshop highlighted several critical aspects necessary for advancing the implementation of telemedicine services. One of the main takeaways was that integrating telemonitoring data can be essential for providing continuous care to patients, ensuring that healthcare providers have real-time access to crucial health information. Securing doctor identification is vital to maintain trust and integrity in telemedicine services, ensuring that patients are receiving care from verified and qualified professionals. The same principle applies to patient identification and authentication, ensuring that the correct individual is verified and authorized to share their personal health data. This aligns with the proposed EHDS regulation, which mandates that such services support the identification of individuals using any electronic identification methods recognized under Article 6 of Regulation (EU) No 910/2014[15]. In cross-border healthcare, however, identity matching can present challenges. Member States may need to issue supplementary access tokens or codes to facilitate the identification process for individuals seeking care abroad.

[79] European Commission. *European Reference Networks* [Available here]

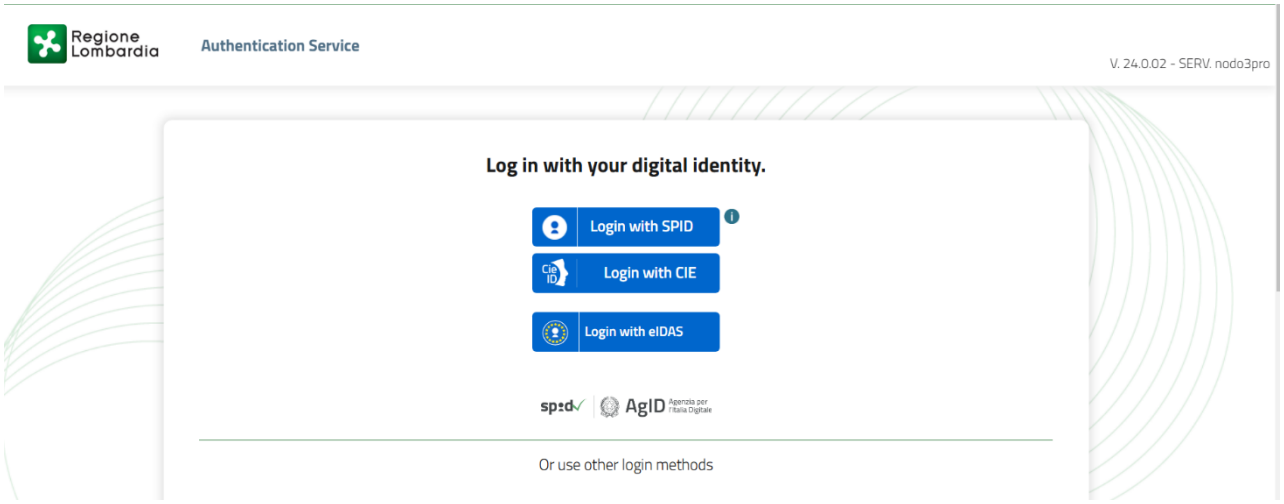
Leveraging AI tools in telemedicine could possibly present an opportunity to enhance diagnostic accuracy, personalize treatment plans, and streamline administrative tasks, thereby improving the overall efficiency and effectiveness of healthcare delivery.

