

ADVANCING EHDS IMPLEMENTATION WITH FHIR IGS IN 2026: TOWARDS A ROADMAP

A session at the HL7 Europe Working Group Meeting 2025

Dorint Hotel An der Messe Köln, Cologne, Germany

Monday, 1 December 2025, 13.45 CET

Session team: Diogo Martins < diogo.martins@uphillhealth.com>; Michael Strübin < Michael.strubin@hl7europe.org>; Rutt Lindström < rutt.lindstrom@hl7europe.org>

Advancing EHDS implementation with FHIR IGs in 2026: towards a roadmap



- Welcome, Objectives, and Session Framing
 Rutt Lindström & Michael Strübin, HL7 Europe, Diogo Martins, i2X
- European Commission Perspective on EHDS Implementation Vanessa Mendes (DG CNECT) and Aurora Joala (DG SANTE)
- xShare, ESHIA and perspectives on ecosystem alignment Marc Lange, ESHIA
- Xt-EHR: Specifications and Implementing Acts Support Andreas Neocleous, Xt-EHR
- MyHealth@MyHands: Wallet-Based Identity & Patient Access Zoltan Lantos, MyH
- Capability-Building for a Learning Ecosystem: XiA's Contribution to FHIR-Enabled EEHRxF
 Adoption
 - Simon Lewerenz, XIA
 - Joint Discussion: Towards Coordinated Implementation and Feedback Loops
- Wrap-up and Next Steps: Shaping a Shared Roadmap for 2026
 Diogo Martins, i2X

Challenges ahead of us



Implementation Support and Feedback Loops

Addressing how can collaborate to shared knowledge on the implementation of the Format, validation environments, and mechanisms that capture lessons learned from real-world deployments

Ecosystem Engagement and Coordination

European and national digital-health actors, including HL7 affiliates, Industry communities, and national clusters, can act as multipliers for consistent implementation of the HL7 FHIR IGS

Clarity

On technical requirements and specifications

Support

Healthcare providers in adapting to the EEHRxF

Capture

Real-world evidence and cost-benefit of structured data

Change

Systems and implementation in duo time

AI readiness

Healthcare systems architecture, infrastructure and Data quality



1. I2X | CONNECTING EU HEALTH DATA





Who we are:

Start date: 1st of April 2025

Lengths: 48months

Partners: 38 Partners involving 12 Member States

What is i2X

i2X is a Digital Europe project that aims to demonstrate the real-world value of the EEHRxF, supporting the European Health Data Space (EHDS) and MyHealth@EU. It is an implementation-based project that will test digital health tools in everyday clinical settings to alleviate the burden of healthcare professionals.

Why it Matters

i2X will:

- Advance digital health through Al-powered and standards-based tool
- Support healthcare providers in adapting to the EEHRxF
- ▼ Capture real-world evidence and cost-benefit of structured data implementation
- Empower patient to access, share, and manage their health information
- Contribute to policy alignment, standardization, and EU-wide interoperability



i2X is an 8M EU-funded project that aims to implement EEHRxF in an intelligent way, involving 38 partners across 12 different EU Member States in the next 4 years



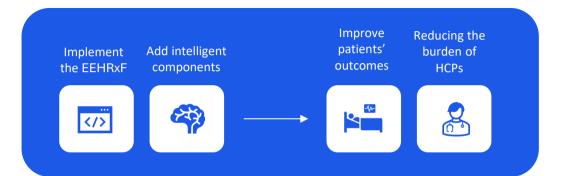


What is the EEHRxF?





What is the purpose of i2X?





How will i2X implement the EEHRxF?







Blueprint to real-world scenarios – i2X implementation Focus





i2X is not just a research project, but an action-driven initiative, proving value in real-world clinical and show the value of implementation in a diverse European landscape.





EHR integration, AI support, decision-making



Testing usability and effectiveness



Real interoperability between systems



i2X Implementation Scenarios & Use Cases



High-Level Areas of Work:

i2X covers real-world implementation of EEHRxF across 5 broad settings in the 5 data categories

Data Categories: Patient Summary, ePrescription/eDispensation, Lab Results, Medical Imaging & reports, Discharge Letters

Cross-border Exchange

(MyHealth@EU)

Regional Exchange

(Inter Org Networks)

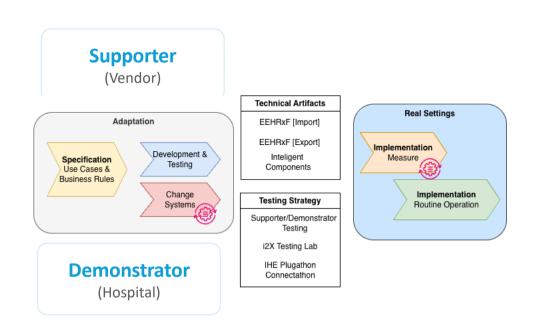
Intra-organization
Workflows

National Exchange

(Country Systems)

(Inside Providers)

Patient Access - (Patient access, portals and apps)



Expansion – Outreach & Ecosystem Engagement



Why it matters: Expanding beyond the consortium enables i2X to scale impact, test interoperability in diverse settings, and align with real-world needs



Special Interest
Groups (SIGs)

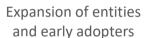
Industry
Healthcare Provid













Co-create and validate standards in real-world settings



Drive adoption and ensure alignment with European Strategies



Foster sustainability and open Innovation



Engaging Networks

i2X Digest - Highlights (Apr-Dec 2025)



Coordination & Ethics

Governance in place: Handbook, PLB, QA & Risk plans



Overall project progress, governance and monitoring Ethics Advisory Board and Advisory Board

Technical work launched:

- WP2 needs assessment
- WP3 testing strategy/Online Testing Tool
- WP4 demonstrator prep & cluster

Project identity & website live: i2xhealth.eu

Tools & Testing (WP2-3)



Needs & challenges assessment (WP2) & field studies underway

Unstructured to Structed data: NPL, NER, AI

Testing strategy and Online Testing Tool(WP3) Online testing

Tools (validators, simulators)

Specs alignment w/ HL7, IHE, openEHR

Demonstrators (WP4–5)



- Use Case & requirements study launched in 11+ healthcare settings
- Use case definitions submitted (Sept)
- User stories & workflows
- WP4 aligned with WP2 tools & WP3 specs

