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The EHDS regulation of EHR systems:

Blind spots and pain points,

and how to address them

This working paper has been prepared in collaboration with the EHTEL EHDS Implementers Task Force.

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Content

1 Introduction

The **European Health Data Space (EHDS)** regulation sets a bold vision for transforming the way health data is accessed, shared, and used across Europe. Building on a significant body and decades of European Union (EU)-funded research and innovation programmes, the Commission launched its draft proposal in May 2022, riding a wave of public interest in digital health after the COVID-19 pandemic. The legislative process focused on sensitive issues including data access, patients' rights, and consistency with other regulations, while the fine print of the EHDS proposal received scant attention. Since the regulation was published in March 2025, actors in European healthcare have focused on implementation and compliance. Some **blind spots** in the EHDS regulation have emerged that may lead to **pain points** for several stakeholder groups.

The regulation of **Electronic Health Record (EHR) systems** forms a central element of the EHDS regulation. Chapter III introduces a new regulatory regime for these systems, setting obligations for economic operators (like manufacturers, importers, distributors), and detailing requirements for CE marking and market surveillance. By requiring interoperability and conformance with agreed specifications specified in the EHDS regulation's Annex II, it seeks to ensure these systems can safely and effectively use and exchange health data under the new framework.

Given the broadness of the regulation's definition of "EHR systems", the EHDS may end up regulating not just recording systems used by providers or patients to collect, document and retain health or medical information, but also virtually all connected health technologies that generate and process health data. These technologies:

- Are pervasive in the healthcare system (and beyond),
- Range from small personal health devices (such as apps, thermometers, glucose meters) to big stationary installations (MRI, scanners, radiology systems), and
- Include hospital information systems, departmental information systems (i.e., for laboratories, picture archiving), ambulatory systems and potentially medical devices, in-vitro diagnostic devices, and many others.

Many of these technologies have lifecycles of five to 25 years or more, and collectively serve millions of patients and citizens in hospitals, in their homes or on the move.

The makers and operators of these technologies now face **significant uncertainty** whether or how to comply with the regulation and specifically the interoperability specifications that will only become available in 2027 (with mandatory compliance for some systems by 2029). How this uncertainty affects various stakeholder groups – hospitals and providers, industry, and the public sector – is outlined in chapter 3; it suffices to say here that there may be effects on access, investment, innovation, and economic

growth. There is an opportunity to address this uncertainty with some policy actions, which are outlined as **recommendations** in the last chapter of this paper.

2 The EHDS regulation of EHR systems

Electronic health records (EHRs) are a **cornerstone** of the EU's plans for the digital transformation of healthcare: reaching universal access for EU citizens to their personal electronic health record by 2030 is a key target of the EU's Digital Decade Policy Programme. EHRs are also at the core of the EHDS regulation: improving access to personal electronic health data and overcoming fragmentation in access services is cited as a key rationale for justifying European action.[1]

The International Organization for Standardization (ISO) defines an EHR as "a digital repository of a patient's medical information that documents their entire healthcare journey in real time", updated in (near) real time and accessible to relevant healthcare professionals and providers.[2] The question is: who manages the EHR and where does it sit? With the family doctor, the nearest hospital, the relevant health authority, or even with the patients themselves? For the European Commission, the answer is clear: the EHDS regulation defines an electronic health record as "a collection of electronic health data related to a natural person and collected in the health system, processed for the purpose of the provision of healthcare".[3]

In contrast, the EHDS regulation's **definition** of an "EHR system", which serves as the basis for a new product regulatory regime outlining rules and obligations for manufacturers and economic operators, is significantly more expansive:

> "[An EHR system is] any system whereby the software, or a combination of the hardware and the software of that system, allows personal electronic health data that belong to the priority categories of personal electronic health data established under this Regulation to be stored, intermediated, exported, imported, converted, edited or viewed, and intended by the manufacturer to be used by healthcare providers when providing patient care or by patients when accessing their electronic health data."[4]

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[1] To learn more about the Digital Decade policy programme and its targets for 2030 go to https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/europe-fit-digital-age/europes-digital-decade-digital-targets-2030_en. For the EHDS rationale, consider EHDS recital (7): "[…] In order to facilitate the free movement of personal electronic health data across the Union and avoid negative consequences for patients when receiving healthcare in a cross-border context, Union action is needed to improve natural persons' access to their own personal electronic health data and to empower them to share those data." The EHDS regulation is accessible at https://eur-lex.europa.eu/eli/reg/2025/327/oj/eng.

