IHE EUROPE WEBINARS

Xt-EHR Projectathon: Testing the EEHRxF and EHR requirements

IHE Europe Webinar Series

28 November 2025

IHE EUROPE Integrating the Healthcare Enterprise

IHE CATALYST

Xt EHR @dataspace

Welcome & Introduction

Sofia Franconi
IHE Europe

Agenda

Time	Topic	Speaker
11:00 – 11:05	Welcome & Introduction	Sofia Franconi
11:05 – 11:10	Strategic role of the Xt-EHR Projectathon	Andreas Neocleous
11:10 – 11:30	EHDS conformity assessment and General EHR requirements (EHDS Annex II)	Haralampos Karanikas
11:30 – 11:45	Projectathon outline and specifications supporting EHDS implementation	Jürgen Brandstätter
11:45 – 11:50	Organizational aspects	Nicole Veggiotti
11:50 – 12:00	Q&A	

Strategic role of the Xt-EHR Projectathon

Andreas Neocleous
Project Manager Xt-EHR

Strategic role of the Xt-EHR Projectathon

Why the Xt-EHR Projectathon Matters

- Accelerates transition from **testable** to **tested** EHDS-aligned specifications
- Ensures **technical readiness** of vendors and national infrastructures
- Strengthens **cross-border interoperability** through real-world validation

Core Strategic Objectives

- Build a **European ecosystem of early adopters**
- Validate Xt-EHR logical models, testable assertions, and test plans
- Align testing activities with **EHDS priority data domains**
- Support a unified **Conformity Framework** for EHDS implementation

Impact on the EHDS Landscape

- Provides evidence for scalable, trusted data exchange
- Bridges specifications, tooling, and implementation
- Creates momentum toward **structured compliance** across Europe

Xt-EHR Projectathon 2026 → A cornerstone for EHDS interoperability maturity

EHDS conformity assessment and General EHR requirements (EHDS Annex II)

Haralampos Karanikas
Associate Professor
Medical Informatics and eHealth systems
Department of Computer Science and Biomedical Informatics, University of Thessaly

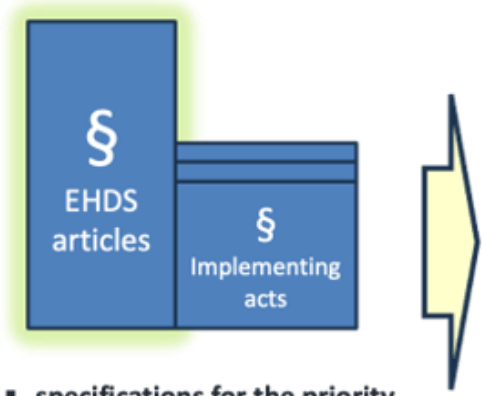
Definitions of basic concepts

• **EHR systems** are defined as (see Article 2(2) point (k) EHDS Regulation) *'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.'*
• **Conformity:** a product, service, or process has met the requirements and criteria set by a given standard or a specification.
• **Conformity Assessment Scheme:** a framework that allows eHealth solutions to be tested for their conformity with a selected set of eHealth standards and profiles (definition from EURO-CAS).
• **Compliance:** adherence of a product, service or process to legal and regulatory requirements, fulfilling legislative and contractual requirements.

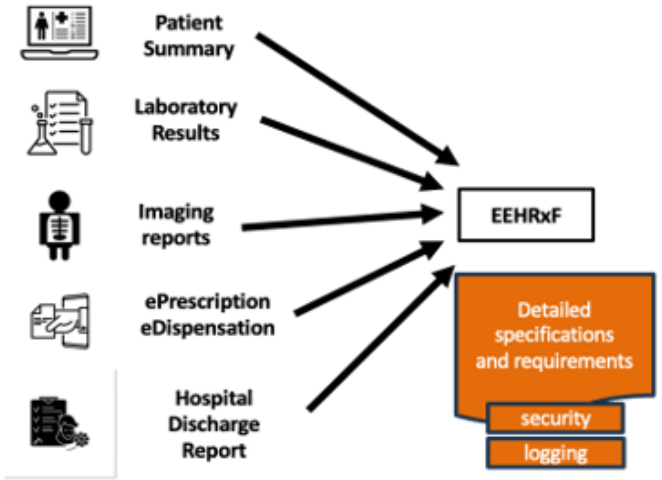
EHR: Two harmonised software components

- To be placed on the market or put into use within the EU, EHR systems must contain the two harmonised software components, namely:
  - The interoperability component,
  - and the logging component.
- These 'components' describe capabilities of EHR systems.
  - The interoperability component provides the capability to import/export data that falls under the priority categories in the EEHRxF.
  - The logging component provides the capability to generate logs that can be used in the health data access service to provide transparency on data access.

