MedTech Europe
from diagnosis to cure

COCIR
Advancing Healthcare

Medical technology industry's input to the XpanDH industry X-net

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Introduction

The European Health Data Space (EHDS) regulation is a groundbreaking initiative designed to enable secure, interoperable, and efficient health data exchange across the EU. This effort holds the potential to transform healthcare delivery, foster innovation, and enhance patient access to critical health information.

In partnership with the XpanDH project, MedTech Europe and COCIR affirm their commitment to supporting the successful implementation of the EHDS by addressing key challenges, particularly those related to the regulation's broad definition of Electronic Health Record (EHR) systems. This medical technology position emphasizes the importance of leveraging established testing frameworks, to validate interoperability and ensure compliance with EHDS requirements. These frameworks, built on decades of industry experience, provide a robust foundation for achieving readiness and maintaining consistency across diverse jurisdictions.

This paper will address three pivotal topics: the need for use-case-driven guidance for interpreting requirements across digital health product categories, scaling testing frameworks for EHDS interoperability, and ensuring the separation of exchanged content and transport transactions within a simplified interoperability architecture.

The medical technology sectors extensive expertise in large-scale eHealth deployment, offering invaluable insights to navigate the complexities of the EHDS regulation. Together, we advocate for a collaborative approach involving policymakers, industry leaders, and healthcare stakeholders to develop clear and actionable guidance for applying EHDS requirements across varied digital health solutions.

Through this expertise, we aim to ensure that the EHDS fulfills its transformative promise—enabling seamless cross-border health data exchange while addressing industry concerns and fostering innovation.’

The need for use-case driven guidance on how different categories of digital health products shall interpret the requirements to implement the harmonized components or the claim for interoperability with "EHR systems"

Introduction

The EHDS regulation sets specific requirements for digital health products which are considered as "EHR systems" according to the definition given in Art. 2(n) of the regulation:

> *"any system where the appliance/software allows to store, intermediate, export, import, convert, edit or view personal electronic health data that belongs to the priority categories of personal electronic health data (referred to in Art.5) and is intended by the manufacturer to be used by healthcare providers in providing patient care or by a patient to access their health data."*

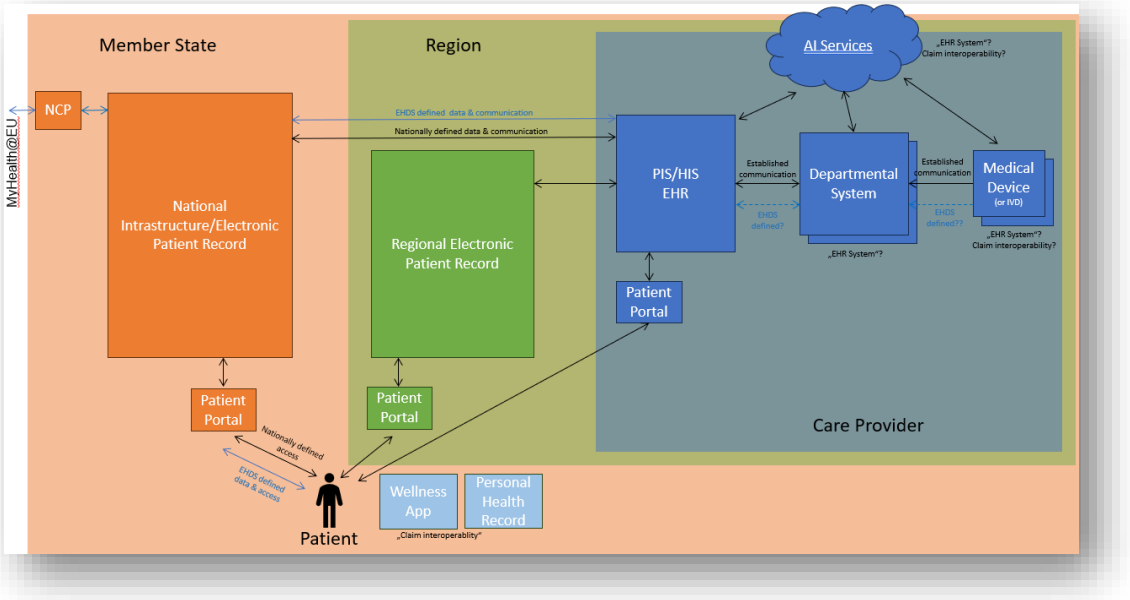
This definition is very broad and applies also to many digital health products which are commonly not considered being "EHR systems" by care providers or manufacturers.