[2] See https://www.iso.org/healthcare/electronic-health-records#toc1

[3] See Article 2(2) point (j) in the EHDS regulation.

[4] See Article 2(2) point (k) in the EHDS Regulation.

This definition does not just cover systems delivering EHRs, but almost any electronic device delivering personal electronic health data in a clinical or even a private setting (if intended for healthcare providers).

From the start, when the EHDS regulation was first introduced in May 2022, trade associations and stakeholder groups alerted the Commission that this definition should be revised.[5] These remonstrations had limited effect: to the surprise of many, when the EHDS was published in March 2025, the definition of an EHR system remained wide. In the FAQ document that accompanied the publication of the EHDS regulation in March 2025[6], the Commission confirmed that, far from an accident or oversight, the wide definition had been intentional all along:

> "This [EHR system] definition is wide, and it is so on purpose: to ensure interoperability throughout the chain of connected systems. It does not only apply to systems that aggregate information, like hospital information systems, but also to the systems 'feeding' them."

The FAQ document continues to list some examples of systems that were in scope or out of scope, however, many systems from real life scenarios are not covered, as is discussed throughout chapter 3. In hindsight, it appears that the European legislators had a limited appreciation (a blind spot?) of the complexity of connected health systems in today's healthcare, as the following discussion shows. The burden of application will fall on those who are tasked with implementing the EHDS.

3 EHR systems in practice

This chapter considers the perspectives of providers, industry, and the public sector.

3.1 Provider perspective

In Europe, it is the Member States that are responsible for healthcare delivery, and many Member States devolve this responsibility further to regions or municipalities. The EHDS regulation requires Member States to adapt their national health data and digital infrastructures. This is a massive task and requires the cooperation and collaboration of a vast array of actors and players involved in delivering healthcare services to citizens and

[5] See, for example, various cross-sector stakeholder consensus statements asking for a clear scope of the EHR systems definition, including one in April 2024. Ultimately there were changes in the definition, but they did not address these concerns.

[6] European Commission, "Frequently Asked Questions on the European Health Data Space", [5 March 2025], https://health.ec.europa.eu/latest-updates/frequently-asked-questions-european-health-data-space-2025-03-05_en (last accessed 18 September 2025).

patients, including those that often serve as the population's primary access point for health services: primary care physicians and hospitals.[7]

Hospitals, in fact, have historically been among the early movers in healthcare digitalisation, building over time advanced hospital information systems capable of processing and integrating health information for patients; moving medical, imaging, lab and other information across departments; streamlining billing and payment systems; and in some cases building local or regional health information exchanges with other provider organisations and physicians. More recently, many hospitals have also built patient-facing portals where citizens and their carers can access information about their health status and the diagnostic and treatment services they received.

Clearly, hospitals have questions about the EHDS regulation's implementation and compliance.

3.1.1 What does it mean for a hospital to be EHDS-ready?

The EHDS regulation appears to assume a homogeneity of systems that does not exist. Many hospitals run patchworks of modern EHRs, legacy information systems, and department-specific platforms. Many of these systems manage just data and images that are relevant and fit for a specific use, rather than comprehensive personal data sets. Many rely on unstructured data and PDFs, and they often store data in legacy formats. Harmonising these data sets and aligning these systems to international standards, and rendering them fit for cross-border data exchange, will not be trivial. A hospital with multiple vendors, customised modules, or hybrid data flows cannot flip a switch and become interoperable. The coming steps to implement the EHDS at EU and national levels must reflect these operational realities.