Dissemination & Engagement (WP7)



- Dissemination Plan (D7.1) finalised (M6)
- Visual identity, website, social media activated
- Channels: LinkedIn (1000+ followers), YouTube, Bluesky

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Leveraging Data with EEHRxF

Advancing EHDS implementation with FHIR IGs in 2026: towards a roadmap 2025, 1st December HL7 Annual WG Meeting

Vanessa Mendes

Programme Officer – EU Policies CONNECT.A6: Artificial Intelligence in Health and Life Sciences





EU Ecosystem supporting innovation in EU

Digital Europe

"bringing digital technology to businesses, citizens and public administrations"

Horizon Europe

research & innovation

EU4Health

"building stronger, more resilient, more accessible health systems"

ERASMUS+

"EU programme for education, training, youth and sport"









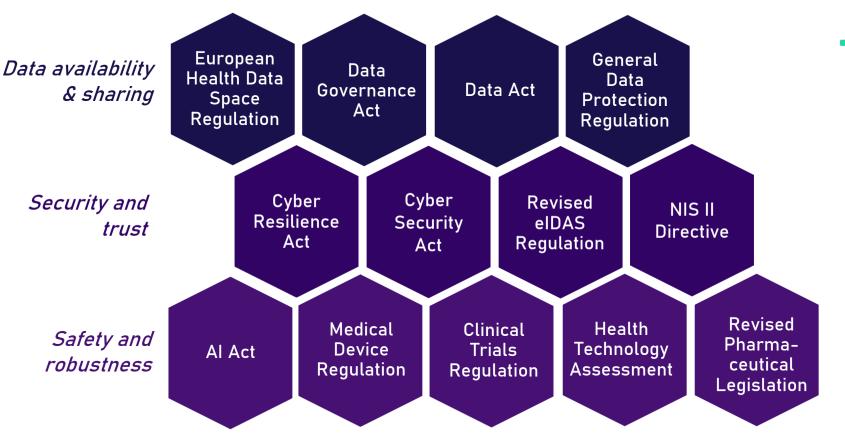








Fostering Safe-Secure-Trust-Based Innovation





Digital Decade Policy Programme

e-Health target
100% of EU citizens access to
electronic health records by
2030

State of play 31 Dec. 2024:

The composite eHealth score for the EU-27 averaged 83%, an increase of four percentage points from 79% in 2023.

Source: <u>Digital Decade 2025:</u> <u>eHealth Indicator Study |</u> <u>Shaping Europe's digital future</u>







EU action

Across the Al value chain, from research to deployment

ECOSYSTEM SUPPORT

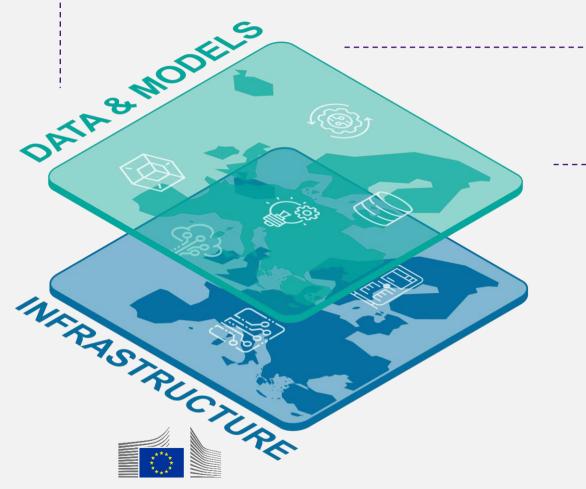
- Healthcare digitalisation
- Networks of excellence
- Interoperability
- Regulatory alignment
- Trust
- Skills





EHDS

 Trusted framework for access to health data for Al innovation



EU action

Data Union Strategy

- Improve data access for businesses and administrations and simplify data rules
- Data Labs in Al Factories will gather and curate high-quality data from different sources

Digital infrastructures

- Genomic Data Infrastructure
- Cancer Image Europe
- Advanced Platform for Virtual Human Twins
- Intensive Care Unit data space



Thank you





EEHRXF

European Electronic Health Record exchange Format

Aurora Joala

Policy Officer - European Health Data Space DG Sante - C1 Digital Health



Work on implementing acts

- In total 28 empowerments for implementing acts; 18 identified as priorities, 12 of which have a legal deadline for adoption.
 - Packed schedule for Committee on the EHDS
 - Collaborative process with Member States
- Inputs to come from a number of Joint Actions / projects, e.g.:
 - Xt-EHR (primary use)
 - <u>TEHDAS2</u> (secondary use)
 - QUANTUM (data quality labelling)



Use cases for the EEHRxF in the EHDS

Article 3(2

• **Download** of an electronic copy of at least the personal electronic health data in the priority categories (access right)

Article 7(4)

• Transmission to healthcare providers chosen by the patient of electronic health data downloaded based on the access right in Article 3(2) (**portability** right)

Article 23

• Exchange of the priority categories of personal electronic health data between national contact points for digital health (MyHealth@EU, Article 23), including to support the portability right of patients across-borders (Article 7(2));

Article 36

• Harmonised interoperability component of electronic health record (EHR) systems (common specifications, and essential requirements for EHR systems, Annex II).

Applicability of use of the EEHRxF for each data category:

- From 26 March 2029 for patient summaries, electronic prescriptions and electronic dispensations
- From 26 March 2031 for medical imaging studies and related imaging reports, medical test results, including laboratory and
 other diagnostic results and related reports, and discharge reports.

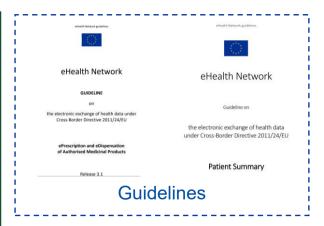
Note: Certification of EHR systems only applies to systems placed on the market or put into service after the application deadline.

