Navigating the European Health Data Space:
A Guide for Healthcare Innovators

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Overview of the European Health Data Space

In March 2025, the European Health Data Space (EHDS) entered into force in the EU. This regulation is designed to unify how health data is accessed, shared, and reused across the EU. March 2025 marked the beginning a phased implementation process with key milestones including the establishment of national digital health authorities by 2027, the start of cross-border data exchange by 2029 and expanded data categories by 2031.

EHDS compliance isn't optional.

If your organization touches health data, you'll need to adapt how you store, process, and trace documents to meet new EU standards.

IT professionals and software developers are familiar with the security and privacy compliance requirements associated with personally identifiable information, including electronic health records and clinical studies. However, the EHDS is a little different. The primary purpose of this regulation is to enhance access to health data; primarily for individual patients, but secondarily to allow anonymized health data to freely circulate across member states to enable research, public health and innovation.

In summary, if your organization touches health data, compliance with the EHDS is necessary, which may require changes to the way you store, process and trace documents and data.

In this eBook, we'll examine the components of the EHDS regulation and challenges your organization may face, but also learn how the EHDS brings opportunities to innovate and improve processes. The good news: Apryse can help, with a robust toolset designed to manage documents securely and maintain standards compliance.

How ready are you?

Skip ahead to the EHDS Readiness Checklist at the end of this eBook to gain a quick insight into how your organization measures up to the new regulation.

Jump to the Checklist →

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Understanding the EHDS Regulation

While some healthcare professionals may be rejoicing about the opportunities to access health data more readily for research and collaboration, technical personnel are likely more focused on the operational challenges required to properly support the specific requirements of the EHDS and to protect the privacy of patients across the EU. Let's look at both.

The specific components of EHDS are:

Interoperability:

EHR systems must be interoperable and CE-certified.

Patient Empowerment:

Patients must be able to access, correct, and share their health data digitally.

Secondary Use of Data:

Health data can be reused for research, policy, and innovation under strict governance.

Infrastructure:

MyHealth@EU and HealthData@EU will facilitate cross-border and secondary data exchange.

Governance:

Enforcement of the EHDS is carried out by the supervisory authorities that are already active under the GDPR. For example, in Belgium, the Data Protection Authority, which handles complaints and can impose administrative fines in the event of a breach.

Penalties:

Non-compliance can lead to fines up to €20 million or 4% of global turnover.

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EHDS Readiness: By the Numbers

Across Europe, healthcare IT leaders are preparing for EHDS, but challenges remain.

A 2025 survey by Black Book Research, conducted across 17 digitally advanced EU countries, gathered insights from 270 healthcare IT leaders and 1,305 EHR/EPR users. The findings reveal key barriers to EHDS implementation:

52%

cite lack of interoperability as a top technical barrier to EHDS readiness

47%

still struggle with legacy systems

43%

report data quality issues as major challenges

39%

Only 39% feel confident in meeting EHDS privacy and security requirements

These insights, released ahead of the HIMSS EU 2025 conference, highlight the urgent need for scalable, secure, and interoperable solutions.

Source: The Financial Analyst – EHDS Readiness Progress and Persistent Hurdles

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From Challenges to Compliance:

Navigating EHDS Requirements

EHDS compliance isn't just a regulatory checkbox, it requires a strategic overhaul of how health data is managed. From modernizing legacy systems to enabling secure, standards-based data exchange, healthcare IT teams must invest in infrastructure that supports interoperability, accessibility, and traceability.

Organizations need to:

Comply with FAIR principles, making data findable, accessible, interoperable and usable.

Secure health data for confidentiality and integrity, including encryption, access controls and monitoring of data traffic.

Make data accessible to authorized parties, including researchers, healthcare providers and governments.

Demonstrate compliance, including being subject to audits and reporting.

As they work to meet these requirements, challenges arise for organizations still struggling with the following:

Legacy Systems:
Many institutions still rely on outdated, non-interoperable systems.

Data Silos:
Fragmented document storage hinders data sharing and reuse.

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Manual Workflows:
Paper-based or semi-digital processes slow down patient access and compliance.

Security & Traceability:
Ensuring data protection and auditability is complex.

In preparation for the EHDS, companies handling health data have begun analyzing their datasets to identify what falls under the EHDS Regulation, including where it's stored, in what format, and any restrictions. They will also assess whether the data includes sensitive IP or trade secrets, and evaluated their technical capacity to label, anonymize, and remove opted-out data. Moving forward, as companies produce new datasets, each will need to be analyzed, labeled, and anonymized in preparation for disclosure.

Fortunately, Apryse SDK provides the digital document processing capabilities to quickly mitigate these challenges, helping put in place robust new workflows that allow your organization to focus on the opportunities the EHDS brings.

Legacy systems and manual workflows won't cut it.

EHDS demands secure, interoperable, and auditable digital processes. Apryse helps you get there faster.

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Opportunities for Innovation

Changes in the regulatory landscape in any industry can provide new opportunities for innovation, and the EHDS is no different. To take full advantage, it's important to adapt to new regulations with agility and confidence.

Organizations leading the way in EHDS compliance will enjoy:

Cross-border Care:
patient outcomes can be improved with more accessible data.

AI & Research:
advanced analytics and machine learning enable innovation with valuable, relevant and structured data.

Patient Engagement:
trust and transparency are fostered, improving patient advocacy and education.

Workflow Automation:
administrative burden is reduced as investments in data infrastructure improve ways of working.

Help your organization reap these benefits by implementing secure, user-friendly document processing technology from Apryse.