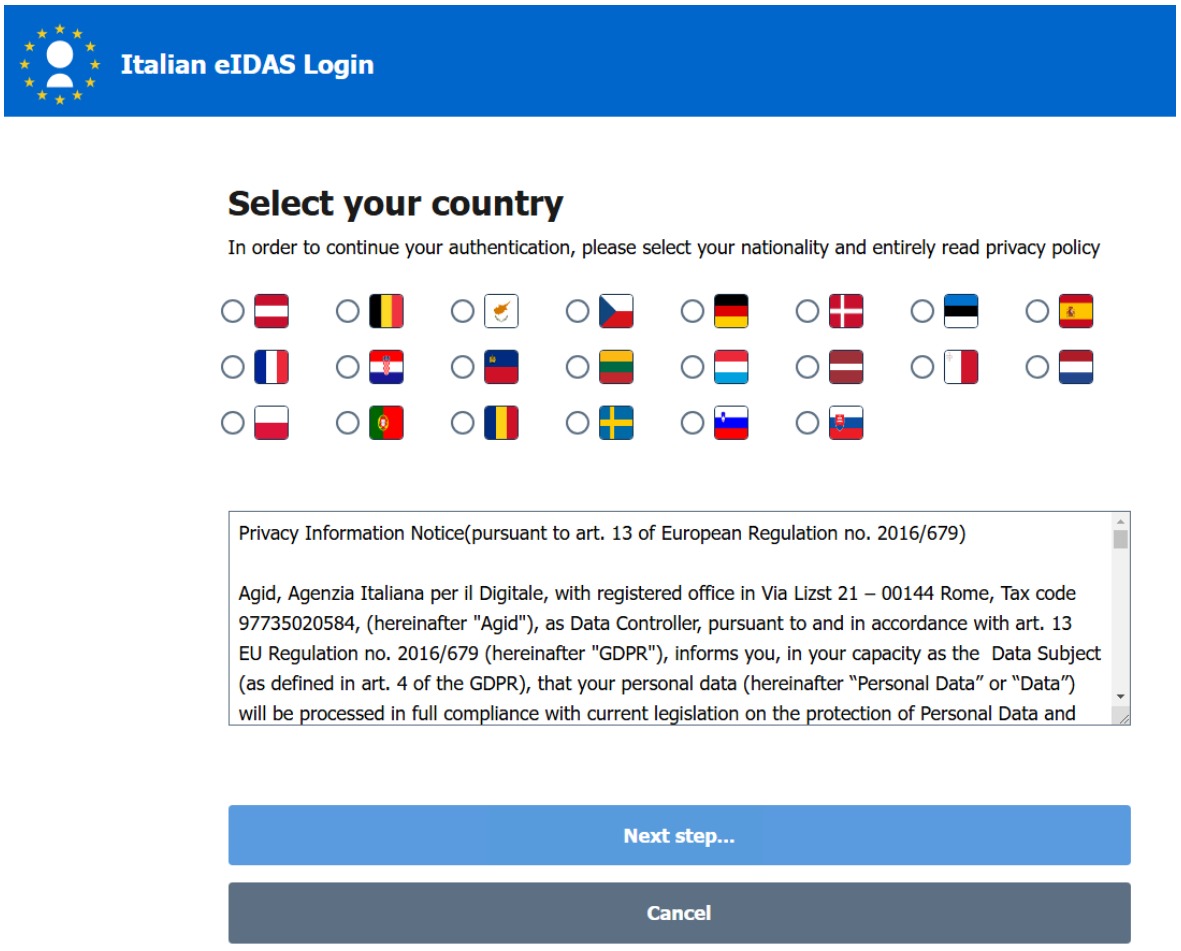
For rare diseases, the guidelines and mechanisms developed by the ERNs are particularly valuable. The ERNs was designed to facilitate collaboration and knowledge-sharing among specialists across Europe, ensuring that patients with rare diseases receive the best possible care regardless of their location. By adapting the ERNs mechanisms within the MyHealth@EU framework, it enables patient-centred telemedicine solutions that are tailored to the unique needs of rare disease patients.

Incorporating these procedures will potentially aid in providing comprehensive and patient-centred telemedicine solutions, significantly improving healthcare delivery across borders and ensuring that all patients, particularly those with rare diseases, have access to the specialized care they need.

## Annex VIII – Example of eIDAS use for public service

The figures below illustrate an example of eIDAS implementation for public services, specifically in the Lombardy region of Italy. This region has developed a webpage[80] where foreign citizens can log in using their national eIDAS authentication system. Users simply select their country's flag, which redirects them automatically to their respective national authentication system.




[80] Regione Lombardia. (n.d.). *MyPay - Cittadino*. Servizi RL. [Available here]

# Annex IX – Identification and Authentication Proposal against an online service in Country-A

**Possible solution for (I.):**

- Health Professional authenticates against a Country B service according to the eHDSI requirements
- Health Professional performs a standard IHE XCPD against Country A according to the data required by Country A's International Search Mask (ISM)
- Before releasing the *patientIdentifier*, Country A needs to authenticate the patient
- A technical solution is implemented for asking the patient to authenticate against a service offered by Country A with her eID, e.g.: via a push notification to her mobile phone, or sending a URI to her mail address – in the first case, the authentication would be performed on the mobile (e.g. using biometrics), in the latter such a URI would contain an online service requesting a strong authentication
- The outcome of the authentication is sent to the MyHealth@EU Country A services (OpenNCP or National Connector)
- Country A services retrieve the *patientIdentifier*, now checked against a strong authentication, and close the XCPD transaction as required by Country B
- The *patientIdentifier* is available and a usual MyHealth@EU flow can be implemented

Pros:

- No need for a reconciliation process in Country B, patient's identity data are retrieved and checked in Country A during the XCPD transaction
- Country B services do not need to be changed

Cons:

- Impact on Country A eHDSI components (OpenNCP or NationalConnector) to trigger the patient's authentication, with potentially different solutions across MSs
- Patient may need a mobile device in case of push notification (this approach would be already EUDIWallet oriented)