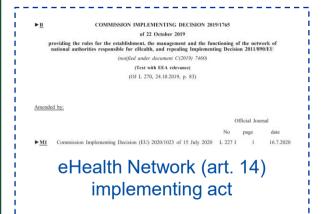


eHealth Network guidelines as a basis

MyHealth@EU under the Cross-border healthcare directive 2011/24/EU

European Health Data Space Regulation





eHealth Network/eHMS



By ... [two years from the date of entry into force of this Regulation], the Commission shall, by means of implementing acts, lay down the technical specifications for the priority categories of personal electronic health data referred to in Article 14(1), setting out the European electronic health record exchange format. Such format shall be commonly used, machine-readable and allow transmission of personal electronic health data between different software applications, devices and healthcare providers. Such format shall support transmission of structured and unstructured health data and shall include the following

European electronic health record exchange format

Article 23 MyHealth@EU

And other articles: 7, 16, 17, 24

SECTION 3

CROSS-BORDER INFRASTRUCTURE
FOR PRIMARY USE OF PERSONAL ELECTRONIC HEALTH DATA



MyHealth@EU

The Commission shall establish a central interoperability platform for digital health ('MyHealth@EU') to provide services to support and facilitate the exchange of personal electronic health data between the national contact points for digital health of the Member States



Zooming in: 3 pillars of the European Electronic Health Record exchange Format (EEHRxF)

Harmonised datasets

 Containing electronic health data and defining structures, such as data fields and data groups for the representation of clinical content and other parts of the electronic health data

Coding systems and values

To be used in datasets containing electronic health data

Technical interoperability specifications

 For the exchange of electronic health data, including its content representation, standards and profiles



Fundamental principles for EEHRxF

- It is essential that the standards used in the EHDS implementation are freely accessible.
- Key implementation resources like validators and guides must remain open-source and accessible to the community to support widespread adoption and compliance and ensure transparency and openness.



Preferred code systems: Example from MyHealth@EU

Example from the eHealth Network guidelines on the patient summary

A.2.3.1 Current problems				
A.2.3.1.1	Problem / diagnosis description	Health conditions affecting the health of the patient and are important to be known for a health professional during a health encounter.	ICD-10* SNOMED CT GPS Orphacode if rare disease is diagnosed	
A.2.3.1.2	Onset date	Date of problem onset	ISO 8601	
A.2.3.1.3	Diagnosis assertion status	Assertion about the certainty associated with a diagnosis. Diagnostic and/or clinical evidence of condition.	HL7	

- Preferred code systems in eHealth Network guidelines
 - **Sender**: NCP A: Send at least in one of the preferred code systems. List of allowed values are included in a Master Valueset Catalogue. If not possible, it should be transferred encoded, preferably in English, and/or in narrative form.
 - Receiver NCP B: Translation and mapping to national codes.



Thank you



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xShare, ESHIA and the EEHRxF ecosystem: towards real life implementation

1 December 2025

Marc Lange, EHTEL, President of ESHIA marc.lange@ehtel.eu

Implementation Challenges & the European EHRxF Standards and Policy Hub



The benefits foreseen by the European Health Data Space are dependent on the specifications of the European EHRxF

Standards based innovation is a key policy objective across the European Union

Users wanting to realise interoperability for their specific use cases will never need the full breadth and complexity of the European EHRxF

The Hub will provide them with dedicated guidance, compliant with the EHRxF

Industry will realise systems conformant with the European EHRxF

The Hub will provide industry engagement from an early stage on

Regulators need to rely on mature specifications for legal reference

The Hub will provide regulatory responsiveness and alignment with (global) standards



Many parts are now in place for you to use

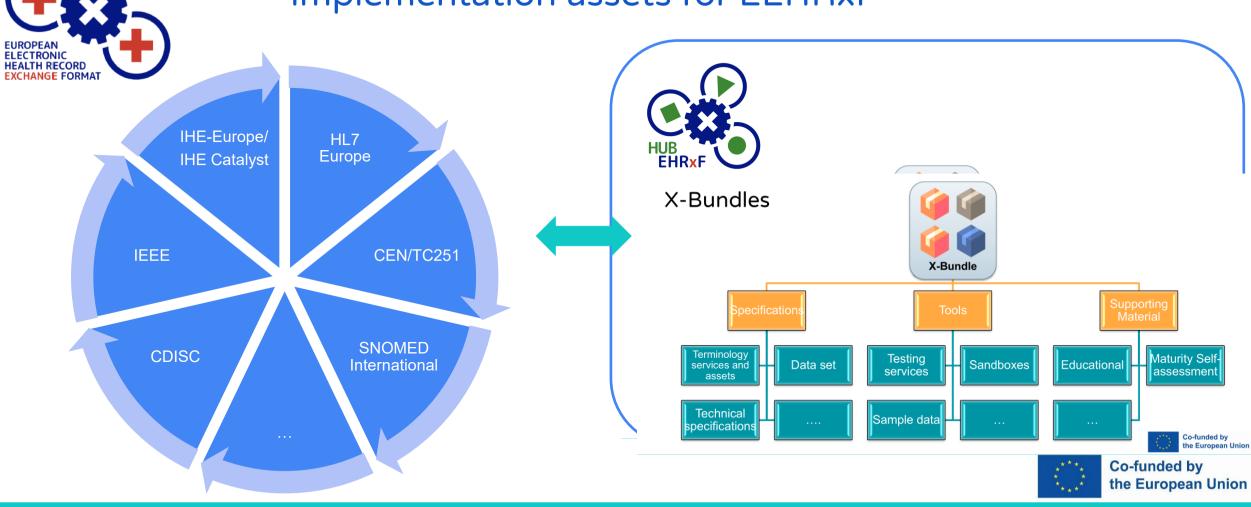


	xShare Community of Excellence	 https://xshare-project.eu/community-of- excellence/ 	
	Business Use Case Repository	• https://usecase-repository.ihe-europe.net/	
	X-Bundle Registry	• https://x-bundles.ehr-exchange-format.eu/	
	Helpdesk	 https://ehr-exchange-format.eu/adopting- ehrxf/helpdesk/ 	
	Industry Forum	• secr-industry-forum@ehrxf-hub.eu	
	Regulators Forum	• secr-regulators-forum@ehrxf-hub.eu	
EHRXF EUROPEAN ELECTRONIC HEALTH RECORD EXCHANGE FORMAT	One website bringing it all together: https://ehr-exchange-format.eu/		



SDOs in support of implementation assets for EEHRxF





The EEHRxF ecosystem in 2025-2026





Implementers

xShare Communities (CoE, Adoption sites, Open Calls)

