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

D8.2 – EHR Conformity Assessment Scheme - Assertions document

Stakeholder Consultation
Briefing Supporting Document

2025, July 04th

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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. 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.

Work Package 8 (WP8) is aiming to support the conformity schemes in collaboration with WPs 5-7, for the implementation of EHDS provisions.

The current deliverable D8.2 establishes the basis for a Conformity Assessment Framework (EHDS-CAS) for EHR systems with respect to specifications and requirements that ensure compliance with the EHDS, particularly with regards to aspects of interoperability, security and logging of healthcare professionals, as defined in Xt-EHR WPs 5-7.

The main aspects that are covered in this deliverable are the following:

- The governance framework of the EHDS-CAS;
- The rules, procedures and methodology for performing conformity assessment;
- Examples of testable assertions that can be added to test tools;
- Examples of means of verification (checklists) for other types of requirements.

This set of evaluation and testing criteria will enable the assessment of the conformity of EHR systems across Europe, using a pragmatic, readiness-based approach according to the intended use of the EHR systems.

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 EHR systems' manufacturers

This document intends to engage stakeholders on the following topics:

1. Elaborating on EHDS provisions and requirements specifically for EHR systems' interoperability in the priority areas.
2. Existing compliance frameworks and their governance schemes.
3. Technical aspects for the implementation of EHDS requirements' compliance framework (testing environments and verification processes).

3 Overview of WP8 and tasks

For the accomplishment of the overall targets of WP8, the primary goal is to develop and propose guidelines in support to the EHDS Regulation (chapter 3, EHR systems and wellness applications), concerning the conformity of EHR systems.

WP8 consists of the 3 following tasks:

a) *T8.1 Classification and functional profiles of EHR systems*

This task focuses on reviewing Functional Models (FM) for EHR systems (such as ISO/HL7 10781:2015 EHR-S FM or similar) 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.

b) T8.2 Assertions for Conformity Assessment

The main purpose of this Task is to elaborate on the elements of the conformity assessment scheme in accordance with the EHDR requirements.

c) 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 the frame of D8.3, guidelines for wellness applications in Europe will be developed considering the EU regulations in place.

4 Deliverable 8.2: EHR Conformity Assessment Scheme - Assertions document

The proposed CAS builds upon recognized international standards, methodologies, and best practices, such as EURO-CAS[1]. By leveraging these foundations, the EHDS CAS ensures the integrity, interoperability, and ongoing improvement of EHR systems and Health applications. It supports manufacturers in meeting EHDS Regulation obligations through structured self-assessment, while fostering trust, innovation, and a harmonized approach to compliance and conformity assessment across Europe.

[1] https://cordis.europa.eu/project/id/727028/results

The scheme guarantees that any EHR system claiming conformity with the EHDS Regulation can seamlessly interoperate with any other such system—regardless of the assessing body or location—ensuring a cohesive, interoperable digital health ecosystem.

D8.2 focuses on updating the governance (initial version in collaboration with WP4) and defining the content of a future CAS. The CAS comprises two distinct parts, one focusing on the governance of the conformity assessment scheme (how to apply conformity assessment in the context of the EHDS Regulation), and the other focusing on the CAS content (testable assertions, test tools and means of verifications).

The CAS governance model ensures a) progressive adoption to allow EHR vendors to be able to adopt, test and incorporate EEHRxF in their products, b) comply with EHDS Regulation regarding the self-assessment procedures and c) ensure equitability of member states to incorporate the governance model.

The CAS content as testable assertions and means of verifications is driven by several sources such as previous established CAS models (EURO-CAS, IHE CAS, Label2Enable CAS, etc), WP5, WP6 and WP7 set of specifications, HL7 EHR functional model requirements. All those assertions are described in a way that they can be tested and verified to allow an impartial self-assessment CAS. Testable assertions cover both interoperability, security and logging specifications.

The CAS governance enables a versioning of the CAS content so that testing procedures and process can evolve based on the maturity models (i.e. Xt-EHR maturity model) allowing the release of versions of the testable assertions having required and optional assertions that can evolve over time to allow gradual adoption by Member States and the vendor's community across the European Union. The governance model includes change management processes and waves in a similar approach with the established processes for the myHealth@EU services. Means of verifications and test plans are based on proposing an evolution of the myHealth@EU testing platform.

Based on D8.2, we are aiming to engage EU Member States and technical experts in clarifying key elements of the EHR CAS in the frame of the stakeholders' consultation process, there are three focused areas structuring the relevant discussions:

- The governance for the CAS,
- The technical aspects of the compliance, and
- The implementation of digital testing environments.

5 Stakeholder feedback requested for D8.2

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

- MyHealth@EU services,
- Data Governance Act,
- Health systems' Interoperability and Security (Including Logging),
- Cybersecurity Regulative provisions
- Interoperability specifications and testing laboratories/conformity assessment

Feedback Requested

- How do you assess the proposed governance model of the EHDS Conformity Assessment Scheme (e.g. role of the EHDS Board/Conformity Assessment Coordination Committee (CACC) national supervisory entities, and testing environments)? What adjustments, if any, would be required to align it with your national regulatory structures?
- Does the structure of testable assertions, as defined in D8.2, sufficiently reflect the essential EHDS requirements (Annex II), including interoperability, security, and logging? Are there areas where further specification or national customization is necessary?
- Are the proposed accreditation criteria and technical requirements for digital testing environments (e.g. ISO/IEC 17025/17020 compliance, use of simulators and validators) sufficient and realistic for national implementation? Are there existing national facilities that could be leveraged?
- How do you view the proposed versioning and change management process (e.g. specification updates, re-testing triggers, shelf assessment revisions)? Is this compatible with your national practices for software certification and post-market surveillance?
- Self-Assessment and Certification Transparency
- What is your opinion on the self-assessment approach outlined in D8.2 (including the test report summary, declaration of conformity, and CE marking)? What additional mechanisms might be needed to ensure trust and traceability of such declarations?
- How can the proposed EHDS CAS best be integrated with your existing national conformity schemes, procurement criteria, or reimbursement mechanisms? Are there overlaps with other certification programs (e.g. MDR, national digital authorities) that should be coordinated?
- 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 EHR systems across Europe?

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 Haralampos Karanikas (h.karanikas@gmail.com) and Angeliki Katsapi (angeliki.katsapi@gmail.com)