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

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

Stakeholder Consultation
Briefing Supporting Document

2025, 8 January

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1   Stakeholder Consultation Target Groups

As part of Xt-EHR strategy, selected deliverables will undergo stakeholder consultation. This document intents to engage stakeholders with knowledge on the following topics:

- MyHealth@EU services
- Telemedicine services
- Identification and authentication mechanisms, including eIDAS-compliant
- Legal experts (e.g., knowledge in GDPR, eIDAS, and EHDS)

This work is closely related to MyHealth@EU[1] services within the scope of the upcoming European Health Data Space (EHDS) regulation[2]. Consequently, specific terminologies associated with these services are used throughout this work.

2   Overview of Work Package 9

WP9 – *Telemedicine under MyHealth@EU in alignment with EHDS proposal*, focuses on establishing the foundation for implementing cross-border telemedicine services leveraging MyHealth@EU, in alignment with the dispositions of the EHDS regulation. These services aim to enhance healthcare accessibility, interoperability, and healthcare continuity across the European Union (EU).

More specifically, WP9 will analyse how MyHealth@EU services can support cross-border telemedicine services, including teleconsultations, to support the dispositions in Article 24 – *Supplementary cross-border digital health services and infrastructures* under the EHDS regulation.[2]

To achieve this, two reports will be developed:

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

[2]   European Parliament. CORRIGENDUM to the position of the European Parliament adopted at first reading on 24 April 2024 with a view to the adoption of Regulation (EU) 2024/… of the European Parliament and of the Council on the European Health Data Space P9_TA(2024)0331 (COM(2022)0197 – C9-0167/2022 – 2022/0140(COD)), 27/11/2024. [available here]

- D9.1 – *Requirements and use cases on the availability of health data in cross-border telemedicine services*
- D9.2 – *Technical specifications on the availability of health data in cross-border telemedicine services*

This document focuses on the stakeholder consultation for D9.1, which will serve as the foundation for the technical specifications to be elaborated in D9.2.

3 Overview of Deliverable 9.1 – Requirements and use cases on the availability of health data in cross-border telemedicine services

D9.1 – *Requirements and use cases on the availability of health data in cross-border telemedicine services* lays the groundwork to enable the use of MyHealth@EU services to support cross-border telemedicine services, by allowing, for example, reusing the current infrastructure to share relevant health-related data (e.g., Patient Summary, Laboratory Results Report, etc) in the context of a cross-border teleconsultation.

For this purpose, this work firstly focused on defining priority use cases aligned with the upcoming EHDS regulation. For the selected use cases, the main actors, processes, proposals and requirements were defined based on the existing MyHeath@EU requirements and specifications, as well as considerations from the compromised text of EHDS regulation.

A summary of the main results is presented below:

Priority use cases	MyHealth@EU services can support the following priority use cases: 1. Teleconsultations between patients and health professionals across borders**.** 2. Teleconsultations between health professionals (HP) from different countries discussing a patient's case, where a HP from a country B needs to consult information on a patient from country A. Transversal to these two use cases: • Sharing a report with the main findings of the cross-border teleconsultation from country B (location of the HP-B) to country A (representing the patient's country of affiliation). The priority use cases were selected based on the upcoming EHDS regulation and involved consortium partners, in order to guide the focus of this report.
Patient Journey	An example of a patient journey flow was created to support the analysis of the main phases of a cross-border teleconsultation (scheduling, pre-teleconsultation, consultation, post-consultation), the main actors, steps and requirements.
Responsibilities, requirements and proposals	For each involved actor, the main responsibilities and requirements were described, including proposals on how to address new challenges. **Key Actors Involved:**

	- **Patient from Country A:** Actively participates in enabling MyHealth@EU services by undergoing identification and authentication processes to authorize access to personal health data securely.
	- **National/Regional Infrastructure in Country A and Country B:** Manages the technological and administrative processes for data exchange, authentication, and storage of reports, ensuring seamless coordination between entities.
	- **NCP-A and NCP-B:** Serve as intermediaries, facilitating secure and standardized cross-border data exchange and ensuring interoperability between the two countries via MyHealth@EU.
	- **Central/Core Services:** Provide EU-level infrastructure to enable cross-border connectivity, interoperability, and support for national and NCP-level service deployment.
	- **Healthcare Provider Organisation in Country B (HCPO-B) and HP-B:** Responsible for managing teleconsultation logistics, including scheduling, platform access, and coordination with patients and other entities, while ensuring effective communication and care delivery.
	- **Challenges in Cross-Border Teleconsultation:**
	  - **Identification and Authentication of Patients:** A critical step in verifying the patient's identity and ensuring authorized access to MyHealth@EU services. Unlike traditional in-person consultations, cross-border teleconsultations require robust digital processes to maintain security and accuracy.
	  - **Patient Consent Management:** Ensuring that patients understand and provide informed consent for sharing their health data across borders, which may involve navigating varying legal and cultural frameworks.
	  - **Data Security and Interoperability considerations:** Addressing the complexities of securely exchanging sensitive health data between countries while maintaining interoperability across diverse national systems and infrastructures.