EHDS
project Consortia and
their communities

Other EHRxF stakeholders

European Commission Xt-EHR

Support Centre for EEHRxF



Industry Forum

Regulator Forum



Owners of specifications, tools and supporting material



SDOs

Co-funded by the European Union

Industry Forum

02/10/2025



EEHRxF Standards and Policy Hub hosted by



Steward of the EEHRxF interoperability assets

- Creating, managing and aligning, harmonising assets
- Cleaning and bundling for user-friendliness
- Capturing and actioning demands for new work items (including new business use cases...)
- IPR transparency

Neutral and supportive environment for EEHRxF interoperability assets

- Serving as one-stop-shop with up-to-date info on EEHRxF assets
- Convening SDOs, industry, regulators and other interested parties for alignment and co-creation
- Operating with transparency and accountability respecting IPR ownership

Enabler of scaling up EEHRxF adoption

- Training and education
- Testing environment, examples, and reference implementations
- · Adoption support services ecosystem including access to services for localization and labeling
- Communication and dissemination about the EHRxF and the Hub support services.

Phases setting up the Hub and ESHIA









Phase 1 2023-2024

Phase 2 2025-2026 (legal entity)

Phase 3
After 2026 (after project end)

The EEHRxF ecosystem from 2027 onward





Digital Health Industry

EHDS project Consortia and their communities

Other EHRxF stakeholders

European Commission **EHR Repository**

Testing Environment

Support Centre for EEHRxF

EHDS Board & Stakeholder Forum



ESHIA

Technical Committee

ESHIA General Assembly

Private sector advisory board

Public sector advisory board



Owners of specifications, tools and supporting material

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Xt-EHR: Specifications and Implementing Acts Support

Andreas Neocleous – Project Manager Xt-EHR



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The European Health Data Space (EHDS) and the role of Xt-EHR

EHDS Overview

- EU-wide framework for secure access & exchange of health data
- · Aims to empower patients and support continuity of care
- Ensures interoperability across Member States
- Defines priority datasets that must be shareable (incl. discharge reports)

EHDS Timeline

- **11 February 2025:** Regulation (EU) 2025/327 adopted
- 5 March 2025: Official publication in the EU Official Journal
- 26 March 2025: Entered into force (20 days after publication)

The role of Xt-EHR

- Translates regulation into practical specifications
- Bridges gaps between regulation and current guidelines (eHN)



Xt-EHR Project Overview

Pillar 1: EHR Requirements (WP5)

Completed 100%

Xt-FHR delivers:

- Functional requirements from FHDS Annex II
- Producer/consumer API model
- Logging requirements
- Blueprint for common specs

EHDS asks:

- EHRs must interoperate
- Must implement harmonised components
- EHDS does NOT say how

Pillar 2: Exchange Format (WP6 & WP7)

Completed 90%

Xt-FHR delivers:

- Terminology bindings
- Document & resource models
- Validation & semantics
- Defines FHIR profiles & structure

EHDS asks:

- EHRs must use the EU format
- EHDS doesn't define data elements or profiles

Pillar 3: Conformity (WP8)

Completed 80%

Xt-FHR delivers:

- Technical test cases
- Assertions from Annex II
- Early conformity model
- Industry/MS alignment

EHDS asks:

- EHRs must pass conformity
- EHDS gives no technical tests

European Alignment & Testing: HL7 Europe (December 2025) ● IHE Connectathons & Xt-EHR Projectathon (March 2026) MoUs (HL7 Europe and IHE Europe) official announcement in Vienna, June 2025.

Xt-EHR Projectathon 2026

- The Xt-EHR Projectathon 2026 will take place in the IHE Connectathon Week
- 24 to 26 March 2026, having a very dynamic agenda alternating educational and testing sessions.
- Monday (25th March 2026) 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



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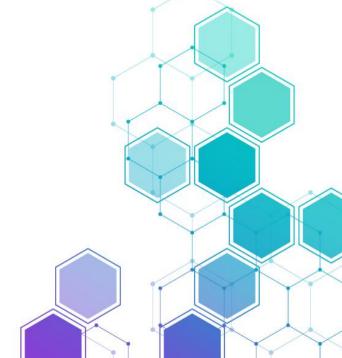
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My Health at My Fingertips

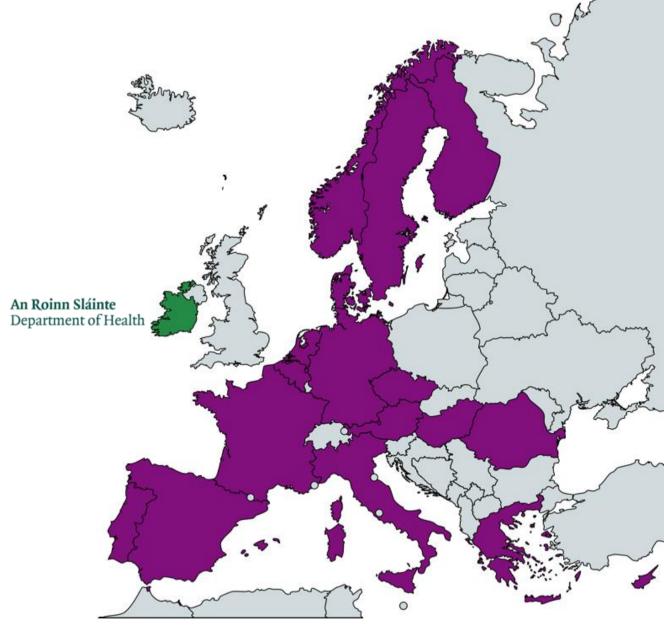
1st of December 2025





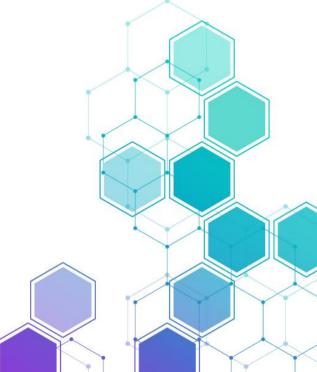


Person-centred health management through access to your health data using EUDI Wallet services 18 countries, 45 organisations





































