



***the European Health
Data Space***

and Internal Medicine

16th October 2026, Brussels

Henrique Martins, MD, PhD,
Mlaw Professor Associado,
ISCTE-IUL, FCS-UBI,
Universidade Lusófona
www.henriquemartins.eu

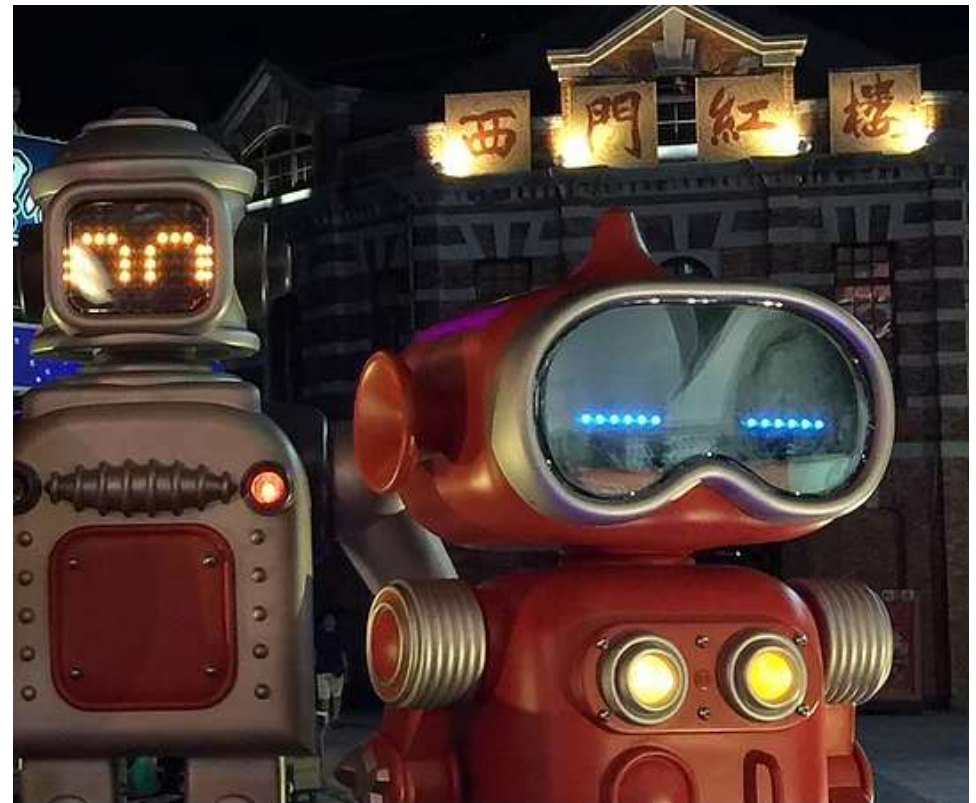


EFIM
www.efim.org

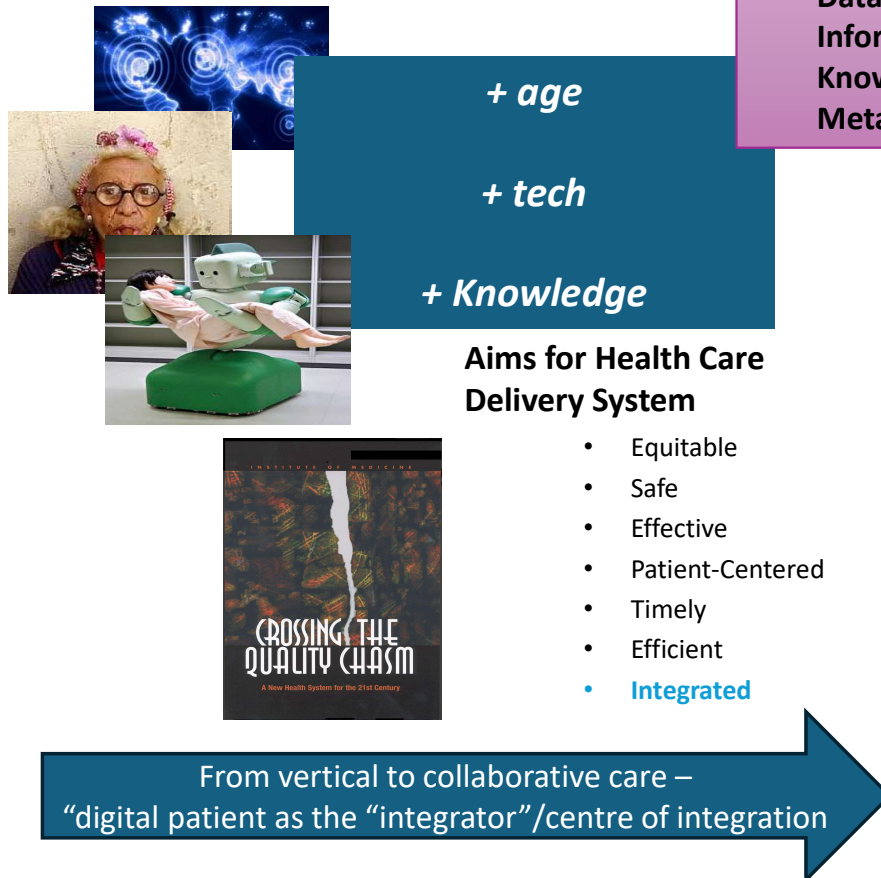
11th EFIM Day
16 October 2026, Brussels

Agenda for our Keynote...

- Digital Health Systems
- European Health Data Space
- Projects that help understand/prepare for the EHDS and the EuropeanEHRxFormat



XXI Century Health & Main Advanced Digital Health Challenges



Data - Open and FAIR principles, (the NEW GOLD)

Information – Sharing is key (content interoperability)

Knowledge – is rare (involves Hybrid-I and Advanced-I)

Meta-knowledge – network and strategy (know who knows what and how it knows)

- **Digital Inclusion** - Capacity to ensure advanced tech is equitably accessible to organizations/citizens
- **Minimally disruptive Tele/meta health services** – Tele/metahealth services that offer high Quality-of-Care
- **Trustworthy Digital Clinical Services** – Including mHealth APPs; AI-based Solutions; Digital Therapeutics
- **Health data economy & health innovation** – Health data spaces for data exploration and care integration/innovation