# Annex X –Patient Identification and Authentication Proposal against an online service in Country-B

**Possible solution for (II.):**

- Health Professional authenticates against a Country-B service according to the eHDSI requirements
- The Country-B service creates a URI including the Health Professional identifier, and the online Country-B service's URL
- The URI is sent to the patient's email address or via other means (e.g. SMS). A process by which a patient's data (email or telephone number) is collected shall be defined
- The patient clicks on the URI and is redirected to the Country-B service, which informs the patient about the Health Professional identity (using his identifier)
- The Country-B service is integrated to the eIDAS cross-border login, so the patient performs a strong online authentication using her eID means released by Country-A
- Upon successful authentication, the Country-B service now has the following patient data: *person identifier*, *name*, *surname*, *date of birth* (eIDAS Minimum Data Set)
- Health Professional receives those data from the Portal
- Health Professional performs a standard IHE XCPD against Country-A according to data required by Country-A's International Search Mask (ISM)
- The *patientIdentifier* is retrieved
- Identification data retrieved from MyHealth@EU (XCPD) and eIDAS are compared by the Health Professional, ideally using services offered by Country-A if allowed by their legal basis, to confirm the patient's identity – since for most of the MS, the abovementioned *person identifier* and *patientIdentifier* are different
- The *patientIdentifier* is now checked against a strong authentication and a usual MyHealth@EU flow can be implemented

Pros:

- eIDAS login has been operational since 2016, a standard way to authenticate cross-border to public services, most of the MSs onboarded
- Patient does not need any special equipment besides a PC or similar device with internet access, email and eID - a mobile device is not mandatory.

Cons:

- impact on Country-B components
- a reconciliation process between the data released by IHE XCPD and eIDAS must be in place (manually, by the Health Professional, or via a new service offered by Country-A, if allowed by Country-A law)

**Additional considerations:**

- Introducing eID, both solutions provide higher confidence in *patientIdentifier* than the current eHDSI setting, based solely on the ISM

- (II.) requires more effort to Country-B, (I.) requires more effort to Country-A
- In both cases, a reconciliation process must be in place: sometimes the *patientIdentifier* is not included in the national authentication scheme, and in most cases not included in the eIDAS SAML assertion.
- From a technical perspective, the SAML profile is covered in both solutions, while SSO is not explicitly addressed.

# Annex XI – Hospital Discharge Report Core Dataset from eHN guidelines

**HOSPITAL DISCHARGE REPORT BODY - Core Dataset**

This section specifies the Core Dataset of what is a Hospital Discharge Report in the scope of this guideline[19]. The Core Dataset represents the set of elements of this document.

| # | Data Element | Description | Preferred Code System (*) (**) |
|---|---|---|---|
| **A.2.0** | **Hospital Discharge Report in its narrative form** | | |
| **A.2.2** | **Alerts** | | |
| **A.2.2.1** | **Allergy and Intolerance** | **A record of allergies and intolerances (primarily to be used for new allergies or intolerances thatoccurred during the hospital stay).** | |
| A.2.2.1.1 | Allergy description | Textual description of the allergy or intolerance | |
| A.2.2.1.3 | Allergy manifestation | Description of the clinical manifestation of the allergic reaction including date of manifestation and severity. Example: anaphylactic shock, angioedema (the clinical manifestation also gives information about the severity of the observed reaction). Multiplemanifestations could be provided. | SNOMED CT |
| A.2.2.1.10 | Agent or Allergen | A specific allergen or other agent/substance (drug, food, chemical agent, etc.) to whichthe patient has an adverse reaction propensity. | (IDMP / EMA SPOR SMS) |
| **A.2.2.2** | **Medical alerts (relevant for the respective hospital stay)** | | |

| # | Data Element | Description | Preferred Code System (*) (**) |
|---|---|---|---|
| A.2.2.2.1 | Healthcare alert description | A warning, other than included in allergies.<br>The warning can be entered in code (there are codes for frequently used alerts) but seeing the dynamic nature of the warnings, these alerts will often be entered as free text.<br><br>Any clinical information that is imperative to know so that the life or health of the patientdoes not come under threat.<br><br>Example 1: the patient has<br>a rare disease that requires<br>special treatment Example<br>2: Airway Alert / Difficult<br>Intubation<br><br>Example 3: Diagnoses such as malignant hyperthermia, porphyria, and bleeding disorders; special treatments like anticoagulants or immunosuppressants; implanted devices.<br><br>Example 4: transplanted organs illustrate other information that has to be taken intoaccount in a healthcare contact.<br><br>Example 5: participation in a clinical trial that has to be taken into account in a healthcarecontact. | SNOMED CTLOINC |
| **A.2.3** | **Encounter** | | |
| **A.2.3.3** | **Admission** | | |

