

EHDS

Et IT-leverandør-perspektiv

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Empower individuals and improve healthcare through better use of health data.



The **European Health Data Space (EHDS)** initiative is a major policy and infrastructure effort by the European Union aimed at transforming how health data is accessed, used, and shared across Europe. Its **overall purpose** is to:



✓ **Empower individuals and improve healthcare through better use of health data.**

Specifically, the EHDS has **two main goals**:

- **1. Primary Use of Health Data**
 - To improve individual **healthcare delivery** by:
 - Giving **citizens control** over their personal health data.
 - Allowing people to access and share their health records **seamlessly across EU countries** (e.g., prescriptions, medical images, lab results).
- Supporting cross-border healthcare and ensuring continuity of care when traveling or moving within the EU.
- **2. Secondary Use of Health Data (e.g. HealthData@EU)**
 - To enable **research, innovation, policy-making, and public health** by:
 - Making health data available (under strict safeguards) to researchers, policymakers, and industry.
 - Driving **medical research, AI development, public health planning, and health system efficiency**.
 - Promoting trustworthy data governance and strong data protection rules.

- **Key Benefits of the EHDS:**

- **Patient empowerment** and easier access to personal health data.
- **Improved care coordination** across EU borders.
- **Boosted medical innovation** through better access to anonymized data.
- **Enhanced public health responses**, e.g., during pandemics.
- In short, the EHDS is about **creating a secure, standardized, and citizen-centered European framework** for health data, balancing **individual rights** with the **collective benefit** of data-driven health innovation.

https://health.ec.europa.eu/ehealth-digital-health-and-care/digital-health-and-care/electronic-cross-border-health-services_da

Elektroniske grænseoverskridende sundhedsydelser

SIDENS INDHOLD

Oversættelser af
patientinformationsmeddelelser
(PIN'er) efter land

Hvilke tjenester findes i hvilke
lande?

Ledelse og finansiering

Informationsmateriale

Se også





Digitaltjenesteinfrastrukturen for e-sundhed er en ordning, der sikrer kontinuitet i behandlingen af europæiske borgere, når de rejser til udlandet inden for EU. Dette giver EU-landene mulighed for at udveksle sundhedsoplysninger sikkert og effektivt via systemer, der kan "tale sammen". Markeringen med "MyHealth @ EU" gør det er nemt for borgerne at tjekke, om bestemte sundhedstjenester er tilgængelige.



My health @ EU
eHealth Digital Service Infrastructure
A service provided by the European Union

Nuværende grænseoverskridende aktiviteter

De følgende to elektroniske grænseoverskridende sundhedsydelser er gradvist ved at blive indført i alle EU-lande:

- **E-recept og eDispensation** (se [e-sundhedsnetværkets retningslinjer for e-recepter](#) , [Seneste opdateringer](#) ) , som gør det muligt for EU-borgere at få deres medicin i et apotek i et andet EU-land ved hjælp af onlineoverførsel af deres elektroniske recept fra bopælslandet, hvor de er tilknyttet sundhedssystemet, til det land, de rejser i.
- **Patientresuméer** (se [e-sundhedsnetværkets retningslinjer om patientresuméer](#) , og [produktbemærkninger](#) ) , som indeholder vigtige sundhedsrelaterede oplysninger om f.eks. allergier, nuværende medicinering, tidligere sygdomme og operationer. De indgår i en større samling af sundhedsdata, der kaldes elektroniske patientjournaler. Det digitale patientresumé skal give lægerne vigtig information på deres eget sprog om patienter, som kommer fra et andet EU-land, og hvor der kan være en sproglig barriere. På lang sigt vil der også være billeddiagnostik, laboratorieresultater og rapporter om udskrivning fra hospitaler til rådighed i hele EU, og senere følger også en fuldstændig sundhedsregistrering. Alle EU-lande kan udveksle både e-recepter og patientresuméer.

Mange EU- og EØS-lande er i færd med at indføre disse tjenester.