3.1.2 At what levels do hospitals need to be interoperable with the EHDS?

For hospitals, aligning with the European Electronic Health Record Exchange Format (EEHRxF – the "format")[8] is a key step toward EHDS compliance, ensuring that their data contributions are both technically interoperable and clinically usable across Europe. But the transition will take a significant effort. How can clinicians be empowered to capture structured data? Are IT teams prepared for semantic integration? Can hospitals deliver the data in the format? And how deep in the hospital will EEHRxF alignment have to go?

Most hospitals run on a hybrid system landscape: they may have centralised or federated clinical data repositories (CDS). Core health record systems capture a patient's medical history, orders, notes, and medications, but most data is captured in departmental systems

[7] Additional actors include specialty doctors, clinics and community health centres, pharmacies and payers, each of which would deserve discussions of their own perspectives that would exceed the scope of this paper.
[8] For information, the Xt-EHR joint action https://www.xt-ehr.eu/ refers to this format simply as "EHRxF".

such as laboratory information systems (LIS), radiology information systems (RIS), and picture archiving and communication systems (PACS). So, which of these systems "feeds" the EHDS? For EHDS compliance, will it be sufficient that the hospital complies as a whole, or will the individual system "producing" or "feeding" data also have to comply? Will the hospital be held institutionally responsible for the compliance of data coming from its departments? The answer is not clear.

The EHDS regulation requires Member States to make patient data shareable via national contact points for digital health (referred to as NCPeH), so that e.g., a French citizen treated in Greece or Poland can access their records regardless of the care setting. Many hospitals have invested in patient engagement portals through which they give their patients access to a predefined subset of their data that is related to services received in that hospital. For such hospitals, it is not clear what the relationship will be between already existing hospital portals and these EU structures. Hospitals are asking: is our portal interoperable with the national eHealth infrastructure? Can we make patient data available through standardised APIs, thereby ensuring alignment with EEHRxF?

3.1.3 Primary care physicians and a fragmented world of health IT

In most Member States, primary doctors (also known as general practitioners, or "GPs") have traditionally been the patient's first and main point of contact for healthcare, and the trusted guardian of personal health information. As a result, patients' longitudinal and historical health data may often reside in the information systems of primary doctors. At the same time, primary care information systems are often fragmented, disconnected and standalone, with high levels of adoption but significant variations in the specific vendors' and system functionalities by country.

Nearly all GPs across the EU use basic IT systems for core functionalities like patient data entry and ordering tests. EHR systems are becoming increasingly available across most Member States. While general IT system use is high, there are noted variations in specific functionalities. Basic administrative data, health data and order-entry functionalities are almost fully adopted in all countries and, in more than half of the countries, most GPs are routinely using clinical decision support functionalities. However, there is a high variation in digital maturity among Member States, and the degree of exchange of clinical, administrative and management data differs.

As a result, primary care physicians will rely on national or regional guidance to assist them with compliance. The presence of a national or regional EHR infrastructure will make a difference.

3.1.4 The role of a national/regional EHR infrastructure

Would the presence of a national/regional EHR infrastructure impact the EHDS operational implementation on the provider level? A national or regional EHR

infrastructure can provide the backbone for implementing the EHDS: it centralises patient history across episodes, providers, and even regions, offering a comprehensive view that transcends institutional boundaries. When deployed well, it reduces duplication, enriches clinical insight, and simplifies data retrieval for secondary uses.

For providers, this means two key things. First, they must feed into this national/regional EHR infrastructure with clean, complete, and coded data. Second, they must be able to query and retrieve data from this record to support clinical decision-making at the point of care. This data exchange comes with challenges (such as timeliness, accuracy, conflict management) and it raises the question of how data use is governed and controlled.

Some Member States and regions have established robust national data platforms into which providers can plug. In other countries, where such infrastructure is fragmented or emerging, providers, especially hospitals, may shoulder more responsibility to ensure EHDS compliance themselves.