Problem statement

Many digital health software and device products provide functionalities which are often very different from "classical EHR systems" (installed to manage care records in care delivery institutions). In contrast to "classical EHR systems" other systems, such as bedside patient monitors or laboratory analysers, contribute only indirectly to the EHDS regulation's aim of facilitating access to electronic health data by healthcare professionals and patients. At the current stage it is unclear to manufacturers how the regulation can be applied to these other products.

The digital infrastructure supporting care providers comprises numerous (inter-) connected systems that process personal electronic health data and contribute to diagnosis and the provision of healthcare in different ways. This infrastructure is also connected to regional and national digital infrastructures which enable the sharing of electronic health data between care providers and patients.

The following diagram depicts a simplified model of a member state's digital health infrastructure, highlighting its various Health IT systems, such as Practice Information System (PIS), Hospital Information System (HIS), Departmental systems as well as additional systems (medical devices and in-vitro diagnostics) and their already established (local) communication mechanisms.



PIS/HIS or "Classical EHR systems" play a key role in these digital infrastructures and traditionally serve as patient dossiers and are commonly considered as being the systems within a healthcare provider which systematically collect, store, and manage patients' health records across different healthcare settings. In addition these systems may also provide so-called "patient portal" functionality which enables patients to access their personal electronic health data, or have a corresponding system closely attached.

There is, however, a multitude of other systems used by care providers, many of which process personal electronic health data within the priority data categories of the EHDS regulation. These systems contribute to care delivery and thus fall under the regulation's definition of "EHR system." Examples include different specialized departmental information systems (such as radiology & laboratory information systems, PACS, treatment planning systems etc.), and even some medical devices and in-vitro diagnostics (e.g. imaging modalities, lab analyzers etc.). These systems either deliver personal health data, which is generated or processed by them, "upstream" for collection in the "classical EHR systems", or form together with the "classical EHR system" a "virtual EHR" ("patient dossier") which encompasses all record relevant data of a patient. They may also just utilise personal health data from the priority data categories which have been created by some other system.

Applying the requirements of the "harmonised components" to other systems comes with challenges and is not fit-for-purpose.

Through the broad definition in EHDS Regulation, these other systems are required to also include the European interoperability software component for EHR systems and a European logging software component for EHR systems (the 'harmonised software components of EHR systems') and to comply with the essential requirements outlined in Annex II.

It is important to highlight that including these other systems within the broad definition of "EHR system" under the EHDS (Art.2) and imposing uniform data and communication requirements across diverse product

categories does not adequately address several critical factors. This approach takes not into account widely established mechanisms, the complex design of innovative technologies, and does not support the goal of facilitating (cross-border) sharing of electronic health data for primary use.
As defined in the Regulation, the European interoperability component shall enable an "EHR system" to "provide and receive personal electronic health data in the European EHR Exchange Format (EEHRxF)". Which suggests that the component's task is twofold:

1. A data task, converting between the EEHRxF and the "EHR system" internal data format.
2. A transactional task, implementing the communication and authentication mechanisms which are defined for the EHDS (see diagram above).

The European interoperability component is meant to enable the access of health professionals and natural persons to personal electronic health data in the EEHRxF through the "access services" defined in the Regulation. This implies that the design of the transactional task of the interoperability component needs to be geared towards exchanging data with these access services, which the Member States are required to establish on national, regional and/or local level. Design requirements for communication with such access services have some fundamental differences to the communication inside a healthcare provider. The communication mechanisms with the access services do not fit to the communication needs between the additional systems, which often require the use of very specialised protocols. Implementing in them the same interoperability component as is needed for communication with the access services (by the actual EHR system) would be an unnecessary burden (mentioned below) and not improve the access to health data as aimed for by the EHDS Regulation.

