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

Proposal number: 101128085

D8.3 – EHDS Guidelines for app developers of wellness applications in Europe

Stakeholder Consultation Briefing Supporting Document

2025, 5, November

(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.

Author(s)

Name	Surname	Country	Organisation	Role
Haralambos	Karanikas	Greece	IDIKA	AE
Angeliki	Katsapi	Greece	IDIKA	AE

ABBREVIATIONS

EHDS	EUROPEAN HEALTH DATA SPACE
EHD	ELECTRONIC HEALTH DATA
GDPR	GENERAL DATA PROTECTION REGULATION
EEHRXF	EUROPEAN ELECTRONIC HEALTH RECORD EXCHANGE FORMAT
EHR	electronic health record

TABLE OF CONTENTS

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, maintain 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. The Regulation establishes clear rules for the use of health data to enhance healthcare delivery, research, innovation, and policymaking. It entered into force March 26, 2025, and will be implemented 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 align with the European electronic health record exchange format (EEHRxF), thereby facilitating seamless data exchange.

WP8 (Work Package 8) of the Xt-EHR project is aiming to support the conformity schemes that are to be developed for the implementation of EHDS provisions. To achieve the overall objectives and tasks of WP8, a key focus is the development of guidelines to support the EHDS Regulation. The current deliverable *"D8.3 EHDS Guidelines for app manufacturers of wellness applications in Europe"* includes structured guidelines for wellness application manufacturers to comply with the requirements deriving from the EHDS Regulation.

To arrive there, the main goals pursued by this deliverable, are the following:

- To evaluate the applicability of the CEN-ISO/TS 82304-2 quality requirements relating to interoperability and security in providing a basis for the labelling scheme for wellness applications [Article 47 to 49], (Chapter 4)
- To analyse the results of Label2Enable, in particular the handbook for CEN-ISO/TS 82304-2, and see its relevance based on the adopted EHDS Regulation to propose guidelines for wellness applications considering the EU laws in place, to support the development of wellness applications according to interoperability and security requirements under ISO standards but also as a checklist of actions to be performed to operate in a secure and ethical way within the European Health Data Space. (Chapter 5)

Additionally, this deliverable describes the role of wellness applications in the EHDS (Chapter 2), introduces CEN-ISO/TS 82304-2 and Label2Enable, listing applicable legislations, standards and ongoing initiatives and the extent to which these informed CEN-ISO/TS 82304-2 and the Label2Enable handbook for CEN-ISO/TS

82304-2 (Chapter 3), and provides further guidance for next steps in the implementation based on the combined analysis of all of the above. (Chapter 6)

2 STAKEHOLDER CONSULTATION TARGET GROUPS

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. Patients and consumers (who have a right to insert data in their own electronic health record)
4. Healthcare professionals (who may consider this patient-provided data) and their medical societies (who may provide guidance as to use of patient-provided data)
5. Industry-market representatives including wellness application manufacturers and EHR manufacturers
6. Standard Development Organisations (as the approach aims to build on existing standards)

3 FIRST TO FINAL STAKEHOLDER CONSULTATION

The development of the specifications under the Xt-EHR Joint Action is firmly rooted in a multi-stakeholder approach. The deliverable reflects extensive consultation with national authorities, healthcare professionals, patient and consumer representatives, public health organisations, medical societies, industry experts, Standard Development Organisations, and other key actors. Their feedback to the first draft of D8.3 has been instrumental in shaping the priorities, technical specifications, and governance recommendations presented in this document. The first draft version of the deliverable distributed in March 2025 has been significantly changed.

In particular:

1. Chapters 1, 2 and 3 of the first version restructured and with clear reference only to the important information needed. In this final version there is a short introduction in chapter 1 for the purpose of the deliverable. The role of wellness applications in the EHDS (Chapter 2), introduces CEN-ISO/TS 82304-2 and Label2Enable, listing applicable legislations, standards and ongoing initiatives and the extent to which these informed CEN-ISO/TS 82304-2 and the Label2Enable handbook for CEN-ISO/TS 82304-2 (Chapter 3).
2. Chapter 4 had major changes in order to evaluate the applicability of the CEN-ISO/TS 82304-2 quality requirements relating to interoperability and security in providing a basis for the labelling scheme for wellness applications [Article 47 to 49].

3. Chapter 5 is new. The previous version had some suggestions but now we analyse the results of Label2Enable, in particular the handbook for CEN-ISO/TS 82304-2, and see its relevance based on the adopted EHDS Regulation to propose guidelines for wellness applications considering the EU laws in place, to support the development of wellness applications according to interoperability and security requirements under ISO standards but also as a checklist of actions to be performed to operate in a secure and ethical way within the European Health Data Space. Sections 5.3 & 5.4 – Contains the Manufacturer Guidelines.
4. Chapter 6 is new. Provides further guidance for next steps in the implementation based on the combined analysis of all of the above.

4 STAKEHOLDER FEEDBACK REQUESTED FOR D8.3

We would appreciate your feedback in this final round of consultation, with kindly specific attention for:

1	**Feedback Requested (All & minimum especially for manufacturers)**
	• **Section 2.2**: ○ The flowchart and additional information, in particular if they provide sufficient clarity if your product is a wellness application subject to EHDS interoperability. If not, where is more clarity needed? ○ More suitable definitions of software and hardware that we should be aware of for reference. • **Section 5.3 & 5.4:** • Understandability of the guidelines. • Automated assessments for the applicable requirements you may be aware of. • Applicability of types of EHR systems for which manufacturers of wellness applications can (or cannot) claim interoperability. If so, is there a standardised list of types of EHR systems available?

2	**Feedback Requested (All)**
	• **Section 2.2**: ○ The flowchart and additional information, if they provide sufficient clarity if your product is a wellness application subject to EHDS interoperability? If not, where is more clarity needed? • **Section 3.4:** ○ If applicable, which standard would require further analysis, and if so, which part for what reason?

- **Section 3.5:**
  If applicable, which ongoing initiative would require further analysis, and if so, which part for what reason?
- **Section 4.2:**
  - The recommended features / best practices that originated in part from the first consultation.
- **Section 4.2.2**
  - The interpretation of mutatis mutandis and related reasoning, especially for Annex II Section 1.1 and 1.2 of the EHDS Regulation as further explained in Section 4.2.3.1 and 4.2.3.2 of the deliverable.
- **Section 4.2.3.3:**
  - How wide interoperability, safety and security features should be interpreted and why?
- **Section 4.2.3.4**
  - How wide reliable and secure should be interpreted and why?
- **Section 4.3:**
  - The applicability of the European ethical principles for digital health adopted by the eHealth Network on 26 January 2022.
- **Section 5.2:**
  - Perspectives to consider regarding an abbreviated CEN-ISO/TS 82304-2 label in the light of Recital 50 of the EHDS Regulation.
  - Perspectives to consider about specificity / understandability to users of the categories of health data for which interoperability was claimed in the label (e.g. “User can insert in their own electronic health record: Sleep data, mood data”).
- **Section 6:**
  - Your perspectives on the suggestions. Anything else to be considered?

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 D8.3 content**: please reach out to the following Xt-EHR WP8 representatives Haralampos Karanikas (h.karanikas@gmail.com) and Angeliki Katsapi (angeliki.katsapi@gmail.com)