It is becoming clear that the EHDS requires healthcare providers and national/regional digital health authorities to have a new conversation. If they have the capacity, hospitals and other large provider organisations (and their representatives) must participate in national working groups, pilot projects, and regulatory consultations. At the same time, providers should advocate architectural decisions that reduce burden and maximise interoperability. They must actively shape, and adapt to, these architectures, to take full advantage of a generational opportunity to transform care delivery, empower patients, and enable data-driven health innovation.

3.2 Industry perspective

Like providers, manufacturers of digital health technologies understand the complexity of health data infrastructures in healthcare. Unlike providers, manufacturers know that the EHR systems they wish to place on the market will have to be CE-marked to comply with the new EHR systems product regulation stipulated in EHDS chapter III, and the EHDS interoperability specifications including the EEHRxF. Manufacturers now face regulatory uncertainty.

3.2.1 In or out of scope?

For a manufacturer of any connected medical technology, it is of critical importance to understand the scope of the EHDS product regulation of EHR systems, and whether the definition of EHR systems, as quoted in chapter 2 of this paper, also covers systems that "feed" EHR systems. Such systems may include products as diverse as:

- Connected medical devices such as thermometers, pulse oximeters, or stethoscopes,

- Devices and apps that assist patients with the management of chronic conditions, like glucose meters (for diabetes) or CPAP machines (for sleep apnoea),
- Diagnostic devices in laboratory systems in or outside hospitals, or their platforms, or
- Medical imaging devices like MRI scanners or X-ray machines.

Many of these devices deliver electronic health data that is intended to be used by healthcare providers and thus may fall under the EHDS definition of "EHR systems", even if they deliver just a single data point. And, as confirmed by the Commission in its FAQs, it was not an accident that this expression of EHR systems was included in the regulation but was intended. As a result, connected medical technologies do not only need to comply with the European Union's Medical Device Regulation (EU MDR) 2017/745 or the In Vitro Diagnostic Regulation (EU IVDR) 2017/746, but they may now also face an additional regulatory pathway under the EHDS, raising the levels of cost and effort required to bring a product to market.

3.2.2 Standards by regulatory fiat

An additional concern for industry is the approach for implementing interoperability of EHR systems. The EHDS regulation requires that the Commission publish implementing acts in 2027 that will lay down the specifications for the EEHRxF, and which then become mandatory two years later. De facto, the Commission plans to impose technical standards for interoperability via fiat, or an administrative act.

This is unusual in standards development. Normally, lawmakers can require compliance with specific standards, but leave the elaboration of these standards to Standards Development Organizations (SDOs). SDOs develop standards in an open, consultative and consensus-based process that is open to technical experts from all relevant and affected sectors, including system architects and software engineers, as well as experts from industry. This process is sometimes called "co-creation", and is an underlying principle by which SDOs like CEN, HL7 or IHE operate.

In contrast, the EHDS has delegated the preparatory development of the initial EEHRxF specifications to the Xt-EHR Joint Action, an EU-funded project that includes experts from the Commission and Member States, but without representatives from other parties, and none from industry.[9] This preparatory work will form the basis of the 2027 implementing act.

These observations raise a second concern: the work on a standard is never finished. New technology developments and new use cases require continuous updates. SDOs

[9] More information on the Xt-EHR Joint Action can be found here: https://www.xt-ehr.eu/.

deliver a pathway for updating standards and to issue new versions and releases, from early drafts via "STU" ("standard for trial use") for evaluation and feedback, before the standards become fully accredited, finalised versions. This pathway allows users to implement a standard for specific, immediate needs, such as meeting regulatory mandates or responding to market demand, while the SDO continues to refine it. Enshrining specifications in regulation without a pathway to further development is unusual, and risks posing challenges to practical implementation down the road.

Finally, industry is keen on technical standards that apply internationally or even globally, so that products can be developed for a worldwide market, overcoming regional or national fragmentation. International SDOs offer pathways for global harmonisation of standards, in a way that an implementing act of the European Commission does not.