| # | Data Element | Description | Preferred Code System (*) (**) |
|---|---|---|---|
| A.2.3.3.1 | Admissionurgency | Admission type, either emergency or planned | hl7:v3-xEncounterAdmissionUrgency |
| A.2.3.3.2 | Admission date | Admission date and time. | ISO 8601 |
| A.2.3.3.6 | Admitting organisation | The healthcare provider organisation information. | |
| **A.2.3.4** | **Admission reason** | | |
| A.2.3.4.1 | Admission reason | Reason or reasons for admission, e.g. Problem, procedure or finding. | ICD-10* SNOMED CT<br>Orphacode if rare disease is diagnosed |
| A.2.3.4.2 | Admission reason comment | Explanation of the reason for the encounter. | |
| **A.2.3.5** | **Discharge** | | |
| A.2.3.5.1 | Discharge date | Discharge date and time | ISO 8601 |
| A.2.3.5.2 | Discharge destination type | Type of location to which the patient will go after the encounter. E.g. home, hospital, nursing home, left against medical advice etc. | hl7.discharge-disposition |
| A.2.3.5.3 | Destinationlocation | The location/organisation to which the patient will go after the encounter. Name, addressand telecommunication contact. | |
| **A.2.3.6** | **Location -** All locations/departments where the patient stayed (was boarded) within the hospital. | | |
| A.2.3.6.1 | Period | Time period during which the patient was present at the location | |
| A.2.3.6.3 | Organisation Part Name | Full name of the organisation part, e.g. Name of the department | |
| A.2.3.6.4 | Organisation Part Details | Address, contact names and contact details, specialty of the organisation part. | SNOMED CT |
| **A.2.6** | **Course of hospitalisation (Hospital stay)** | | |
| **A.2.6.1** | **Diagnosticsummary** | All problems/diagnoses that affect care during the inpatient case or are important to be recorded to ensure continuity of care. The | |

| # | Data Element | Description | Preferred Code System (*) (**) |
|---|---|---|---|
| | | diagnostic summary differentiates, in accordance with the international recommendation, between problems treated during hospital stay and other (untreated) problems. Treated problems are problems that were the subject of diagnostics, therapy, nursing, or (continuous) monitoring during the hospitalisation. Furthermore problems could be divided into three categories: problems present on admission (POA), conditions acquired during hospital stay (HAC) and problems that cannot be classified as being of any of the two (N/A). The diagnostic summary contains all conditions as they were recognised at the end of hospitalisation, after all examinations. This section contains concise, well specified, codable, summary of problems. Problems are ordered by importance (main problems first) during hospital stay.<br>Description of the problem might be completed with additional details in the medical history section and/or inthe Synthesis section. | |
| A.2.6.1.1 | Problem description | Problem specification in narrative form | |
| A.2.6.1.2 | Problem details | Problem details include code that identifies problem, specification of the body structure, laterality, and other aspects of the problem. | ICD-10* SNOMED CT ICD-O-3<br>Orphacode if rare disease is diagnosed IPS Absent and Unknown Data |
| A.2.6.1.3 | Onset date | Onset date of a problem/condition | ISO 8601 |
| A.2.6.1.5 | Category | Category of the problem allows flagging for conditions acquired during hospital stay.<br>- Present on admission [POA])<br>- Hospital acquired condition [HAC]<br>Not applicable or unknown | |

| # | Data Element | Description | Preferred Code System (*) (**) |
|---|---|---|---|
| A.2.6.1.6 | Treatment class | Class of the problem (treated, other) in relation to the hospital encounter. Treated problems were treated or affected provisioning of care (diagnostics, therapy, nursing, monitoring) during the hospital encounter. At least one problem should be marked as Treated. Other problems are recorded only if they are important for continuity of care(after discharge). | Treated, Other |
| **A.2.6.2** | **Significant procedures** | Significant surgical and non-surgical procedures performed during hospitalisation which are significant for continuity of care, e.g. surgeries and other "instrumental" interventions (endoscopic, intravascular), chemotherapy, radiotherapy, purification methods (dialysis, hemoperfusion), circulation support methods (counterpulsation, etc.), administration of blood derivatives or others.<br><br>This section does not include purely diagnostic procedures (MRI, CT, etc.). If no significant performance hasbeen performed, this fact must be explicitly stated using the IPS Absent and Unknown Data. | |
| A.2.6.2.1 | Procedure code | Procedure code | SNOMED CT<br><br>IPS Absent and Unknown Data |
| A.2.6.2.2 | Procedure description | Narrative description of the procedure | |
| A.2.6.2.4 | Procedure date | Date and time when procedure was performed | ISO 8601 |
| A.2.6.2.8 | Focal device | A reference to the device or devices that is/are implanted, removed, or otherwise manipulated (calibration, battery replacement, fitting a prosthesis, attaching a wound-vac, etc.) as a focal portion of the Procedure. | |
| **A.2.6.3** | **Medical devicesand implants** | Implants and used medical devices that affected or may affect the provision of health services (diagnosis and treatment). Also medical devices explanted, or its use was stopped during hospitalisation. If the section is blank, the reason must be | |

