

EHDS Checklist for application vendors

The initial EHDS mandates will take effect in 2029—a date that may seem distant. However, the EHDS will demand substantial planning from application vendors. What steps should be taken in the next 12 to 18 months to prepare for the EHDS?

1. Understand the Regulatory Landscape and its applicability to you

- Read and understand the EHDS regulation as well as the related Implementing Acts, focusing on the parts related to EHR systems, patient access, and interoperability;
 - Monitor for EU-level and national-level updates, mostly by participating in updates provided by vendor organizations and/or national e-health authorities.
- Determine whether your software falls within the EHDS definition of EHR systems or wellness applications;
 - Clarify whether any parts of your system qualify as medical device software under the MDR, or if there are any parts that fall under the AI Act.

2. Perform a Gap Analysis & create a roadmap

- Run a gap analysis (interoperability, logging, access, architecture);
- Develop a roadmap for aligning with EHDS architectural principles, interoperability and technical specs by 2029.

3. Check Against EHDS-Defined Requirements

- Map internal data to standard terminologies (e.g. SNOMED CT, LOINC, ICD-10) and relevant EHR exchange formats (e.g. FHIR) to ensure semantic interoperability;
- Implement strict role-based access control and ensure traceable audit logging of all EHR data access;
- Enable secure patient access to their health records, including download, real-time viewing as well as patient initiated data corrections. Allow patients to view access logs, showing who accessed their data and when;
- Support eID/eIDAS-compatible identity systems for professionals and patients.

4. Technical Documentation & Conformity

- Maintain documentation covering architecture and access control;
- Be prepared to issue an EU Declaration of Conformity (for harmonised EHR systems);
- Prepare for testing in digital testing environments to verify EHDS conformity.

5. Organizational Readiness & Governance

- Assign internal responsibility (product/regulatory teams) for monitoring and implementing EHDS requirements;
- Train relevant staff on EHDS requirements and updates, both in terms of the bigger picture as well as a working knowledge of the details;
- Allocate funding to support organizational readiness;
- Monitor national-level requirements and implementations (Member States may add their own EHR rules under EHDS).

This is a high-level checklist; please suggest improvements via ehds@ringholm.com

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EHDS Checklist for healthcare provider organizations

The initial EHDS mandates will take effect in 2029—a date that may seem distant. However, the EHDS will demand substantial planning from healthcare provider organizations. What steps should be taken in the next 12 to 18 months to prepare for the EHDS?

1. Understand the Regulatory Landscape and its applicability to you

- Assess EHDS scope and impact;
- Understand which parts of your organization and data flows fall under the EHDS;
- Review contracts and data sharing agreements with third parties.

2. Check EHDS requirements

- Enable secure patient access to their health records, including download, real-time viewing as well as patient initiated data corrections. Allow patients to view access logs, showing who accessed their data and when;
- Upgrade or integrate EHDS-compatible systems;
 - Engage with system- and hardware vendors
- Integrate with MyHealth@EU infrastructure;
- Ensure cybersecurity and data protection.

3. Organizational readiness & Governance

- Assign internal responsibility for coordinating EHDS implementation;
 - Stay updated with regulatory changes
- Train staff on EHDS requirements;
 - IT staff, and clinical/administrative staff.
- Allocate funding to support organizational readiness;
- Inform patients about their rights under EHDS, including access, correction, and data sharing.

Various HL7 Affiliates, in cooperation with Ringholm, will be offering a 1-day ‘EHDS-on-FHIR’ training course from Q2 2026 onwards. This training course offers an overview of the impact of EHDS. The training course focuses on the use of FHIR and other interoperability standards to support the primary use of healthcare data, as well as the EHDS requirements when it comes to EHRs. Please see <https://www.ringholm.com/en/training.htm> or the QR code below for details.