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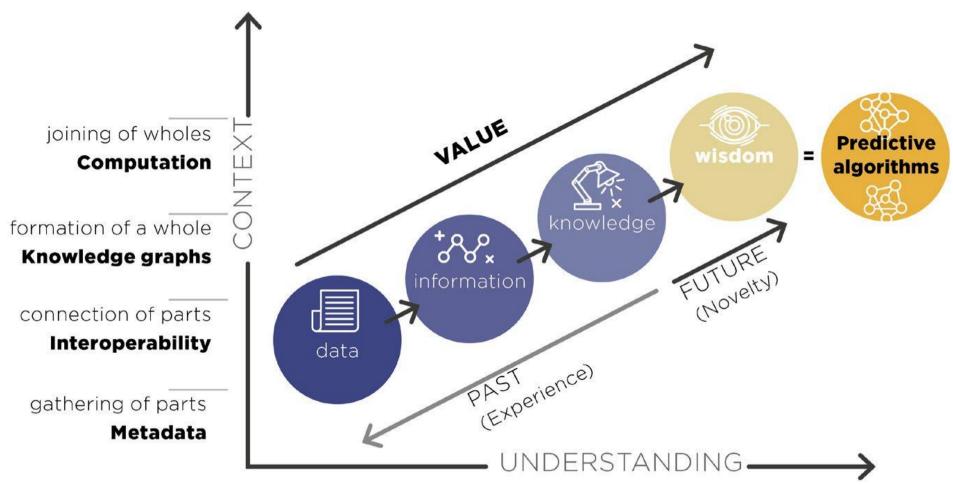












User Interface of the Data Value Chain









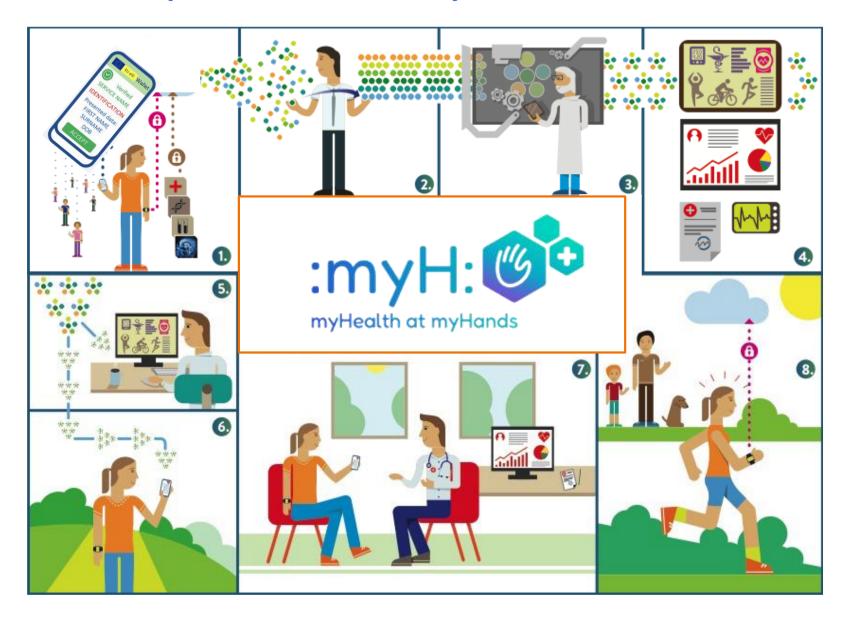
Identification and authentication

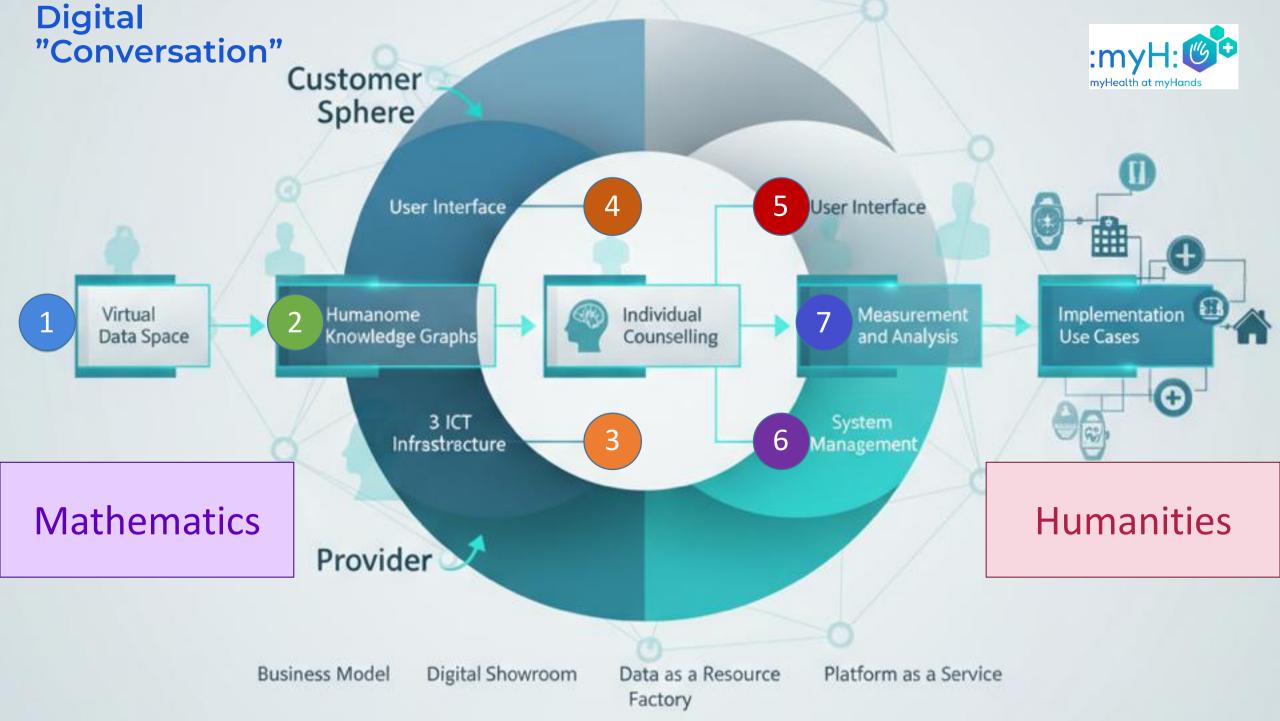
Presentation of "attributes"

