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

Call: EU4H-2022-JA-IBA/Joint Actions 2022, Topic: EU4H-2022-JA-09
Type of Action: EU4H-PJG/EU4H Project Grants, Proposal number: 101128085

D8.3 – EHDS Guidelines for app developers of wellness applications in Europe
Stakeholder Consultation
Briefing Supporting Document

2025, 26 February

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1 Introduction

European Health Data Space (EHDS) Regulation is a significant regulatory initiative by the European Union aiming to enhance accessibility and utilization of health data across member states. Its core objectives are to improve individual access to electronic health data (EHD) and to facilitate the sharing of such data for care provision as well as making such data accessible for secondary use for research and innovation. The EHDS aims to create a trusted environment for the secure access and processing of a wide range of health data. It builds upon existing frameworks such as the General Data Protection Regulation (GDPR), the Data Governance Act, the Data Act, and the Network and Information Systems Directive, maintaining or enhancing rights under the existing legislation and providing specific sectoral rules tailored to supporting easier access to health data to support care, health improvement and research.

In January 2025, the European Council adopted the EHDS Regulation, marking a pivotal step toward its implementation. This regulation establishes clear rules for the use of health data to enhance healthcare delivery, research, innovation, and policymaking. It is due to enter into force in March 2025 and into implementation in a phased approach from March 2027.

A significant aspect of the EHDS is the establishment of common standards and compliance rules to ensure interoperability of data and digital solutions for healthcare across EU member states. This includes mandating that all electronic health record systems (EHR systems) align with the European electronic health record exchange format (EEHRxF), thereby facilitating seamless data exchange.

WP8 (Work Package 8) materialized in the frame of the Xt-EHR project is aiming to support the conformity schemes that are to be developed for the implementation of EHDS provisions.

2 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 EHDS provisions and aims.

The main stakeholder groups that are addressed in the current deliverable are the following:

1. Regulators (Commission and EU Member States representatives)
2. Digital health agencies and market surveillance authorities of the EU Member States
3. Industry-market representatives including wellness application[1] manufacturers

This document intends to engage stakeholders on the following topics:

1. Explanatory notes- elaborating on EHDS provisions and requirements specifically for wellness applications
2. Currently applied quality and compliance framework - criteria of CEN ISO/TS 82304-2 and labelling process (Label2Enable project)- other regulatory provisions affecting the market

[1] For the purpose of the current work. “Wellness application” means any software, or any combination of hardware and software, intended by the manufacturer to be used by a natural person, for the processing of electronic health data, specifically for providing information on the health of natural persons, or the delivery of care for purposes other than the provision of healthcare.

3. Essential parts of the Guidelines for wellness app manufacturers (content list, reference standards, tools and examples).

3 Overview of Work Package 8 and tasks

For the accomplishment of the overall targets of WP8, the main element is to develop and establish guidelines for manufacturers in support of the upcoming EHDS regulation and more specifically in support of chapter 3, Electronic Health Record (EHR) systems and wellness applications, concerning conformity of EHR systems to the requirements deriving from the EHDS and from existing frameworks.

WP8 consists of the 3 following tasks:

1. T8.1 Classification and functional profiles of EHR systems focusing on reviewing functional models for EHR systems (such as ISO/HL7 10781:2015 EHR-S FM or similar) in order to propose a series of profiles to be adopted to support the certification and conformance of EHR systems and labelling of wellness applications. EHR profiles will be proposed in alignment with EEHRxF and the specifications and guidelines delivered in Xt-EHR WP5, 6 and 7.
2. T8.2 Assertions for Conformity Assessment, aiming to conclude on
   - a set of testable assertions that can be added to test tools necessary to support the interoperability certification.
   - means of verification such as checklists for other types of essential requirements for conformity.
3. T8.3 EHDS Guidelines for developers of wellness applications in Europe.
   Task 8.3 will review and evaluate ongoing initiatives on labelling processes such as the EU-funded project Label2Enable.
   In particular, it will review and evaluate
   - the applicability of the interoperability and security assessment and specification documented in ISO/TS 82304-2 in providing the basis for the voluntary labelling scheme for wellness applications,
   - interoperability requirements under EHDS when applications are designed to allow upload of data from the application to the EHR or to allow access to patient summary data on the specific consent of the patient,
   - the results of Label2Enable and see its relevance to the requirements set out in the EHDS Regulation (Label2Enable will provide a scoring system, and a conformity assessment scheme based on ISO/TS 82304-2).

In the frame of D8.3 (Deliverable 8.3) Guidelines for wellness applications in Europe will be developed considering the EU regulations in place. The scope of this guideline is to support the development of wellness applications according to interoperability and security requirements under ISO standards but also to function as a checklist of actions to be performed to allow applications to be used within the EHDS environment in a secure and ethical manner.

4 Impact of EHDS on wellness applications and health data exchange

The EHDS enables access to health data for patients and healthcare providers through electronic health records (EHR), patient summaries etc.

Data interoperability: Wellness applications that are designed and marketed to collect personal health data that could, at the request of the patient, be integrated into EHRs and Patient Summaries, are required to conform to the

interoperability and security requirements set out in the EHDS Regulation. The data from such applications may serve an important role for continuous health monitoring and personalized care**.**

With clear, standardized guidelines wellness applications could operate more effectively across EU countries, allowing users to access their data seamlessly regardless the time and the place. This could help users track their health progress and keep their wellness apps synchronized with the systems of their healthcare providers.