Specifications needed



- **specifications for the priority categories** of personal electronic health data referred to in **Article 14 (1)** of the EHDS regulation
- **common specifications** with respect to essential requirements as outlined in **Annex II** of the EHDS regulation



The EHR systems built according to the specifications need to be tested.

Role of Annex II in EHDS

- Annex II sets out the **“essential requirements”** for the harmonised software components of electronic-health-record (EHR) systems.

- These requirements also apply (mutatis mutandis) to any other digital health products or services that claim interoperability with EHR systems — for example medical devices, in vitro diagnostic devices, AI systems, or wellness applications.

- Annex II splits the requirements into:
  - **General Requirements.** These ensure basic safety and usability.
  - **Interoperability Requirements.** These ensure that health data can be exchanged, read and used consistently across different systems and countries.
  - **Security and Logging Requirements.** Because this concerns sensitive health data, Annex II also mandates strong security, data integrity, confidentiality, and auditability

- Why Annex II Matters:
  - Creates a common, harmonised standard across all EU Member States.
  - Enforcing interoperability and security
  - Provides an assessment framework

XT-HER: Technical Requirements for EHRs and key system interfaces

- **Xt-EHR JA** supports the European Commission and the Member States in preparing the Implementing Acts for Annex II of the EHDS Regulation by providing a structured set of functional requirements for the harmonised software components of EHR systems.

- It translates the legal provisions of Annex II into technical and functional concepts that can inform the common specifications to be developed through the Comitology procedure.

- These requirements establish the foundational standards for performance, interoperability, logging and security that harmonised software components of EHR systems must meet to operate safely, efficiently, and in full compliance with regulatory mandates.

- In addition:

It serves as a roadmap for manufacturers.

-

Clarifying how Annex II obligations may be operationalised in practice.