| # | Data Element | Description | Preferred Code System (*) (**) |
|---|---|---|---|
| | | explicitly statedusing the IPS Absent and Unknown Data coding system | |
| A.2.6.3.1 | Device and implant description | Describes the patient's implanted and external medical devices and equipment uponwhich their health status depends. Includes devices such as cardiac pacemakers, implantable fibrillator, prosthesis, ferromagnetic bone implants, etc. of which the HP needs to be aware. | SNOMED CTEMDN<br>IPS Absent and Unknown Data |
| A.2.6.3.3 | Implant date | The date and time the device was implanted or when its use began. | ISO 8601 |
| A.2.6.3.4 | End date | Date and time when the device was explanted from the patient or the external device wasno longer in use; likewise when the device is planned to be explanted | ISO 8601 |
| **A.2.6.5** | **Pharmacotherapy** | Selected drug treatment during hospitalisation. Medicinal products that were administered during hospitalisation and whose administration has already been discontinued before discharge. Only products which are important for continuity of care (antibiotics other than completely routine, corticosteroids in high doses, etc.) will be listed. Products which administration will continue after discharge will be also recorder inthe Medication summary section.<br><br>Medicinal products, the administration of which was started during hospitalisation, but is also recommendedafter discharge, will be listed in the summary table in the recommendation section. | |
| A.2.6.5.2 | Code | Product code | IDMP |
| A.2.6.5.4 | Brand name | Brand name if biological medicinal product or when justified by the health professional (ref. Commission Directive 2012/52/EU) | |
| A.2.6.5.10 | Period oftreatment | The time interval when the patient was, or was not, given the medication. | |

| # | Data Element | Description | Preferred Code System (*) (**) |
|---|---|---|---|
| **A.2.6.6** | **Significant ObservationResults** | Results of significant functional, diagnostic, and imaging examinations to ensure continuity of care, performed during hospitalisation. Results of examinations ordered but not yet delivered should be presented separately from results already delivered. | |
| A.2.6.6.1 | Date | Date and time of the observation | ISO 8601 |
| A.2.6.6.3 | Result description | Narrative representation of the observation result and findings. | |
| A.2.6.6.4 | Observationdetails | Observation details include code that identifies observation, specification of the observedbody structure or specimen, date and time of the specimen collection, observation method or protocol used and other aspects of the observation. | LOINCNPU<br>SNOMED CTISO 8601 |
| A.2.6.6.5 | Observation result | Result of the observation including numeric and coded results of the measurement, details about how the tests were done to get the result values, information about reference ranges and result interpretation. Content of the observation result will vary according to the type of the observation. | SNOMED CT<br>UCUM<br>(measurement units) |
| **A.2.6.7** | **Synthesis** | This section provides clinical synthesis (e.g. description of reasons and course of hospital stay) clustered by managed conditions, Clinical synthesis may include clinical reasoning (differential diagnostics, explanation of clinical context) in clinically complex conditions. | |
| A.2.6.7.1 | Problem synthesis | Summary description of the reason and course of hospitalisation for a specific problem. | |
| **A.2.7** | **Discharge details** (structured information should be provided, however if not available, at least a summary note should bepresent). | | |
| **A.2.7.1** | **Objective findings** | | |
| A.2.7.1.1 | Date | Date and time of the examination at or before discharge | ISO 8601 |