Xt-EHR goals – a potential driver of the technical specifications

General Requirements for EHRs and System Interfaces, led by ESZFK HU and VR and spanning from Month 1 to Month 30, aims to define essential requirements and specifications for **EHR** systems and their interfaces. Task descriptions within this package outline activities such as enumerating functional and non-functional requirements for implementing standardized **EHR** systems under the **EHDS** Regulation, and addressing challenges related to data input and output for algorithm-based clinical decision support. Additionally, the package focuses on requirements for patient identification processes across Europe and defining metadata standards for the



European Electronic Health Record Exchange Format (EEHRxF). Through these efforts, WP5 seeks to establish a robust framework for interoperable **EHR** systems and interfaces, ensuring **compliance** with **EHDS** Regulation standards and facilitating seamless data exchange across the European Union.





Xt-EHR findings so far in draft material

- Comprehensive material
- Many 'recommend' sections
- Lack of references to existing industry standards
- Very specific rabbit hole diving requirements
- Uncertain areas in terms of clinical safety (e.g. alarming)



Vendor concerns 1/3

-  **1. Data Governance and Compliance Burden**
 - **Strict obligations** under the EHDS Regulation for data sharing, consent, anonymization, and transparency.
 - Vendors will be required to **enable patient access and cross-border interoperability**—adding complexity and compliance costs.
 - Fear of **non-compliance penalties** due to ambiguous or evolving regulations.
-  **2. Loss of Competitive Advantage**
 - Vendors often treat health data or data formats as a **proprietary asset**.
 - EHDS mandates **data portability and openness**, which may:
 - Undermine existing **data-based business models**
 - Lead to **commoditization** of services previously seen as value-added (e.g., data analytics, portals)

Vendor concerns 2/3

-  **3. Technical Interoperability Challenges**
 - Integrating with **MyHealth@EU** and adhering to **EU-wide standards (e.g., HL7 FHIR)** can be technically difficult and costly.
 - Legacy systems may not be designed for **semantic interoperability** or **cross-border sharing**.
 - Risk of **incompatibility** with national systems or existing platforms.
-  **4. Costs of Transition and Upgrades**
 - EHDS may require **significant investment** in system redesign, infrastructure upgrades, cybersecurity, and interoperability tools.
 - Smaller vendors may lack the **resources** to implement these changes efficiently.
 - Concern over **unfunded mandates**—expectation to comply without financial support.

Vendor concerns 3/3

-  **5. Ambiguity Around Roles and Responsibilities**
 - Uncertainty over:
 - What exactly vendors must deliver
 - Their role as a "health data holder" or "data user"
 - Who bears responsibility for errors or breaches in shared data flows
-  **6. Market Disruption and New Entrants**
 - The EHDS may encourage **new players (startups, Big Tech, data intermediaries)** to enter the space.
 - Risk of **disintermediation** for traditional vendors who may lose control over direct relationships with clients or patients.


Summary Table:

Concern Area	Key Issues
Compliance & Governance	Legal obligations, penalties, data protection
Business Model Impact	Data monetization limits, openness undermines differentiation
Technical Complexity	Interoperability, integration with EU systems, outdated legacy systems
Financial Burden	Cost of compliance, upgrades, certifications
Responsibility & Liability	Role clarity, error accountability, legal grey zones
Competitive Landscape	Market entry of new players, loss of customer control


Why the specs under EHDS won't be enough for defining clinical systems

- [EHR systems functional model requirements - https://build.fhir.org/ig/HL7/ehrs-fm-ig/](https://build.fhir.org/ig/HL7/ehrs-fm-ig/)
- +300 functional requirements





HL7 Electronic Health Record System Functional Model, Release 2.1.1
2.1.1-ballot - Normative Ballot



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HL7 Electronic Health Record System Functional Model, Release 2.1.1, published by HL7 International / Electronic Health Records. This guide is not an authorized publication; it is the continuous build for version 2.1.1-ballot built by the FHIR (HL7® FHIR® Standard) CI Build. This version is based on the current content of <https://github.com/HL7/ehrs-fm-ig/> and changes regularly. See the [Directory of published versions](#).

1 Home Page

Official URL: http://hl7.org/ehrs/uv/ehrs-fm-2/ImplementationGuide/hl7.ehrs.uv.ehrs-fm-2	Version: 2.1.1-ballot
IG Standards status: Normative	Maturity Level: 1
Computable Name: EHRSFMR2	

1.1 This Project

Within HL7, since 2020, the Common H7 Toolset initiative to develop the same underlying publication process technology stack across all HL7 standards has been underway. The intent is to provide the same look and feel, to leverage inherent [validation and versioning](#), to ease annual updates, and to avoid the unwieldy word and pdf publication process. This publication of EHR-S FM R2.1 is the realization of that intent for the [EHR-S FM product family](#).