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How Apryse Helps Enable Your EHDS Opportunities

Apryse's document technology directly supports EHDS goals. Because Apryse provides a full suite of functionality offered as part of our core package and separated into add-on packages, you can get the tools you need and extend capabilities in the future as needed.

Apryse Advantage:
Encryption, redaction, audit trails, and format conversion — all built into our SDKs to support EHDS compliance.

Secure Document Handling

With viewing and editing capabilities for PDF, DOCX, spreadsheets, images and more, Apryse supports document security and traceability.

- Encryption and Secure Redaction protect sensitive health data.
- Audit Trails help track document access and changes for compliance.
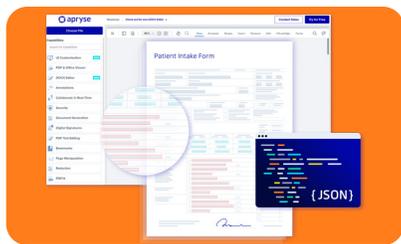
Interoperability & Data Extraction

To manage a large backlog of health datasets, Apryse offers programmatic server-side tools to batch convert, modify and process documents at scale. In addition, our WebViewer SDK puts document processing capabilities at users' fingertips with a WCAG 2.2 Level AA accessible UI.

- **Format Conversion:** PDF to XML, HTML, DOCX, and more
- **Data Tagging & Extraction:** Make health data searchable and structured
- **Barcode Scanning Technology:** Extract barcode data from patient records, medication labels, and lab reports
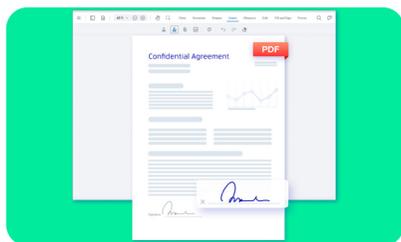
Digital Workflows

Paper-based or ad-hoc workflows involving email or third-party file sharing tools are now obsolete. Bring document workflows into your environment and unify, trace and secure data with:

- **Digital Signatures & Forms:** Enable digital consent, intake, and correction workflows
- **Remote Document Access:** Patients and providers can interact with documents anywhere

Secondary Data Use

Beyond preparing your organization's data output, Apryse also helps handle the data your organization has gained access to from other sources. Use AI-powered Smart Data Extraction and OCR to prepare data in JSON format for use in a variety of applications.

- **Automated Processing:** Extract anonymized data for research
- **Integration with AI Pipelines:** Feed structured data into analytics platforms

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In any industry, new regulations bring challenges, but also opportunities.

For healthcare organizations navigating the EHDS, new requirements for how health data is stored, recorded and made available to patients and other stakeholders requires investments in digital document capabilities. However, in addition to the opportunities provided by newly accessible health data, new technology can help improve internal document workflows, easing your administrative burden and reducing delays, errors and costs.

Apryse is ready to help your organization navigate EHDS compliance and unlock the full potential of health data.

Contact us to get started.

Contact Sales   **Try the Demo**   **Start Your Trial**

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Checklist:

Is Your Healthcare Organization Ready for EHDS Compliance?

Use this checklist to assess your organization's preparedness for the European Health Data Space regulation, and how Apryse can help you meet key requirements.

Interoperability & CE Certification Support

- ☐ Are your EHR systems interoperable across EU borders?
- ☐ Do your document workflows support CE certification criteria (e.g., traceability, integrity)?
- ☐ Can your system convert & process documents in multiple formats (PDF, XML, HTML, DOCX)?
- ☐ Are you using tools that support structured data extraction from clinical documents?

Apryse Advantage:
Format conversion, data extraction, and PDF interoperability to support CE-ready systems.

Security, Privacy & Traceability

- ☐ Is sensitive health data encrypted & protected at rest and in transit?
- ☐ Do you have redaction capabilities for anonymizing patient data?
- ☐ Can you generate audit trails for document access & modifications?
- ☐ Are your workflows compliant with GDPR & EHDS data governance?

Apryse Advantage:
Encryption, redaction, and audit trail features built into the SDKs.

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Digital Workflows & Patient Empowerment

☐ Can patients digitally access, correct, & share their health records?

☐ Are your forms & consent documents available in digital, mobile-friendly formats?

☐ Do you support eSignatures that comply with EU standards (eIDAS)?

Apryse Advantage:
eSignature, form filling, and responsive document viewing across devices.
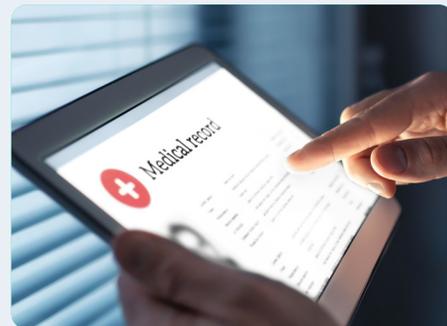
Secondary Use of Health Data

☐ Can you extract anonymized data from documents for research & analytics?

☐ Are your systems capable of integrating with AI/ML pipelines or analytics platforms?

☐ Do you use tools that enable automated document processing as part of broader workflow automation?

Apryse Advantage:
Automated document processing and structured data extraction for research and innovation.

Operational Readiness

☐ Are your teams aware of EHDS requirements & timelines?

☐ Do you have a roadmap for upgrading legacy systems & workflows?

☐ Are you working with technology partners who understand EHDS & healthcare compliance?

Apryse Advantage:
Proven healthcare integrations & developer-first tools to accelerate compliance.

Next Steps

If you checked fewer than 10 boxes, your organization may benefit from a deeper look at Apryse's healthcare solutions. Contact Apryse for a demo, technical consultation, or access to our SDKs and developer resources.

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