| # | Data Element | Description | Preferred Code System (*) (**) |
|---|---|---|---|
| **A.2.7.1.3** | **Anthropometric observations** | Observation of Body weight and height of the patient, BMI, circumference of head, waist, hip, limbs and skinfold thickness.<br>Result of the observation includes text, numeric and coded results of the measurement includingmeasurement units. Multiple observations could be provided. | |
| A.2.7.1.3.2 | Observationdetails | Observation details include code that identifies observation, specification of the observed body structure or specimen, date and time of the specimen collection, observation method or protocol used and other aspects of the observation. | SNOMED CTLOINC<br>ISO 8601 |
| A.2.7.1.3.3 | Observation result | Result of the observation including numeric and coded results of the measurement, details about how the tests were done to get the result values, information about reference ranges and result interpretation. Content of the observation result will vary according to the type of the observation. | UCUM<br>(measurementunits) |
| **A.2.7.1.4** | **Vital signs** | Observation of Vital signs:<br>• Recommended: systolic and diastolic blood pressure including site of measurement, pulse rate, respiratoryrate<br>Optional: 02 saturation, temperature, pain (scale), ... | |
| A.2.7.1.4.2 | Observationdetails | Observation details include code that identifies observation, specification of the observed body structure or specimen, date and time of the specimen collection, observation method or protocol used and other aspects of the observation. | SNOMED CTLOINC<br>ISO 8601 |
| A.2.7.1.4.3 | Observation result | Result of the observation including numeric and coded results of the measurement, details about how the tests were done to get the result values, information about reference ranges and result interpretation. Content of the observation result will vary according to the type of the observation. | UCUM<br>(measurementunits) |

| # | Data Element | Description | Preferred Code System (*) (**) |
|---|---|---|---|
| **A.2.7.1.5** | **Physical examination** | Physical examination (at discharge) is the process of evaluating objective anatomical findings. Physical examination can be performed through observation, palpation, percussion, and auscultation. | |
| A.2.7.1.5.1 | Observation Note | A narrative description of the observation. It should be structured by the organ system(e.g. head, neck, body, arms, ...) | |
| **A.2.7.2** | **Functional status** | Functional status can be assessed in several different ways, usually with a focus on the person's abilities to perform basic activities of daily living (ADL), which include basic self-care such as bathing, feeding, and toileting and instrumental activities of daily living (IADL), which includes activities such as cooking, shopping,and managing one's own affairs.<br><br>For details see: https://paciowg.github.io/functional-status-ig/ | |
| A.2.7.2.1 | Description | Need for the patient to be continuously assessed by third parties; functional status may influence decisions about how to plan and administer treatments | |
| **A.2.8** | Care plan and other recommendations after discharge. | | |
| **A.2.8.1** | **Care plan**<br>Care plan after discharge. Multiple care plans could be provided. | | |
| A.2.8.1.3 | Description | A description of the scope and nature of the plan. | |
| **A.2.8.2** | **Medication summary** | **Summary information on the medication recommended for the period after discharge, indicating whether the medication is changed or newly started. Compared to previous practices, the overviewis supplemented with medication that has been discontinued.** | |
| A.2.8.2.1 | Medication reason | The reason why the medication is or was prescribed or used. It provides a link to the Past or current health condition(s) or problem(s) that the patient has had or has and for which this medication was prescribed. | ICD-10* SNOMED CT<br>Orphacode if raredisease is diagnosed |
| A.2.8.2.2 | Reason forchange | Reason for change of medication | hl7:reason-medication- status-codes |

| # | Data Element | Description | Preferred Code System (*) (**) |
|---|---|---|---|
| A.2.8.2.3 | Code | Product code. | IDMP |
| A.2.8.2.4 | Brand name | Brand name if biological medicinal product or when justified by the health professional(ref. Commission Directive 2012/52/EU) | |
| A.2.8.2.5 | Active ingredientlist | Substance that alone or in combination with one or more other ingredients produces the intended activity of a medicinal product. Example: "paracetamol" | ATC (IDMP / EMA SPOR SMS) |
| A.2.8.2.6 | Strength | The content of the active ingredient expressed quantifiably per dosage unit, per unit of volume or per unit of weight, according to the pharmaceutical dose form. Example: 500mg per tablet | UCUM<br>EDQM Standardterms |
| A.2.8.2.7 | Pharmaceuticaldose form | The form in which a pharmaceutical product is presented in the medicinal productpackage (e.g. tablet, syrup) | EDQM Standardterms |
| A.2.8.2.8 | Dosage Regimen | Number of units per intake and frequency of intake over a specified duration of time. Example: 1 tablet every 24h, for 10 days | |
| A.2.8.2.9 | Route of administration | Path by which the pharmaceutical product is taken into or makes contact with the body. | EDQM Standardterms |
| A.2.8.2.10 | Period oftreatment | The interval of time during which it is being asserted that the patient is/was/will be taking the medication (or was not taking). | |
| A.2.8.2.11 | Days supplied | Number of days for which the patient was provided with the drug. Supply is intended to either hand over the medicine or write out a prescription. A 0 value indicates that the | UCUM |
| **A.2.8.3** | **Other recommendations** | **Other recommendations (advice) after discharge. Multiple recommendations could be provided. E.g., recommendation to suggest hip replacement, reduce number of cigarettes, stop smoking, increase physical exercises, etc.** | |

