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

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D9.3 –Requirements for Large-Scale Uptake of Telemedicine Service Stakeholder Consultation Briefing Supporting Document

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1 Stakeholder Consultation Target Groups

As part of Xt-EHR strategy, selected tasks and outputs undergo stakeholder consultation to ensure co-creation and a practical approach to build up a mutual understanding for the adaptation of all the involved parties to European Health Data Space (EHDS) provisions and aims. This work is closely related to MyHealth@EU[1] services within the scope of the EHDS regulation[2]. Consequently, specific terminologies associated with these services are used throughout this work.

This document intents to engage stakeholders with expertise on the following topics:

1. Telemedicine services
2. MyHealth@EU services
3. EHDS regulation (Commission and EU Member States representatives)
4. Legal aspects (e.g., knowledge in EHDS)
5. Policy making

[1] MyHealth@EU - Flyer addressed to patients and health professionals [available here]
[2] Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 (Text with EEA relevance). [available here]

2 Overview of Work Package 9

WP9 – *Telemedicine under MyHealth@EU in alignment with the 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.

Task 9.2 will lay the groundwork for large-scale uptake of telemedicine services and contribute to the EHDS as referred to in Articles 3-9, 17, 22, and 24 of the EHDS regulation.

To achieve this, one report will be developed:

- D9.3 Requirements for Large-Scale Uptake of Telemedicine Service

This document focuses on the stakeholder consultation for D9.3

3 Overview of Deliverable 9.3 Requirements for Large-Scale Uptake of Telemedicine Service

D9.3 – Requirements for Large-Scale Uptake of Telemedicine Services lays the groundwork to accelerate large-scale uptake of telemedicine services, with an emphasis on cross-border scenarios, by collecting information regarding existing pilots and Member States' experience in telemedicine services. The deliverable assesses validation and reimbursement best practices while also taking into consideration interoperability between telemedicine solutions and Electronic Health Records (EHRs).

For this purpose, this work focuses on mapping the current policy, legal and ethical challenges faced by EU telemedicine systems, along with identifying relevant best practices across Member States. Based on this comprehensive assessment, the deliverable provides conclusions in the form of specific requirements and policy interventions needed to accelerate the large-scale uptake of telemedicine services, particularly in cross-border scenarios, in order to support the effective implementation of the EHDS regulation.

The methodology implemented includes:

Methodology Approach	**Summary of the representative findings**
Landscape Analysis of validation and reimbursement practices of telemedicine across EU countries[3].	According to the landscape analysis research, several significant reimbursement frameworks exist across European countries that could inform cross-border telemedicine implementation: • Fee-for-Service Frameworks, where digital

[3] References from research documents are available in D9.3 document

	health solutions are reimbursed per use cycle. This approach is implemented in countries like Germany (through its "Fast-Track" process for digital health applications) and France (with its PECAN early access program). • Integrated Care Pathway Frameworks, where digital health is incorporated into broader healthcare processes. This approach is exemplified by Belgium (and Israel), which reimburse the clinical pathway rather than the digital solution itself. • Payment Parity Systems ensure equivalent compensation regardless of delivery method. Italy has implemented this approach across all regions with standardized telehealth tariffs. Payment parity removes financial disincentives for digital care delivery, making it particularly valuable for encouraging provider adoption in cross-border scenarios. • Cross-Regional Reimbursement Models addressing compensation when health care crosses jurisdictional boundaries. Sweden's 2019 recommendations for compensating regions when citizens seek digital care outside their home region offer a practical prototype that could be scaled to cross-border contexts. • Provisional Coverage Models supporting innovation while evidence develops. France's PECAN program and the Netherlands' "promising types of healthcare" financing provide temporary coverage during evidence development.
Cross border survey gathering expert insights on • Telemedicine and Cross-border telemedicine services implementation, • Validation methodologies, • Reimbursement practices, • Legal and regulatory barriers.	• Highlighted successful national examples such as pediatric teleconsultations in Latvia, advanced teleradiology in Germany, post-COVID primary care adaptations in Spain, and emergency remote care in Lithuania etc. • Provided cross-border telemedicine initiatives, projects or pilots. The initiatives eCAN, JADECARE, eHAction, xShare, RENEWING HeALTH, Thalea, epSOS and EDiHTA collectively drive innovation in Europe’s digital health landscape. The MAST framework offers a structured approach to evaluating telemedicine applications, providing critical evidence to inform cross-border healthcare policy. Projects like the Portugal-Spain Electronic Prescription Pilot