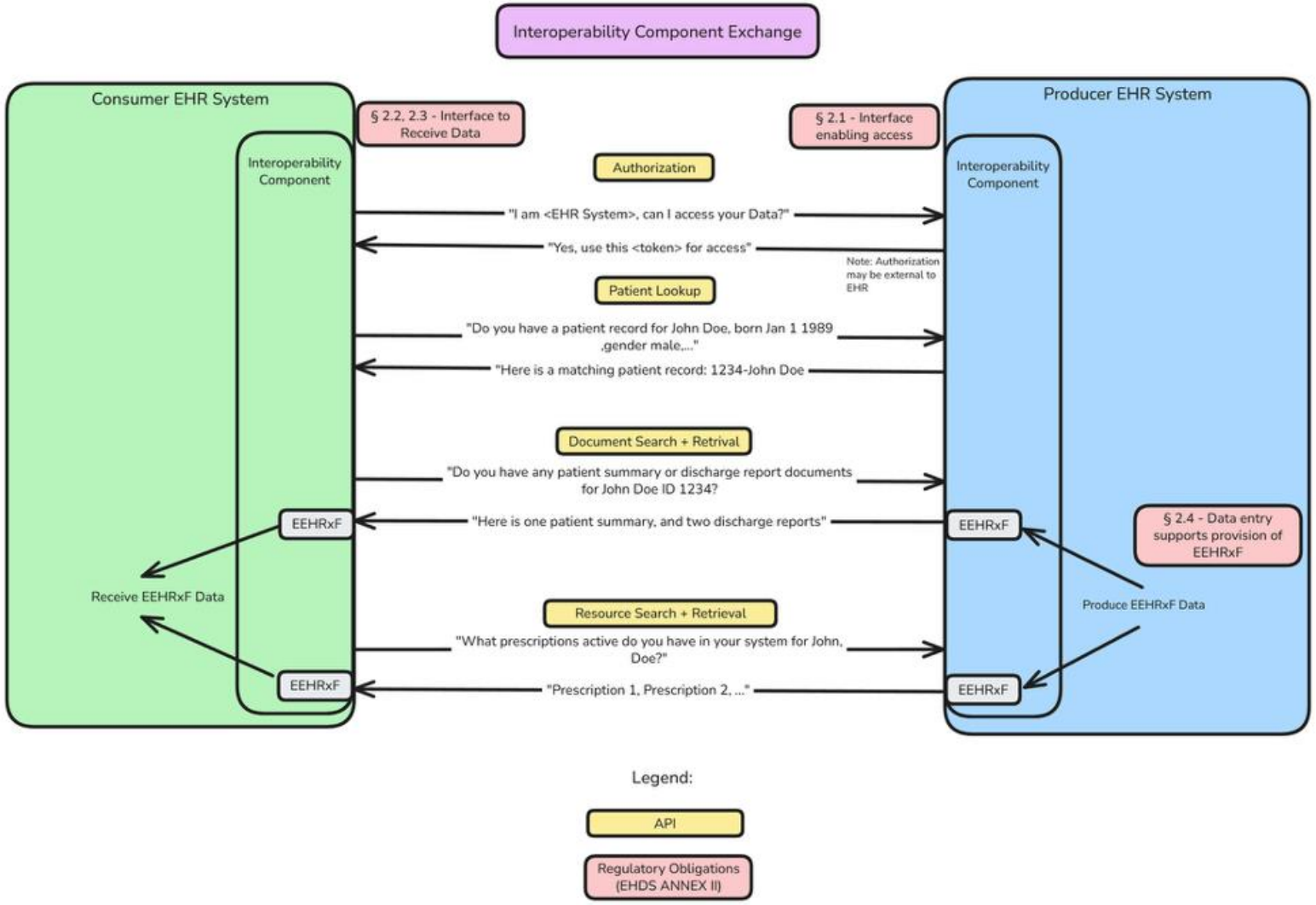
Example: Patient Story

John Doe arrives at a new healthcare facility for a scheduled cardiology review.

His longitudinal clinical history - past discharge summaries, medication lists, allergy records, lab results and imaging - is stored at his previous healthcare provider, which uses a different EHR.

*For clarity, we refer to the EHR system that stores the existing records as the **Producer system** (the system that originally created or holds the data that will be shared), and the EHR at the new facility as the **Consumer system** (the system that requests and uses those data to support current care).*

Example: Idealized exchange between two interoperability components



EHR systems Requirements List

Requirement ID	Scope
api-producer-general	Interoperability Software
api-consumer-general	Interoperability Software
api-producer-authDiscovery	Interoperability Software
api-producer-authProvideToken	Interoperability Software
api-consumer-authObtainToken	Interoperability Software
api-producer-authRequireToken	Interoperability Software
api-consumer-authPresentToken	Interoperability Software
api-producer-patient	Interoperability Software
api-consumer-patient	Interoperability Software
api-producer-doc	Interoperability Software
api-consumer-doc	Interoperability Software
api-producer-resource	Interoperability Software
api-consumer-resource	Interoperability Software
api-producer-data	Interoperability Software EHR system

Common specification	**INTEROPERABILITY – Consumer - General EHDS API**
Requirement ID	**api-consumer-general**
Legal requirement	**EHDS Annex II § 2.2** Where an EHR system is designed to store or intermediate personal electronic health data, it **shall be able to receive** personal electronic health data in the European electronic health record exchange format, by means of the European interoperability software component for EHR systems.
Scope	Interoperability Software Component
Applicability to different categories of EHR systems or functions included in them	Any EHR system acting as a Consumer for the priority categories it stores or intermediates. Not applicable to categories the product does not hold.
Actor	Consumer EHR System

Normative part	The EHR system Interoperability Component SHALL support consuming external priority category data via the EHDS API
Explanatory part	
In-scope for digital testing environments	Yes