> *For example, lab analysers have established mechanisms for making laboratory results (an EHDS priority data category) available to laboratory information systems (LIS), which in turn have mechanisms for making laboratory reports available to the classical EHR system. The same holds true for imaging modalities and Picture Archiving Communication Systems (PACS)/Radiology Information Systems (RIS).*

Mandating to add an additional, EU-defined, communication mechanism and certification to the other systems adds little to no value. For manufacturers to be able to plan their multi-year product development planning, to ensure having their products enabled in time it is vital to have clarity on which of their products are affected by the Regulation. There is typically a multi-year development cycle (e.g., 2 years for a "classical EHR system") which need to be followed by a 2 to 3 years deployment cycle by the care providers for installed products that are upgradable.

Conclusion

In conclusion, to accomplish this it is necessary to **create product guidance documents** in which the use case and integration profiles are mapped to specific product types required to contribute to the goals of the Regulation. Including a differentiation of the requirements for the harmonized components which are in alignment with the role of the respective product category in the context of the EHDS. However, it is important for this guidance to be developed in coordination and collaboration with manufacturers to ensure that best practices are taken into account and enable a fast and successful integration of the required functionality into affected products (naturally the manufacturer will align with the corresponding care providers needs).

In the next six months, we request the Commission and the leadership of Xt-EHR to engage manufacturers' stakeholders in an effort to **jointly develop product guidance documents** in which the use case and integration profiles are mapped to specific product types required to contribute to the goals of the Regulation. The group should define the product types for which differentiated requirements regarding the harmonized components and the claim for interoperability are necessary and detail these requirements.

Scaling Testing for EHDS Interoperability

Introduction

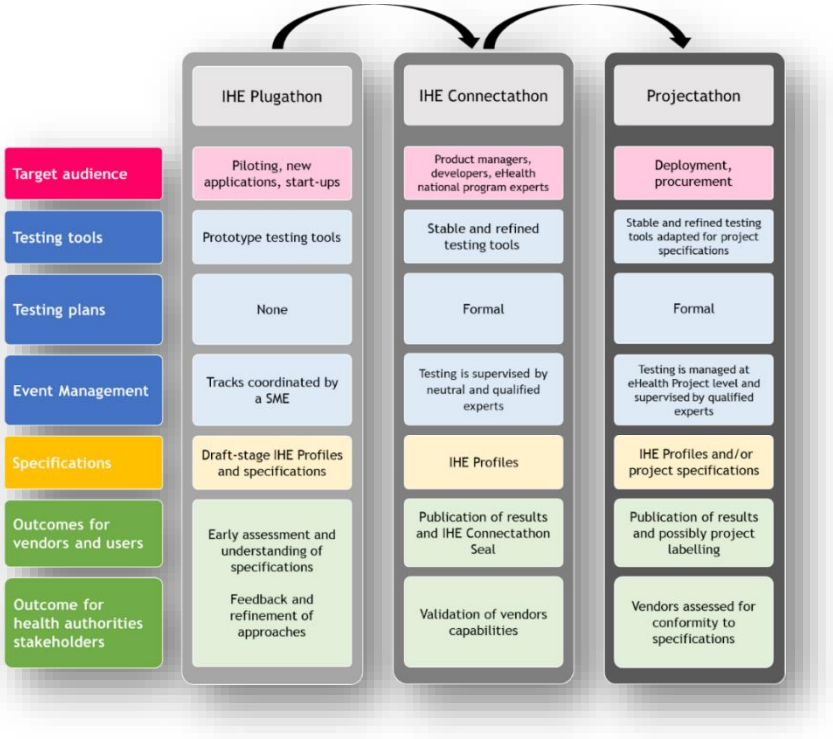
The European Health Data Space (EHDS) regulation aims to enable seamless, secure, and efficient cross-border health data exchange across and within EU Member States, improving healthcare access and innovation while ensuring compliance with GDPR. However, individual countries may introduce specific rules on top of the EHDS framework, which can complicate the self-certification of products. Vendors must navigate these national variations while ensuring compliance with the overarching EU regulation.

Testing plays a crucial role in addressing these challenges, ensuring that products meet EHDS requirements while reducing the need for country-specific extensions. A comprehensive and adaptable testing process is essential for achieving interoperability and security, making products ready for deployment across diverse jurisdictions.