	and the European Commission's Digital Health Infrastructure facilitate seamless access to electronic prescriptions and patient data across national borders, ensuring continuity of care for citizens on the move. Initiatives such as POCTEP and Telemedicina aim to expand telemedicine access in remote and underserved regions, especially in the Euro-Mediterranean area. Meanwhile, the Cross-border Cooperation Program between Serbia and Montenegro reflects the EU's commitment to enhancing healthcare resilience and fostering collaboration with neighboring non-EU countries. • Provided information regarding the validation and reimbursement practices of telemedicine services. The EU Cross-Border Healthcare Directive (2011/24/EU) supports reimbursement for telemedicine services across Member States, as seen in Latvia, where it enables cross-border consultations. In the Netherlands, validation is managed through platforms like Zorg bij Jou and digizo.nu. Lithuania's success hinged on a dual reimbursement model, compensating both the consulting and requesting hospitals, ensuring sustainability of telemedicine services. • Provided information regarding legal and regulatory barriers to implementing telemedicine, including GDPR compliance and data privacy concerns, non-harmonized professional licensing, and unclear liability and jurisdiction frameworks. Inconsistent reimbursement policies and regulatory fragmentation across member states further complicate implementation. Additionally, the lack of dedicated legal frameworks in some countries, divergent prescription regulations, and ethical ambiguities around informed consent pose significant challenges to seamless, secure, and equitable cross-border digital healthcare delivery.
Expert Interviews providing qualitative data on policy, legal, and interoperability aspects.	Expert interviews will be implemented with the scope to provide valuable insights into existing telemedicine pilots, validation and reimbursement practices, as well as key challenges related to telemedicine and cross-border telemedicine services. Specific countries will be targeted such as Belgium, France, Estonia, Sweden, and Norway.

Cross-border telemedicine scenarios were developed to form the foundation for identifying the requirements necessary for implementing telemedicine services across EU Member States. These scenarios represent the most common and impactful use cases that the MyHealth@EU infrastructure must support to enable effective cross-border healthcare delivery.

1. **Cross-border Teleconsultation**

Scenario A: "A patient with a rare autoimmune condition in Portugal contacts a healthcare professional (HP) specializing in the condition in Sweden via a telemedicine service platform. The HP reviews the patient's medical information, which is accessible through the MyHealth@EU, offers a clinical assessment, and prescribes a customized care plan. The prescription is electronically sent to a pharmacy in the patient's home country where it is recognized."

2. **Cross-border GP Communication**

Scenario B: "A general practitioner (GP) in Italy encounters a complex cardiac case and initiates a remote consultation with a cardiologist in Germany through a cross-border telemedicine platform. The German specialist reviews the patient's electrocardiogram (ECG) data remotely, provides diagnostic insights, and recommends further diagnostic tests. The GP incorporates this specialized guidance into the patient's care plan without requiring an in-person referral to the specialist."

3. **Cross-border Telemonitoring** via MyHealth@EU

Scenario C: "A patient with chronic heart disease in Germany is equipped with a smart health device that continuously monitors heart rate and blood pressure. The medical device transmits real time health data to a telemedicine platform accessible to the patient's cardiologist in France through the MyHealth@EU. When abnormal signs are detected, an automatic notification alerts the French specialist, enabling remote adjustments to the patient's care plan in coordination with German healthcare providers."