Example of testable assertions: Patient Match

Requirement ID	Normative part	Suggestion for testable implementation (Example)
api-producer-patient	The EHR system Interoperability Component SHALL offer a patient lookup API sufficient for a consumer to unambiguously identify the patient electronic health record in the producer system given patient identification data (demographics or other forms of patient identity) as search parameters.	The EHR system interoperability component acting as producer SHALL support the IHE PDQm profile as a Patient Demographics Supplier actor to offer a way for consumer to unambiguously identify the patient.
api-consumer-patient	The EHR system Interoperability Component SHALL support an external patient lookup query API in order to unambiguously identify the patient electronic health record in an external system (such as a producer EHR system), using the consumer system's available patient identification data (demographics or other forms of patient identity)	The EHR system interoperability component acting as consumer SHALL support the IHE PDQm profile as a Patient Demographics Consumer actor with the Patient search option to unambiguously identify the patient at the producer.

Key points

- **The issue of maturity and readiness.** All stakeholders have different maturity and readiness levels concerning EHDS regulation and EEHRxF adoption
  - Suggestion to proceed with an incremental EU declaration of conformity to assist the market progressively based on EHDS regulation timeline

- **The Conformity assessment and Labelling references in the Regulation**
  - The concept of **purpose of use** is important.
  - Both the self-declaration of conformity and the labelling process rely on Annex II of the regulation as they both focus on the same harmonized components.
  - The Conformity Assessment Scheme should refer only to the harmonized components of EHRs

- **Open collaboration with stakeholders, especially the industry**

Projectathon outline and specifications supporting EHDS implementation

(relevant IHE profiles in the Xt-EHR deliverables)

Jürgen Brandstätter
Global Standards Director
IHE Catalyst

Testing Approach and Key Aspects

- **Setting and format: “Projectathon”**
  - Layout: Own area with tables within Connectathon area

- **Participants spectrum**
  - EHR / EMR / LAB / RAD / HIS vendors
  - National eHealth teams & digital health authorities

- **Test-setting**
  - No-peer tests, peer-to-peer tests
  - Testing of Xt-EHR referenced standards

- **Agenda will be a mix of …**
  - Education
  - Testing

Testing of content

- **Content – Testing (no-peer)**
  - Euridice FHIR IGs for …
    - ePrescriptions/eDispensations
    - European Patient Summary
    - Discharge Summary
    - Laboratory Report
    - Imaging Report