(*) In a foreseeable future, the suggested preferred vocabularies might be superseded or complemented, as mentioned in Guidelines Article11(2). (**) The Preferred code system(s) has been selected based on adequacy to convey the information using the methodology of the Subgroup onSemantics. When more alternative international code systems are available, all are listed when it is assumed to be unlikely that agreement canbe reached short term. Mapping between code systems could be proposed for specific use cases.

## Annex XII – Preliminary analysis of MyHealth@EU eHDSI Requirements

The table below summarizes the preliminary impact analysis of cross-border teleconsultation use cases on the current eHDSI requirements as defined in the *eHDSI Requirement Catalogue* V8.0 OR[16]. Each requirement was carefully reviewed to evaluate its relevance and the potential impact in the proposed telemedicine use cases. This analysed aimed to identify potential new requirements or existing requirements that may need amendment.

| eHDSI requirements | Impact to the scenario | Analysis |
|---|---|---|
| **01. Ensure Health Professional (HP) Identification, Authentication and Authorization** | No | The same process is applicable to the cross-border telemedicine services, including teleconsultations. |
| **01.01. Uniquely identify and authenticate the Health Professional (HP) in Country of treatment** | No | |
| **01.02. Authorize Health Professional (HP) according to assigned roles and profiles** | No | |
| **02. Ensure Patient Identification.** | Yes | A new solution is proposed to enable secure a reliable remote identification and authentication of patients in the country of affiliation, facilitating the access of HP-B to cross-border telemedicine, including teleconsultation in the context of MyHealth@EU services.<br>The proposed process starts with the HP-B inputting the required attributes for Patient Search using the existing ISM attributes. Validation of the patient's identity will then be conducted by national infrastructure of the country of affiliation. If the patient is correctly identified and authenticated, the HP-B will receive a notification to proceed with further requests regarding the intended MyHealth@EU services. This access to the services may happen prior or during the teleconsultation.<br>It is essential that HP-B is able to identify the patient remotely in this situation because patient identification cannot be done on-site. Remote identification needs to guarantee comparable security and verification criteria, in contrast to on-site identification, which usually entails a document with a photo and demographic information. Therefore, in order to guarantee a smooth and safe telemedicine experience, the patient needs to be able to remotely authenticate themselves to HP-B, using electronic identification methods recognized under Article 6 of Regulation (EU) No 910/2014[15]. |
| **02.01. Uniquely identify the Patient** | Yes | |
| **02.01.01. Identification and authentication of a patient with demographic data or demographic data and eID** | Yes | |
| **02.01.02 Creation of the national patient and document search file** | No | Same attributes are expected to be reused. |

| eHDSI requirements | Impact to the scenario | Analysis |
|---|---|---|
| **03. Create and apply policies and procedures to ensure trust between countries** | Maybe | This requirement may need updates. New policies and procedures might need to be created to guarantee operability of the telemedicine services, including errors in remote teleconsultations. Additionally, training of staff and health professionals must occur in the specificity of cross-border telemedicine services, to allow the user to experience a secure and quality delivery of healthcare. |
| **03.01. Manage Incidents, Problems and Support services** | Maybe | |
| **03.02. Manage the changes to the cross-border services** | No | |
| **03.03. Assess and validate the cross-border services** | No | |
| **03.04. Education, training and awareness of the cross-border services** | Yes | |
| **04. Ensure lawful processing of personal and health data** | Yes | To support teleconsultation and other forms of cross-border telemedicine, it is crucial to adapt the requirement to allow HP-B to lawfully access patient data even when the consultation is not conducted in person.<br>Moreover, new mechanisms for obtaining prior patient consent remotely may need to be integrated in order to allow the HP-B to access necessary health data at any time while maintaining data integrity, traceability, and security. |
| **04.01. Identify the applicable legal basis for processing personal and health data within MyHealth@EU** | Yes | |
| **04.02. Identify the controller(s) and processor(s) of the personal and health data within MyHealth@EU** | Yes | |
| **04.03. Inform data subjects about their rights as concerns the protection of their personal and health data** | No | Same attributes are expected to be reused. |
| **04.04. Ensure compliance of the MyHealth@EU central services with the applicable data protection provisions** | No | Same attributes are expected to be reused. |
| **05. Make Patient Summary available to HP** | No | The same process is applicable to the cross-border telemedicine services, including teleconsultations. |
| **05.01. Create the MyHealth@EU Patient Summary content** | No | |
| **05.02. Transcode, translate and exchange cross-border the Patient Summary** | No | |
| **05.03. Display the Patient Summary to the Health Professional** | No | |
| **06. Make ePrescription available to HP** | Maybe | This requirement may be impacted by the introduction of new telemedicine services within MyHealth@EU, depending on decisions made by Member States. For instance, during a teleconsultation, HP-B might need to issue an electronic prescription (eP) for patient-A, which could be require dispensing in patient's country of affiliation. |
| **06.01. Create the MyHealth@EU Prescription(s) content** | Maybe | |
| **06.02. Transcode, translate and exchange cross-border the ePrescription** | Maybe | |
| **06.03. Display the ePrescription to the Health Professional** | Maybe | |
| **07. Handle Dispensation of medicine and Substitution** | Maybe | Following the previous note, any eP issued and exchanged through MyHealth@EU should be accompanied by the electronic dispensation (eD) process. This ensures the prescription cycle is completed and prevents the risk of the same eP being reused inappropriately. |
| **07.01. Create the MyHealth@EU eDispensation content** | Maybe | |
| **07.02. Transcode, translate and exchange cross-border the eDispensation** | Maybe | |