4. **Cross-border Emergency Monitoring**

Scenario D: "A Finnish tourist in Spain experiences severe chest pain while travelling. The tourist's wearable smart health device detects irregular cardiac activity and automatically sends an alert with vital sign data to Spanish emergency medical services. When the patient arrives at the hospital, Spanish clinicians access the patient's medical history through the EHDS infrastructure. The instant access to health records enables the healthcare team to quickly evaluate the patient's condition and provide appropriate treatment."

The list of requirements stems from the analysis of cross-border scenarios, recommendations gathered from MS and also supported by the EHDS regulation[4]. The requirements are structured in the following three batches.

1. **<u>Critical Policy Requirements</u>**
   - 1.1. Equal Recognition of Cross-Border Telemedicine Services
   - 1.2. Interoperability Specifications
   - 1.3. Standardized Reimbursement Mechanisms
   - 1.4. Implementation of GDPR-Compliant Data Processing Framework
   - 1.5. Definition of Liability Allocation

2. **<u>Operational Governance Requirements</u>**
   - 2.1. Establishment of National Contact Points for Telemedicine
   - 2.2. Patient Data Access and Rights
   - 2.3. Healthcare Professional Training Programs
   - 2.4. Implementation of Quality Assurance Frameworks

[4] Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 (Text with EEA relevance). [available here]

2.5. Adherence to EHDS Enforcement Mechanisms

3. **Enhancement Requirements**
   3.1. Data Transmission and Sharing Mechanisms
   3.2. Patient Control and Privacy Mechanisms
   3.3. Terminology and Definition Standardization
   3.4. Framework for Secondary Use of Health Data

Each sub-chapter of the above, outlined requirements is structured followingly:

Requirement Description	Provides a comprehensive explanation of the requirement's purpose and significance in the context of cross-border telemedicine services and the EHDS regulation.
a. Objective	Outlines the specific area of application, boundaries, and key stakeholders affected by the requirement, defining its strategic and operational context.
b. Requirements	Details the specific, actionable mandates that must be implemented to ensure compliance with the EHDS regulation and support effective cross-border telemedicine service delivery.
c. Policy Interventions	Defines the policy actions, regulations, and strategic measures needed to implement the requirement.
d. Details	Provides additional in-depth information, including implementation considerations and potential challenges.

4 Stakeholder feedback requested for D9.3

To ensure that the description of requirements and their implementation aspects comply with cross-border telemedicine service standards and can be effectively implemented by healthcare providers following the adoption of the EHDS regulation, WP9 seeks specific feedback from participants regarding the requirements. Therefore, the following area constitute the main focus for the stakeholder consultation process:

01 Cross-border scenarios (section 5.1)

Section 5.1 presents cross-border telemedicine scenarios that demonstrate potential applications of MyHealth@EU in real-world healthcare contexts. These scenarios serve as practical examples to identify requirements and inform policy recommendations for large-scale telemedicine adoption within the EHDS framework.

1	Feedback Requested
	• Do the identified cross-border telemedicine scenarios comprehensively cover the most important use cases? • Are there additional cross-border scenarios that should be considered to ensure comprehensive requirements development? • For each scenario, are there specific challenges or considerations that should be emphasized?

02 Requirements for Large-Scale Uptake of Telemedicine Services (section 5.2)

Section 5.2 presents the analysis of requirements[5] to accelerate the large-scale uptake of cross-border telemedicine services, alignment with Articles 3, 8, and 13 of the EHDS regulation proposal. This analysis identifies the necessary policy, governance, and enhancement interventions to lay the groundwork for widespread implementation.

2	Feedback Requested
	• Are the three main branches of requirements (Critical Policy Requirements, Governance Requirements, and Supplementary Requirements) sufficient, or should additional categories be considered? Note that technical requirements will be addressed in D9.2. • Are these requirements clearly and appropriately described? Please provide comments to improve the clarity and categorization of requirements. • Are there any requirements that are essential to accelerate the large-scale uptake of telemedicine services that are missing? If yes, provide the description of such requirement in the following structure: a) its objective, b) description of its mandatory aspects, c) policy interventions, d) details.

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

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 D9.3 content**: please reach out to the following Xt-EHR WP9 representatives: admin@3ype.gr, elitrigazi@gmail.com