Digital signature

A Gateway to Patient Autonomy





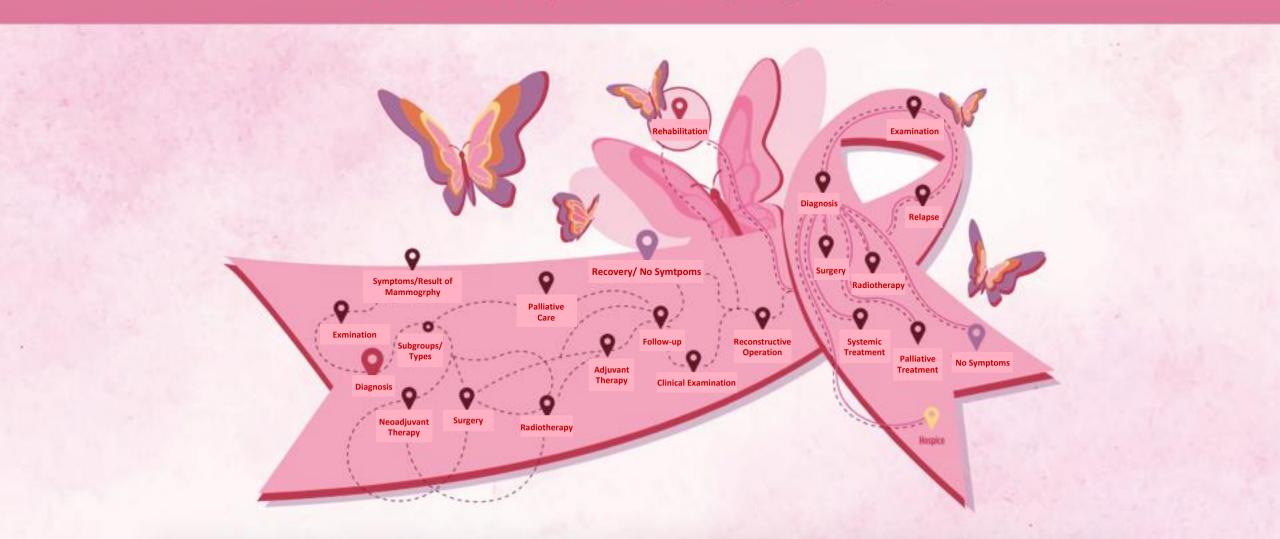


End-User Experience in Health Co-Management



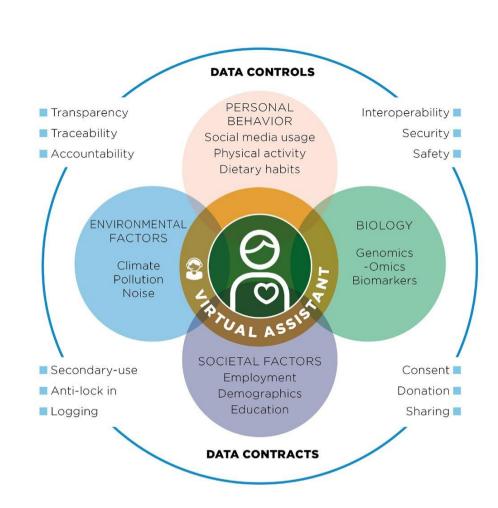
BREAST CANCER PATIENT JOURNEY FOR WOMEN

You can also reach the patient route stations by clicking on the image.



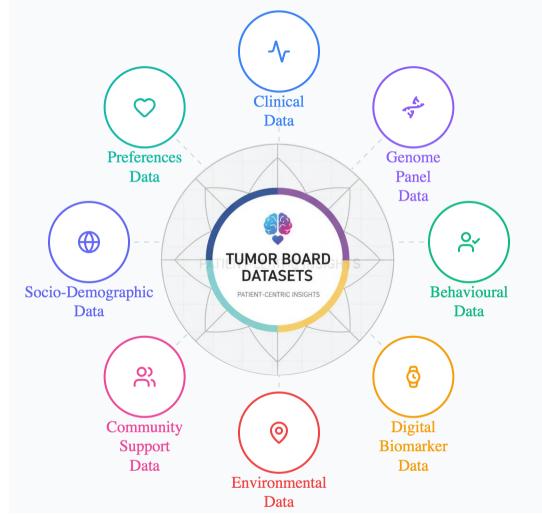
Humanome Data Model for Multidisciplinary Tumour Boards





The Next Era in Global Health by Copenhagen Institute for Futures Studies, 2020.

In the eGovERA / EIRA Framework

















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Capability-Building for a Learning Ecosystem: XiA's Contribution to FHIR-Enabled EEHRxF Adoption

Coordinator: Prof. Henrique Martins (ISCTE)

Presented by: Simon Lewerenz (ISCTE)

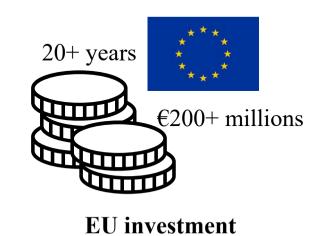
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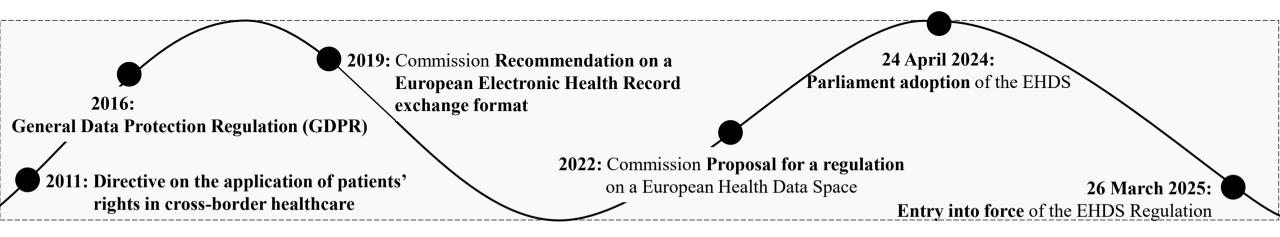