Problem statement

The EHDS testing approach is expected to build upon established methodologies developed and refined by organisations like IHE and national infrastructure programs, which have successfully supported initiatives such as MyHealth@EU and have a large industry uptake. This creates a strong foundation for scaling the process to accelerate and support industry readiness and strengthen EHDS credibility with both market stakeholders and political authorities.

On the basis of existing practice (IHE testing process), the figure below highlights the three typical phases of testing and their specificities in terms of audience and associated processes.



Note: The above phases fall under the scope of EHDS but do not attempt to cover the testing phases performed internally by vendors to ensure product quality that includes interoperability, nor the testing phases performed

internally by ehealth deployment projects (pilot or full operation) such as pre-production testing as defined by MyHealth@EU.

The benefits of each event in the IHE process provide opportunities for vendors at different stages of product development:

- In an IHE Plugathon, vendors benefit from learning and prototyping opportunities. It allows them to get early, real-world feedback on draft-stage specifications, helping them refine their solutions and better align with the evolving requirements.
- The IHE Connectathon offers a more advanced validation of interoperability. Vendors can test pre-product or product implementations, collaborating with other vendors to ensure compatibility. It also provides a chance to evaluate the maturity of the specifications, giving vendors insight into how ready the standards are for widespread adoption.
- At a Projectathon, vendors gain the opportunity to test more mature versions of their solutions that have already been proven in an IHE Connectathon. The tools used are refined and allow for testing with country-specific customizations, helping vendors ensure that their products can meet local regulatory and operational requirements.

As the testing process for the EHDS matures, the testing tools and test plans will evolve and expand to meet the growing needs of the industry and deployment projects. These tools are designed to be adaptable, allowing for extensions and customization. They have to be professionally maintained by a neutral third party and funded with a stable baseline from EHDS, ensuring long-term sustainability and consistent updates.
These tools need to be designed to be used across various testing events, such as Plugathons, Connectathons and Projectathons, providing vendors and deployment projects with the necessary resources to validate interoperability and compliance.

Self-certification as envisioned by the EHDS regulation can only be effectively implemented once the testing ecosystem is fully mature and trusted by the industry.

Note: As an example, the IHE Connectathon seal, an official designation given to vendors that have successfully demonstrated interoperability and conformance to IHE standards during an IHE Connectathon, can play a key role as an initial building block in this process.

Conclusion

In conclusion, effective testing is the cornerstone of achieving interoperability (content, transaction, security, privacy and architecture) within the EHDS. By building on proven frameworks like MyHealth@EU supported by IHE-Catalyst, the EHDS will be well-positioned to scale its testing processes to meet the needs of the industry. The phased approach to testing, from IHE Plugathons to IHE Connectathons to Projectathons, provides the necessary structure to ensure that vendors can achieve compliance while adapting to country-specific regulations. The continued evolution of testing tools and plans will further strengthen EHDS implementation, fostering greater collaboration and industry readiness.

In the next six months, the focus should be on expanding the testing tools and test plans that have been used by MyHealth@EU to accommodate EHR testing so that industry early needs can be met to motivate early product implementations.

Separation of exchanged content and transport transactions in a simplified interoperability architecture for EHDS

Introduction

EHDS has a clear and explicit scope to share 6 types (use cases) of clinical content: Prescriptions, Dispensations, Patient Summaries, Imaging Studies, Imaging Reports, Discharge Reports and medical test results. In addition to such classes of clinical content, transactions and interactions need to be defined for EHDS to be successful. On one hand, they need to span the large-scale "cross-border, national, regional and local healthcare delivery" and on the other hand need to support the small-scale "patient/local access to data". The data flows and the clinical data quality constraints associated to these two sub-architectures call upon different technical approaches.

Problem statement

In this document, we will focus first on the large-scale cross-border, national, regional and local interoperability of healthcare data for care delivery by EHR systems :

- These exchanges need to span a large federated architecture that span over 30 countries, several of them with federating regions, and hundreds of EHR Systems across which data from a given patient may be distributed. **Therefore content has to be managed in a way that ensures that clinical information and its context are conveyed together,** thus facilitating clinical quality control and greatly simplifying intermediate storage. T**hese properties are simple to deliver by the proven use of the source generated document content** (e.g. bundle of FHIR resources, legacy PDF), which is much more difficult to ensure when information is accessed and transferred at the level of individual clinical observations.