3.2.3 Ambitious timelines for compliance

The EHDS approach to implementing interoperability of EHR systems also clashes with the industry's product lifecycles. The EHDS regulation foresees just two years between the publication of the implementing act defining the EEHRxF in March 2027, and compliance in March 2029: from then on, EHR systems new on the market – or newly released – will have to conform with the EEHRxF and undergo a new testing regime. This will affect all EHR systems as well as medical technologies and AI devices that meet the EHDS definition of an EHR system (or claim interoperability with such a system). For some EHR systems, manufacturers may have only two years' time, from the publication of the implementing act onwards, to ensure compliance.

However, the innovation cycle for medical technologies from concept to market can take anywhere from three to 15 years; even just upgrading an existing device to comply with new data specifications may require testing again and CE marking (again, under different regulatory regimes), and take years. Bringing an entire cohort of medical technologies into EEHRxF compliance within a short time period is challenging, and may lead to regulatory bottlenecks, market shortages, and risks for timely patient access to medical technologies.

In sum, from an industry perspective the Commission should develop a workable approach for EHR systems (including clarifying their definition, which would be best through obtaining robust guidance), taking into account best practices from SDOs when delivering advancing interoperability specifications.

3.3 Public sector perspective

Among Member States' new responsibilities under the EHDS regulation is the considerable task of building national infrastructures for the primary use of health data, or upgrading existing systems. By 2029, all EU Member States are required to be able to exchange patient health data (starting with summaries and ePrescriptions /

eDispensations), so their systems have to comply at least in part with the EHDS specifications. Naturally, they are keenly interested in the detail of the EEHRxF specifications.

While the EHDS regulation sets the legal obligations, much of the technical and organisational detail will be defined in implementing acts. Input for the EEHRxF specifications is being developed in Xt-EHR, the Joint Action of Commission and Member States that will end in spring 2026. Xt-EHR represents the public sector's joint effort to transform legislative text into operational reality.

3.3.1 Specification development

The Xt-EHR Joint Action has produced deliverables that will serve as the basis for the March 2027 implementing act:

- Technical requirements for EHR systems (Xt-EHR Deliverable 5.1, 2024) specify security protocols (logging, access control, encryption), metadata standards, and interfaces. These directly support Annex II, point 1 of the EHDS regulation on interoperability and security.
- The European Electronic Health Record Exchange Format (EHRxF), developed in Xt-EHR Work Packages 6 and 7, defines semantic and syntactic interoperability specifications on which the Commission's implementing act will build.
- A Certification and Labelling Framework (Xt-EHR Work Package 8) will support Article 23 of the EHDS, requiring all EHR systems placed on the EU market to comply with essential requirements and undergo conformity assessment.

3.3.2 Transparency

This process for standards development comes with weaknesses: as outlined under the industry perspective above, standards are more robust if they are developed in a co-creation process that is open to all interested parties.

There is a "division" between the inner and outer circles of Xt-EHR participants. The "inner circle" includes Member States and competent authorities participating in the Xt-EHR Joint Action who "sit at the table" and have direct access to collaboration mechanisms, draft specifications, and working documents. The "outer circle" (comprising non-Xt-EHR countries, regional authorities, and industry) must wait for periodic consultations to offer their written input.

There is a qualitative difference between an open and inclusive process where all interested parties (can) have a seat at the table and join in for deliberation and discussion,

and one in which there is a closed inner circle that only periodically opens a window for external contributions. One is open, inclusive and consensus-oriented, the other is not.

3.3.3 Implementation timeline, funding, and regulatory bottleneck

Like providers and industry, Member States may face problems with the implementation timeline. The compliance obligations are binding across all Member States: by 2029, EHR systems placed on the EU market must comply with Annex II of the EHDS (essential requirements for interoperability, security, and data portability). This applies to new systems as well as those systems that have undergone significant change. These ambitious compliance timelines do not always harmonise with regular upgrade or replacement timelines.

Accordingly, EHDS implementation will require significant investment in new infrastructure, training and change management. The EHDS regulation has not come with a commensurate long-term funding mechanism that matches these challenges. There is a risk that, without coordinated European funding strategies, the quality of EHDS implementation may diverge between Member States and regions, reinforcing existing healthcare inequalities.