MyHealth@EU requirement catalogue	The MyHealth@EU Requirement Catalogue (version 8.0.0, Operation ready), which defines the business and functional requirements of MyHealth@EU services, was analysed to assess the impact of enabling the support for cross-border teleconsultation services on the existing requirements. To minimize the overall impact of the integration of cross-border telemedicine under MyHealth@EU, the key focus was placed on reusing existing requirements as much as possible, reducing implementation complexity and ensuring alignment with the existing operational processes and infrastructure. From the analysis, it was concluded that: - **6 requirements need amendment**, which is necessary to accommodate cross-border teleconsultation services under MyHealth@EU. These amendments primarily focus on enhancing functionality to support cross-border

telemedicine while maintaining compatibility with current MyHealth@EU operations.
- **1 new requirement** was identified as essential to enable the effective integration of cross-border teleconsultation services under MyHealth@EU. This **requirement addresses the creation**, **translation** and **exchange of a report across borders**, with essential information related to cross-border teleconsultation.

4 Stakeholder feedback requested for D9.1

To ensure D9.1 is complete and aligned with the stakeholder needs, WP9 seeks **specific feedback** mainly in section 3 - *Telemedicine Under Myhealth@EU Proposal*, where the main proposals are described. Therefore, the following areas are the main focus for the stakeholder consultation process:

01 General definitions

The document presents different definitions that were summarised for the use of this document. The main sources used for the definitions were the proposed EHDS regulation and MyHealth@EU. Other sources were used when available to complement missing definitions.

1	Feedback Requested
	• Are the definitions clearly and appropriately described for the context of this document?
	• What improvements would you like to propose?

02 Use Case description (section 3.1)

In section 3.1[3], **Table 1** – *Telemedicine under MyHealth@EU use case description, based on the structure of the eHN guidelines* – was derived having as a baseline the current structure of eHealth Network guidelines. It contains a brief explanation of the purpose, relevance, situation, context, main participants, and functional process steps. As mentioned, two main uses cases were proposed:

- A teleconsultation between a patient in their country of affiliation (Country A) and a health professional (HP) in another country (Country B).

- A teleconsultation between two HPs, one in Country A and the other in Country B, discussing a patient from Country A.

2	Feedback Requested
	• Are these use cases feasible and suitable for implementation?
	• How can the use cases be refined/improved?

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[3] Please note that minor changes in section numbering may occur. Therefore, kindly refer to the titles mentioned in this document.

- Functional Process steps:
    - Are the functional process steps for each use case clear and logically sequenced?
    - Do the steps for each use case adequately address the needs and objectives of cross-border teleconsultation under MyHealth@EU?
- Should additional scenarios or improvements be considered? If so, please provide examples and a corresponding justification.

03 Patient journey (section 3.2), responsibilities and requirements (section 3.3) and process description (section 3.3.2 and 3.3.3)

The deliverable is structured according to the main use cases, with section 3.3.2 focusing on the MyHealth@EU services for a Patient – Health Professional Teleconsultation and section 3.3.3 focusing MyHealth@EU services for a Health Professional – Health Professional Teleconsultation. The later section also reuses concepts covered in section 3.3.2, when applicable, due to existence of common elements. Both sections are intended to be subjected to the stakeholder consultation.

The patient journey presented in section 3.2 serves as an example to illustrate the integration 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. Section 3.3 provides a summary of the key responsibilities and requirements of the involved actors, along with potential proposals to address the gaps identified for enabling the use of MyHealth@EU services in a cross-border teleconsultation.

For both sections 3.3.2 and 3.3.3, a process description has been included, outlining each step and corresponding proposals to facilitate the use of MyHealth@EU services in the context of cross-border teleconsultations.