- Such **source generated document content,** each specific to an EHDS use case**, calls for content neutral transactions for search** (with associated search m/filter metadata) **and retrieve** (e.g. FHIR Document Reference that has been profiled for this approach by the IHE MHD Profile**).**

- The content layer for this large scale sub-architecture shall be specified as a collection of Documents (e.g. Bundle of HL7 FHIR resources) on top of a **transport layer that specifies a query based on a minimal set of well defined common search parameters, such as metadata, and a retrieve of the above documents**. The search metadata specifies a content generic set of attributes (ex: patient, creation date) and some content specific extensions (e.g. body part for imaging). Search metadata at the document level is simpler, easier to make common across types of document and more friendly to health professionals and patients as they have to use a variety of applications and portals.

The above approach is characterized by separation of "transport" from "content". Its benefits are :

a) **easily extendable to additional use cases** with other types of clinical content in the future. The main infrastructure that spans cross-border, national, regional infrastructure needs only minimal extensions when new document content is added.
b) **easier to secure and offers patient friendly privacy**:
    - Event Logging is already built into the IHE MHD Profile by leveraging the IHE ATNA FHIR extensions.
    - Health professional and patient authentication (Oauth2)
    - Patient consent: needs a lot of work between the various rules in various countries. The current MyHealthEU approach is a good basis.

- System level trust and transport encryption with digital certificate to secure use of off-the shelf Internet.

c) able to cover sharing through registries and repositories in a centralized or partially/full distributed architecture to **accommodate different countries/health systems structures**

d) MyHealth@EU has been built on the proven IHE XCA cross-border infrastructure, It is operational today and effectively supports both structured and unstructured (document) content. **Several existing national/regional infrastructures (XDS/XCA) and MyHealth@EU can be easily bridged to the proposed IHE MHD transactions proposed in this sub-architecture**.

e) **cheaper to implement and operate**:
   - available portfolio of proven large scale document repositories and registries
   - critical for countries that need to catch-up and meet the EHDS schedule.

f) Similar transactions cover pull/query/retrieve and point-to-point push transport (even a notified pull to accomplish a push-like is a simple extension)

g) **Avoiding the risk of further fragmentation in implementation across member states by specifying the transactions for the EEHRxF**, which if left unspecified would slow its deployment and significantly reduce the impact of a digital single market.

The "edge access to data" is the other sub-architecture that complements the above large scale sub-architecture. It supports point-to-point approaches to access individual observations (HL7 FHIR resources APIs) suited for simple data consumers (e.g. patient mobile devices, or practices of individual health professionals such as GP, nurses, social workers). These are deployed in environments where there is a need for targeted interoperability between a larger system (e.g. hospital clinical information systems, patient or professional ehealth portals) and simple lightweight edge applications that essentially consume clinical data for specific display functions and highly specialized processing of specific data. For the purposes of the EHDS use cases, Individual HL7 FHIR Resources API's (e.g. HL7-Europe implementation guides) and OAuth2 as described in the HL7 International Patient Access (IPA) have been shown to be successful at meeting this need and scaling around the world.

Conclusion

In conclusion, bringing these two sub-architectures together to form the EHDS EHR Interoperability results in making each sub-architecture best fit to address our use cases, simpler to design, to implement and to operate as it relies on existing products and experiences. These sub-architectures can be easily bridged, as long as we have consistent clinical content spanning both sub-architectures, thus ensuring a consistent flow of information.

The next step to be implemented in the next 6 months with the on-going specification is to clearly establish this "transport layer"(content neutral transactions for search with associated filter metadata) and document retrieval. A serious standard candidate to consider is the IHE MHD Profile that is based on the FHIR Document Reference Resource has also a well organized specification of the search metadata that can be simply mapped to the 5 EHDS use cases. The IHE MHD profile provides a strong foundation as it has wide industry uptake having been tested in products by over 67 companies at recent IHE Connectathons in Europe.

About COCIR

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries. Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium) with a China Desk based in Beijing since 2007. COCIR is also a founding member of DITTA, the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (https://www.globalditta.org/).
https://www.cocir.org/

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.
www.medtecheurope.org.

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