Problem Statement



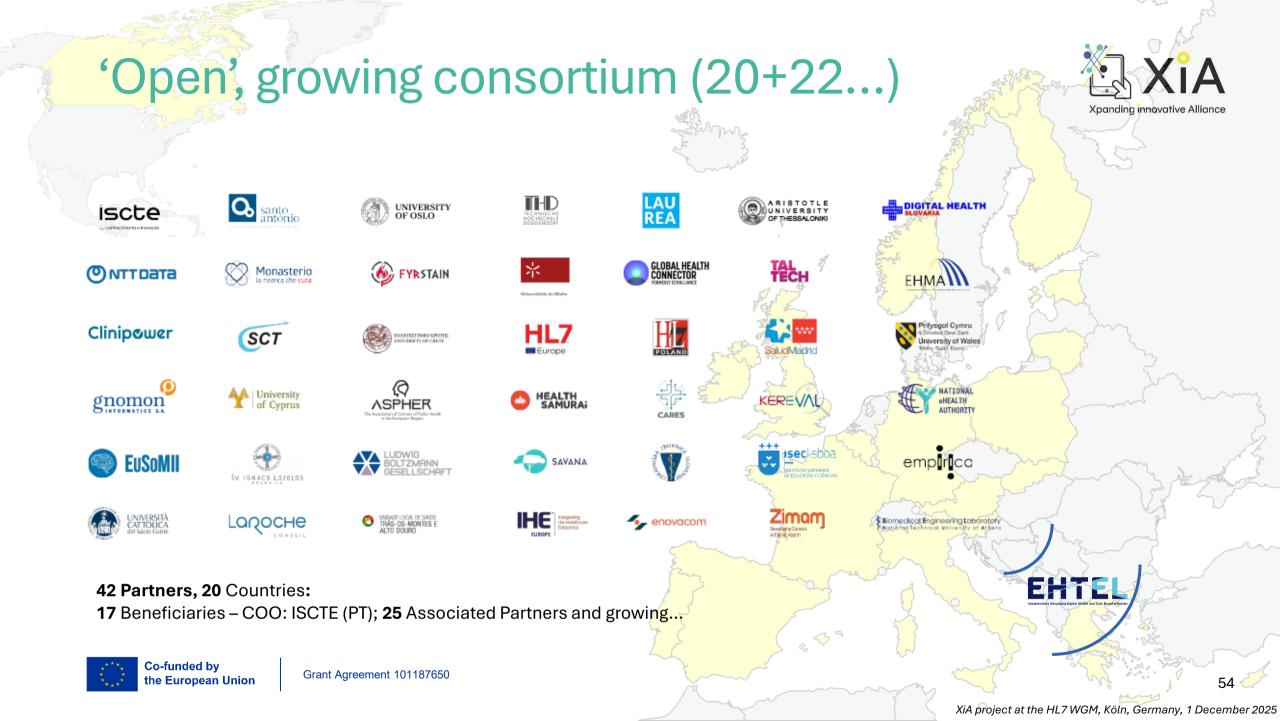
- The European Health Data Space (EHDS) and the European Electronic Health Record Exchange Format (EEHRxF) demand a workforce fluent in digital health interoperability
- Yet healthcare and ICT professionals lack shared understandings, competences and skills to act collaboratively.
- How can we integrate key interoperability matters into education and continuous training, so that digital health professionals can effectively contribute to seamless, secure and meaningful data exchange?







Grant Agreement 101187650



Project overview

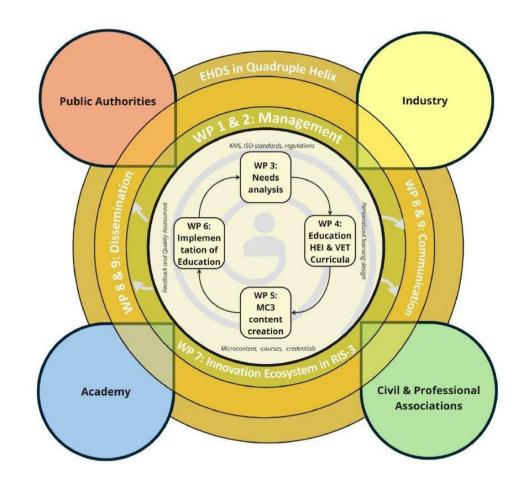


General Objectives

- Enhancing Digital Health Interoperability Skills
- Developing Future-Oriented EEHRxF Education
- Building an Educated Pan-European Digital Health Ecosystem

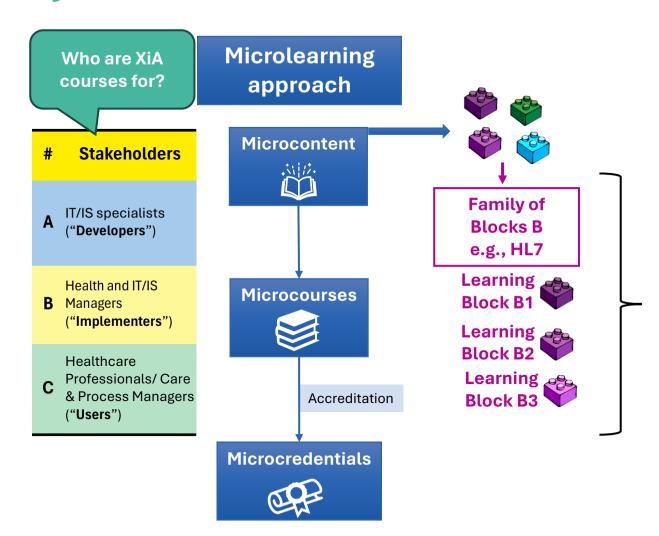
Specific Objectives

- Digital Health Needs Analysis;
- Skill and Curriculum Development;
- Micro-Content Mapping, Creation and Delivery;
- Community Building and Sustainability;
- Certification and Quality Assurance; Outreach and Impact



Project overview





20 Families of Micro-Content Learning Blocks (MCLB)

various topics on Key Advanced Interoperability Standards

including HL7 Standards

A peek into...



What is the Gap in Skills vs Needs?