Main areas to be analysed by stakeholders:

- In section 3.3, *Table 2 – Summary of responsibilities, requirements and proposals by actors to enable MyHealth@EU services in a cross-border teleconsultation,* outlines detailed responsibilities, requirements-proposals for each actor involved in implementing and operating cross-border teleconsultation services under MyHealth@EU. It is important to obtain feedback regarding this table, given that it is intended to give the reader a clear and detailed definition of the tasks of each actor involved in the cross-border teleconsultation.
- **Blue boxes** – In addition to the specific feedback areas outlined in this document, we seek validation particularly for the blue boxes present throughout the **process description section**. These blue boxes highlight proposals for mechanisms and requirements designed to enable the uptake of cross-border telemedicine services under MyHealth@EU. The **key proposals** include:
    - Securely transmitting the **PIN document** to the patient during scheduling phase via email or other secure methods, with patient acknowledgment.
    - For **patient consent**, three options are proposed:
        - Real-time identification and authentication;

- Consent via an electronically signed form;
- Consent managed by Country A's NCP and verified by Country B.

o **General observations:** these proposals levarage **eIDAS** and **EUDI Wallet** for secure, interoperable patient identification and authentication remotely cross-borders.

3	Feedback Requested

- **Actors** involved in the teleconsultation:
    - Are all relevant actors and their roles clearly identified?
    - Are there any key actors missing from the process?

- **Responsibilities**:
    - Are the responsibilities of each actor well-defined and appropriate?
    - Are there overlaps or gaps in responsibilities that need addressing?

- **Requirements and Process steps**:
    - Are the process steps for each use case clear and logically sequenced?
    - Do the steps for each use case adequately address the needs and objectives of cross-border teleconsultation under MyHealth@EU?

- **Proposals**:
    - Are the proposed solutions for the instruction's availability for patients, HP and HCPO practical?
    - Are the proposed solutions for PIN document transmission and patient consent practical?
    - Are the proposed collecting, storing and sharing ISM attributes feasible?
    - Are the proposed solutions for patient identification and authentication feasible? Do you agree with the proposal to use the eIDAS-compliant mechanisms and EUDI Wallet? If not, what alternatives should be considered?
    - Which patient consent option is most feasible, and why? Are there other approaches you would recommend?

- **General questions:**
    - Have the primary challenges in cross-border teleconsultation under MyHealth@EU been identified and addressed? If so, please provide examples and the corresponding justification.
    - Should additional solutions be proposed? If so, please provide examples and the corresponding justification.

04 Sharing of the information generated during the teleconsultation back to the patient's country of affiliation (section 3.3.4)

The information generated during a cross-border teleconsultation can be highly valuable for inclusion in the patient's EHR. The data that falls under essential categories such as diagnoses, treatment plans,

ePrescriptions, and imaging results, as described in Article 14 of the upcoming 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.

4	Feedback Requested
	• Are the proposals for the **creation, translation, display, sending back, and storage of the teleconsultation report** effective and aligned with the needs of cross-border teleconsultation under MyHealth@EU? • Do you agree with basing this report on the eHN guidelines Hospital Discharge Report, as it allows to share a report from country B to country A?

05 Analysis of eHDSI Requirements to support cross-border teleconsultation (section 3.4)

The MyHealth@EU Requirement catalogue (version 8.0.0, Operation ready), which defines the business and functional requirements of MyHealth@EU services, was analysed to assess the impact of enabling the support for cross-border teleconsultation services on the existing requirements. Given the evolving nature of telemedicine and the dispositions in the future EHDS regulation, it is crucial to adapt the existing MyHealth@EU framework to support cross-border teleconsultation.

Table 3 - *New and updated requirements to support cross-border telemedicine services under the MyHealth@EU infrastructure*, provides a summary of the new and updated requirements necessary to support cross-border telemedicine services under the MyHealth@EU infrastructure. On the other hand, **Annex IX** – *Overview of MyHealth@EU eHDSI Requirements* outlines the analysis and associated impact of cross-border teleconsultation support on the existing requirements.

5	Feedback Requested
	• Are the proposed changes to the eHDSI framework feasible and sufficient to support telemedicine? • Are there additional requirements that should be considered to meet the needs of cross-border teleconsultation? • Does the analysis adequately address the impacts on current MyHealth@EU services?

5   Contacts for questions

- **For questions related to the organisation of the consultation**: please ask the representative from your country who shared the information and documents on the stakeholder consultation.

- **For questions related to D9.1 content**: please reach out to the following Xt-EHR WP9 representatives:

o   WP9 Leaders (SPMS): internationalaffairs@spms.min-saude.pt