| eHDSI requirements | Impact to the scenario | Analysis |
|---|---|---|
| **07.03. Inform Country of affiliation about the dispensed medicine** | Maybe | |
| **07.04. Option to discard a previously performed dispensation** | Yes | |
| **08. Make original Clinical Documents available to HP** | No | The same process is applicable to the cross-border telemedicine services, including teleconsultations. |
| **08.01. Create the MyHealth@EU Original Clinical Document content** | No | |
| **08.02. Exchange cross-border the Original Clinical Document** | No | |
| **08.03. Display the Original Clinical Document to the Health Professional** | No | |
| **09. Make Patient Access available** | No | The same process is applicable to the cross-border telemedicine services, including teleconsultations. |
| **09.01. Make Translated Documents available for Patient Access** | No | |
| **09.01.01. Retrieve List of Available Languages for Patient Access** | No | |
| **09.02. Accessibility, traceability and display the clinical information for Patient Access** | No | |
| **10. Ensure understandable information is exchanged between countries** | Maybe | HP-B will generate a non-structured document from the teleconsultation, which may allow the HP to insert free text in the document. In this way, it is required the possibility to exchange the information from the teleconsultation in a non-structured document that is sent to the country of affiliation for further evaluation and validation. |
| **10.01. Ensure structured and coded information is exchanged between countries** | Maybe | Aside from the possibility of a non-structured document from HP-B, the inclusion of any relevant information must ensure the correct terminology and coding from MyHealth@EU. |
| **10.02. Ensure equivalent information is exchanged between countries** | No | Same attributes are expected to be reused. |
| **10.03. Ensure understandable information is exchanged between countries** | No | Same attributes are expected to be reused. |
| **11. Ensure the security, performance, traceability and auditability of the services, data and systems** | No | The same principles should be applicable to the cross-border telemedicine services, including teleconsultations. |
| **11.01. Ensure security of the services, data and systems** | No | |
| **11.01.01. Ensure confidentiality of the services, data and systems** | No | |
| **11.01.02 Ensure integrity of the exchanged data** | No | |
| **11.01.03. Ensure service availability** | No | |
| **11.01.04. Detect service anomalies** | No | |

| eHDSI requirements | Impact to the scenario | Analysis |
|---|---|---|
| **11.01.04.01. Detect anomalies by an applicative solution** | No | |
| **11.01.04.02. Detect anomalies by a human intervention** | No | |
| **11.02. Ensure and monitor service performance** | No | |
| **11.03. Ensure traceability of the exchange data** | No | |
| **11.04. Ensure auditability of the exchanged data** | No | |
| **12. Ensure the non-repudiation of the exchange data** | No | The same process is applicable to the cross-border telemedicine services, including teleconsultations. |
| **12.01. Handle the non-repudiation mechanisms** | No | |
| **13. Make laboratory results report available to HP** | No | The same process is applicable to the cross-border telemedicine services, including teleconsultations. |
| **13.01. Create the MyHealth@EU Laboratory Result Report Content** | No | |
| **13.02. Transcode, translate and exchange cross-border the Laboratory results report** | No | |
| **13.03. Display the laboratory results report document to the Health Professional** | No | |