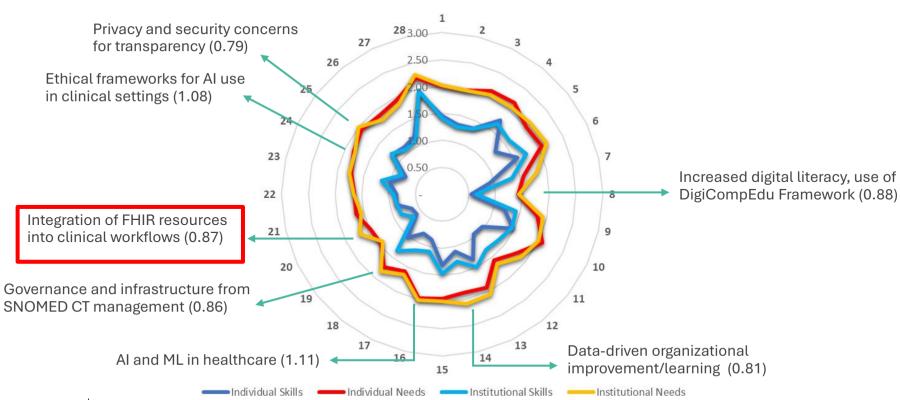
Avg. current skill level: Avg. current skill need:

1.11

1.84

Basic understanding

Average understanding





Key contribution: XiA...



- 1. ...builds the workforce able to implement and maintain the EEHRxF FHIR IGs in practice
 - FHIR IGs cannot scale without people who know how to execute them. XiA builds that human capacity across IT systems developers, implementers, and users.
- 2. ...turns the FHIR IGs behind the EEHRxF into modular, teachable, reusable knowledge assets

XiA translates the IGs from technical documents into structured learning blocks that can be adopted by hospitals, vendors, training bodies and national clusters—supporting coherent implementation across Europe.

- 3. ...supports a feedback-loop model where real-world implementation inform iterative improvements to FHIR IGs in a learning ecosystem
 - XiA creates the human capacity needed for informed feedback to HL7 Europe, the X-Format projects, and the Commission
- 4. ...prepares the workforce for AI-assisted structuring and validation of FHIR-conformant data

Al can help generate or validate FHIR-conformant structures, but only if professionals know how to supervise, validate, and govern Al outputs. XiA provides that skill foundation with Family of MCLB n°20.





Contact

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Thank you!

Obrigado – Gracias – Ευχαριστώ – Tak – Hvala – Dank u – Děkuji – Danke – Takk –

Kiitos – Köszönöm – Go raibh maith agat – Ďakujem – Köszönöm – Dziękuję – Grazie

– Mulţumesc – Благодаря – Grazzi - Aitäh – Paldies – Ačiū – Merci – Tack



Advancing EHDS implementation with FHIR IGs in 2026: towards a roadmap

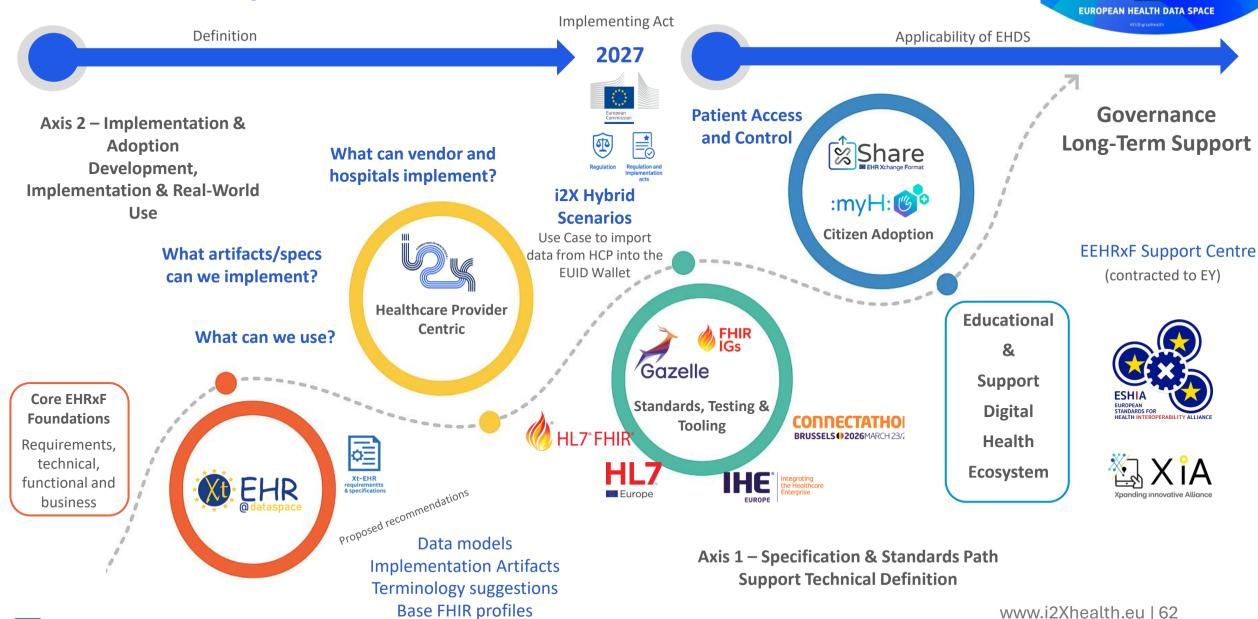


- Welcome, Objectives, and Session Framing Rutt Lindström, HL7 Europe & Diogo Martins, i2X
- **European Commission Perspective on EHDS Implementation** Vanessa Mendes (DG CNECT) and Aurora Joala (DG SANTE)
- xShare, ESHIA and perspectives on ecosystem alignment Marc Lange. ESHIA
- **Xt-EHR: Specifications and Implementing Acts Support** Andreas Neocleous, Xt-EHR
- MyHealth@MyHands: Wallet-Based Identity & Patient Access Zoltan Lantos, MvH
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Joint Discussion: Towards Coordinated Implementation and Feedback Loops

Wrap-up and Next Steps: Shaping a Shared Roadmap for 2026 Diogo Martins, i2X

X-Format Projects Intersections



Advancing EHDS implementation with FHIR IGs in 2026: towards a roadmap

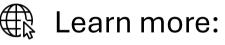


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