This is a EHR-S FM specification that uses FHIR R5 Requirements resource to define its functional model sections, headers, functions and criteria. It references FHIR resources for data requirements and is based on FHIR R5 but not in a way that FHIR Implementation Guides would be based by profiling FHIR resources. It is important and relevant to declare the version of FHIR structures that are being used for toolsmiths and others using those structures.






The content comes from ISO/HL7 10781 as the most recently balloted version of the EHR-S FM. HL7 last balloted/published it in 2000, ISO in 2023. The ISO version is identical except that it has new graphics and we fixed some minor errata.

Note To Balloters
Targeting May 2025 ballot This is the publication of the EHR-S Functional Model using the Common HL7 Toolset (FHIR IG Tooling).

- [This Project](#)
- [Introduction](#)
- [EHR WG CoChairs and Publishing Facilitators](#)



Adoption deadline - 26 March 2029



- <https://eur-lex.europa.eu/eli/reg/2025/327/oj/eng>
 -  Article 8 – Right to Restrict Access (and denying it)
 -  Article 14 – Priority Categories of Electronic Health Data (IG's)
 -  Article 7 – Data Portability (import/export)
 -  Article 10 – Right to Opt-Out (secondary processing)
 -  Articles 25–30 – Requirements for EHR Systems (interop and logging)



Vendor opportunities in EHDS Context 1/4

-  **1. New Service Models & Value-Added Offerings**
 - Vendors can develop **interoperability-as-a-service**, patient data access tools, or **cross-border health record exchange modules**.
 - Offer **EHDS-compliant data processing** and consent management solutions to healthcare providers.
 - Create **analytics platforms** aligned with EHDS secondary use rules (e.g., dashboards for research institutions).
-  **2. Market Expansion Through Standardization**
 - EHDS pushes EU-wide **data format and interoperability standards** (e.g., HL7 FHIR, SNOMED).
 - Vendors that comply early can more easily **enter new EU markets** by plugging into MyHealth@EU infrastructure.
 - Smaller or local vendors can **scale** their products to other EU countries with less friction.





Vendor opportunities in EHDS Context 2/4

-  **3. Trust-Based Competitive Differentiation**
 - Demonstrating **compliance, data protection, and ethical AI practices** can become a **market advantage**.
 - Vendors can brand themselves as **EHDS-ready** or “**trusted data stewards**”, appealing to both public and private clients.
-  **4. Innovation with Secondary Data Use**
 - Use de-identified or anonymized data (under license) for:
 - **AI development** (clinical decision support, diagnostics)
 - **Digital therapeutics**
 - **Clinical research and drug discovery**
 - Build **platforms for researchers or pharma** to request and analyze EHDS data.




Vendor opportunities in EHDS Context 3/4

-  **5. Partnering with Public Sector**
 - EHDS requires **Health Data Access Bodies**, **national contact points**, and technical platforms.
 - Vendors can partner with governments to:
 - Provide **data infrastructure**
 - Build or operate **technical intermediaries**
 - Consult on **national EHDS implementation**
-  **6. Modernizing Legacy Systems**
 - Offer services to **upgrade old EHRs**, PACS, and lab systems to become EHDS-compliant.
 - Target **hospitals, clinics, and labs** who may need help with compliance but lack internal capacity.



Vendor opportunities in EHDS Context 4/4

-  **7. Data Commercialization under EHDS Framework**
 - Structured secondary-use licensing could enable **fair, regulated monetization** of anonymized data insights.
 - Vendors can act as **certified intermediaries** facilitating data access between holders and researchers.

Summary Table:

Opportunity Area	Description
New Services	Interop modules, patient portals, compliance-as-a-service
Market Expansion	Easier EU market entry via standardization
Competitive Differentiation	Trust, ethics, and compliance as brand value
AI & Innovation	Use of anonymized data for R&D and product development
Public-Private Partnerships	Build or operate EHDS infrastructure and access platforms
Legacy System Modernization	Help providers upgrade to EHDS-ready platforms
Regulated Data Monetization	Licensed secondary data use with safeguards

- Q&A?

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