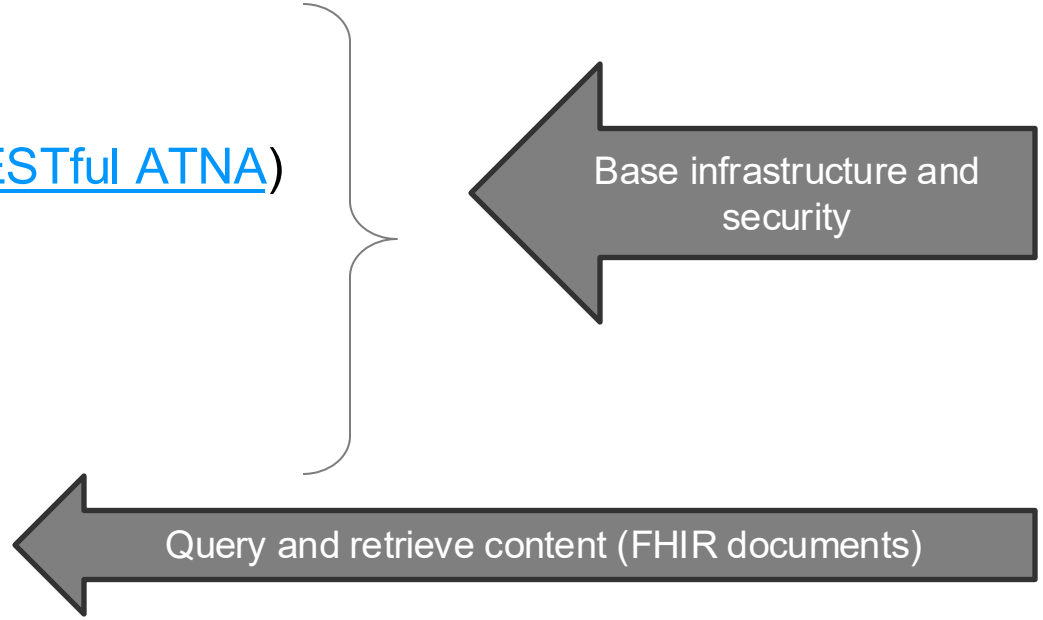
EURIDICE

European Interoperability Specifications for Digital Solutions in Healthcare

https://euridice.org

Testing of transactions

- **Transaction – Testing (peer-to-peer or peer-to-simulator)**
  - IHE Profiles for Infrastructure
    - Consistent Time (CT)
    - Audit Trail and Node Authentication (ATNA, RESTful ATNA)
    - Internet User Authentication (IUA)
    - Query for Existing Data for Mobile (QEDm)
    - Patient Demographics Query (PDQm)
    - Mobile access to Health Documents (MHD)



Testing of transactions

- **Transaction – Testing (peer-to-peer or peer-to-simulator)**
  - IHE Profiles for Imaging
    - Web-based image access (WIA) ← International standard for WADO-RS
    - Cross-Community Web-Based Access to DICOM Objects (XC-WADO)
    - Manifest-based Access to DICOM Objects (MADO) ← Developed by Xt-EHR (D7.2)

*The Manifest-based Access to DICOM Objects (MADO) Integration Profile specifies actors and transactions to **retrieve patient-relevant DICOM Instances from medical imaging studies** being held within a community. Each community may have multiple sources of medical image data that publish it for sharing within the community. It may be combined with XC-WADO for cross-community access.*

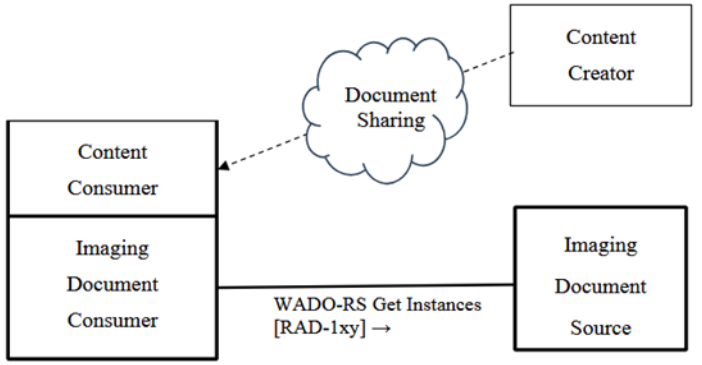


Figure X.1-1: MADO Actor Diagram

Schedule and program

- **Monday: Preparation**
  - Only for participants with systems to test
  - Configuration, Connectivity, Preparation for testing

Participants may come with systems to test

- **Tuesday – Thursday: Projectathon**
  - Education
  - **Testing**
  - Discussion
  - Break-out sessions
  - Cross-overs

… or just to listen & learn

Cross-overs

- **Cross-overs with other EU projects, Plugathons and events**
  - IHE Europe Experience Days
  - MyHealth @ MyHands Plugathon
    - “patient-mediated” sharing of prescriptions
    - Wallet architecture
  - I2X Plugathon
    - EEHRxF use cases
    - AI extensions
  - OpenEHR Plugathon
    - IPS Alignment
  - JIC “International Patient Summary” Summit

Organizational aspects

Nicole Veggiotti
IHE Catalyst

Organizational aspects

The IHE Connectathon Week 2026 will take place from Monday, 23 March to Friday, 27 March 2026, in Brussels, Belgium.

The Xt-EHR Projectathon 2026 will take place in the IHE Connectathon Week from Tuesday, 24 March to Thursday, 26 March 2026, having a very dynamic agenda alternating educational and testing sessions.

Monday afternoon will be dedicated to connectivity/preparatory test in Gazelle

Where? The EGG, Rue Bara 175, 1070 Brussels.

About a 10-minute walk from Brussels-South Station (Gare du Midi)

Registration period: From mid December until mid January

Series of Webinar to get ready for the Projectathon

Next webinar:

- 12th December 11h CET: draft agenda of the educational program and launching the registration
- More are coming in the next year!!

Stay tuned!!

Questions?