There is a sense among EHDS implementers that the regulation did not consider sufficiently the realities in healthcare. It is believed that it underestimated the complexity of legacy information systems in healthcare settings (e.g., hospitals, primary care, pharmacies) and the significant costs involved in transforming them. Public health systems across Europe face heavy investment needs to adapt decades-old infrastructures to new requirements. Without phased, realistically funded migration pathways, there is a risk of overextension of clinical IT teams, and delays to other modernisation programmes.

There is an acute risk of a regulatory bottleneck: conformity assessment, as specified in the EHDS, could overwhelm both notified bodies and suppliers, lead to shortages in compliant systems, and result in significant delays in implementation timelines.

3.3.4 Opportunity to share knowledge and develop collaboration

Member States see an opportunity for information and knowledge sharing and to propose practical common solutions that ensure successful adoption. They see two areas where efforts could have an impact:

1. On one hand, there is potential in promoting synergies and economies of scale. By fostering collaboration among healthcare providers, one can reduce unnecessary duplication of effort and accelerate the transformation of legacy EHR systems. This common approach allows smaller entities to benefit from shared resources and expertise while reducing individual implementation costs.

2. On the other hand, Member States recognise the importance of strategic funding priorities. By aligning public financing with joint actions and harmonised standards, one could improve efficiency in adoption while ensuring that investments remain sustainable over the long term. This approach might help avoid situations where private vendors capture disproportionate benefits, while also discouraging them from pursuing technological upgrades that may not prove to be sustainable in the long run.

In sum, the public sector remains positive towards the EHDS and is committed to making it work.

4 Policy recommendations

All stakeholder groups – providers, industry and Member States and regions – are affected by the **blind spots** in the EHDS that cover:

- A limited appreciation among lawmakers of the complexities of healthcare delivery, the legacy of information systems, and the pervasiveness of connected medical technologies,
- A top-down approach towards the healthcare sector and the standards development process, combined with overly ambitious timelines, and
- Insufficiently open, transparent, participatory and collaborative approaches in the development of the EEHRxF specifications, and in their further development.

These blind spots have led to **pain points** among different stakeholder groups which have been sketched in this working paper. But the EHDS regulations shortcomings can be fixed, because most stakeholders agree with the vision of the regulation, are grateful for Europe's leadership, and there is abundant good will.

It is understood that the EHDS regulation cannot and should not be re-opened, but that many of these recommendations can be ensured through **implementing acts, regulatory guidance, or policy decisions and actions**. To ensure the success of the EHDS vision, we recommend the following **actions**:

1. **The scope of the EHR systems definition should be clarified.**
   The Commission should work with implementers to issue practical guidance on applying the definition with a more balanced approach, taking into account the functions of information systems and medical technologies in delivering or managing personal electronic health data.
2. **For some types of "EHR systems", the EEHRxF compliance timelines should be relaxed.**
   Care should be taken to avoid regulatory bottlenecks, slower innovation pipelines,

or risks of access to connected medical technologies. A phased approach could be considered – that requires compliance for EHR systems (as traditionally understood) first; then other hospital and departmental IT systems; and, later, connected medical devices – which takes into account system maturity and product lifecycles.

3. **Appropriate governance and process for updating the EEHRxF should be organised.**
   Steps should be taken to organise an appropriate governance and process for maintaining and updating the EEHRxF after the publication of the implementing act, ensuring an open, transparent, collaborative environment for co-creation, driven by technical experts from SDOs, the public sector, industry, experts and practitioners. A role for the xShare project's European Standards and Policy Hub, governed by the new European Standards for Health Interoperability Alliance ESHIA, should be considered.[10]
4. **EEHRxF governance needs to be integrated into the EHDS governance.**
   The future EHDS Board, composed of the Commission and Member States, should supervise the governance and maintenance of the EEHRxF, with appropriate engagement with SDOs, experts and stakeholders, and the future EHDS Stakeholder Forum.

EHTEL and its multistakeholder platform of members will be ready to help.

[10] More information on the European Standards and Policy Hub and ESHIA can be found at www.eshia.eu.