Data Privacy and Security: Wellness applications that are designed to interact with EHR systems health data must comply with EHDS provisions on data protection which reflect the duties of data controllers and processors set out in the GDPR, which is important for fostering trust among users.
New Service Models: Wellness applications might be able to expand their service models by offering more comprehensive, **healthcare-adjacent services**, such as virtual health coaching on health promotion and management of health conditions. However, as this will require access to the patient's EHR and potentially also to healthcare professional's decision support, triage or other support services, it is crucial that application manufacturer can build interoperability with such tools directly into the application design.

Main areas that are relevant to the scope and purpose of D8.3. for wellness application manufacturers:
Chapter 2 - Background – 2.1. Definitions
Chapter 3 - Existing framework evaluation and Gap analysis
Chapter 4 - Main requirements- Interpretation of EHDS issues concerning major stakeholders. Explicitly describes the provisions of EHDS about wellness applications and the relevant requirements that apply for these products and their interoperability aspects with EHR systems. Based on the analysis that was conducted on the finally approved version of EHDS (2024_11_27 EHDS_0140COR01_EN) the requirements and elements of the Regulation related to wellness applications are hereby summarized. This is an attempt to identify the framework for the implementation acts and substantial guidance that must be elaborated in the context of the manufacturers' guide.
In this chapter the EHDS relevant paragraphs and articles are elaborated, categorised into the following areas:

a) Scope/ Definitions/ Health Data holders
b) EU member states responsibilities
c) Registration- EU Database
d) Competencies (common specifications and Procurement standards)
e) Conformity assessment/ Certification- labelling
f) Data primary use
g) Data secondary use
h) Data portability
i) Compliance elements derive from common specifications and Annex II, including:
    a. Interoperability (interface/ …)
    b. Security (logging, authorization access rights)
j) Information to users about wellness application compliance with EHDS (as per Art 48)
k) Capacity of users to choose which data is shared with the EHR system (as per Art 48)

Requirements are also categorized based on the party that is addressed through each requirement. The parties/ stakeholders to whom the references concern, are the following:

- EU Commission
- Member States

- Digital health authorities/ market surveillance authorities
- Wellness applications' (claiming interoperability) manufacturers

Chapter 5- Guidelines- proposals: The proposed content list of the Guidelines is hereby presented.

5 Stakeholder feedback requested for D8.3

The requested feedback is addresed to stakeholders with knowledge on the following topics:

- MyHealth@EU services,
- Health and wellness apps regulatory conformance (i.e. MDR, AI Act, ISO 1701),
- Health system Interoperability and Security (Including Logging),
- Legal experts (e.g., knowledge in GDPR, MDR, eIDAS, and EHDS),
- Manufacturing of health and wellness apps.

1	**Feedback Requested (General issues)**

- **Addressed stakeholders - Responsibilities**:
  - Are the responsibilities as described at the different areas - (a) to (i) – clear and understandable?
  - Are there overlaps or gaps in responsibilities that need addressing?
- **Explanatory Notes - Points for discussion:**
  - Which are the major points that should be clarified? Which are the requirements that should be elaborated in a more detailed and specified manner?
  - Are the references provided adequate to clearly address the requirements of the EHDS Regulation? At which points do you need more references and/ or explanations?
- **Guidelines content:**
  - Are there any other topics- points that you would like to be added in the Guidelines' content list?
  - Does the provided example reflect in a clear and understandable manner the meaning of the relevant requirement?
- **Important points to be clarified within the deliverable/Guidelines. Are the following points enough or what else is needed?**
  - Is my product within the scope of a wellness application within the EHDS?
  - Which EHDS requirements must I design and implement into my wellness application?
  - Which specifications must I implement to fulfil all EHDS requirements which are relevant for my wellness application? How should I implement harmonised components in my wellness application?
  - What do I have to do to demonstrate compliance to EHDS essential requirements?
  - How do I further evolve my wellness application?
  - How do I make use of system integrations or national/ regional infrastructures to comply with the requirements?

2	Feedback Requested (Specific issues)

- Are you aware of a certification scheme in your country for wellness applications?
- Are you familiar with the results of Label2Enable project? Could it become (after amendment to reflect interoperability & logging requirements of the EHDS Regulation) the criteria framework to be utilised as a *mandatory* certification scheme to be applied by Certification Bodies respectively accredited in the EU Member States?
- Do you have any suggestion of how the compliance with EHDS Regulation Article 36 and Annex II requirements could be checked depending on the relevant authorities active in your country in this area (as per the provisions of 47-7)?
- Is there a registration process (national official database) in your country for health and wellness apps? Does this differentiate between health and wellness app, if so, how? Is such differentiation related to applicability of Medical Device Regulation (Relevant reference in article 49 for the registration of applications in the EU Database)?
- Should additional Implementing Acts by the EU be considered or additional national level legal measures? If so, please provide examples and a corresponding justification (i.e. national legal framework for related issues).
- Are the proposed specifications and directions feasible and sufficient to support interoperability of wellness apps with EHR systems?

6 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 D8.3 content**: please reach out to the following Xt-EHR WP8 representatives at konavl570@gmail.com