- **Digital sovereignty & sustainability** – Creation of digitally advanced infrastructures and processes that cybersecurity, governmental sovereignty and cost-effective architectures
- (FOR EU) – **Adoption and Adaptation to the Reg. European Health Data Space** (2024---2030) including: European EHR Exchange format, wellness APPs, Secondary Use of Data

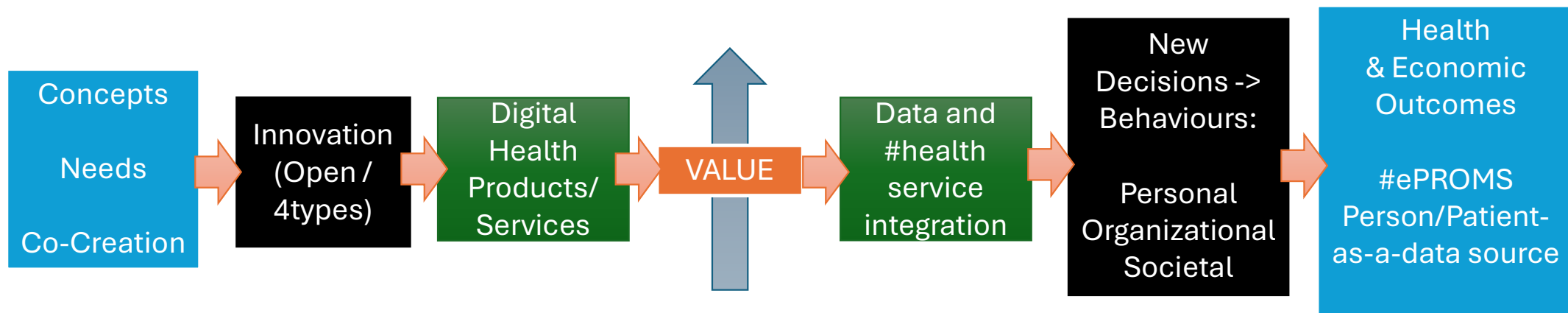
Digital Health Systems

- Preventive, paperless, empowering, personalised, and accountable. Digital healthcare strengths lay not in technology but rather that digital technology will be present in processes, professionals and people, in ways such that **everyone can be a healthcare creator**.
- He/she can be a prevention specialist; care for him/herself and family with the best scientific support; access digital therapeutics by default. Moving to any form of needed physical care, drug therapy, surgery, hospital admission, or ventilation support, etc, as last resource



Digital Health Developments for Quality?

“better” health (care)/
society value/economic value



Problems with or state of 6 AIMS* “less” health (care)/
AND/OR sustainability issues in society value/economic value

Human Intelligence - Artificial Intelligence (*experiments, trials, certified services*) - Orchestrated AI - Hybrid Intelligence

* - Efficiency, effectiveness, timeliness, safety, patient(person) centricity, equality **and integrated**

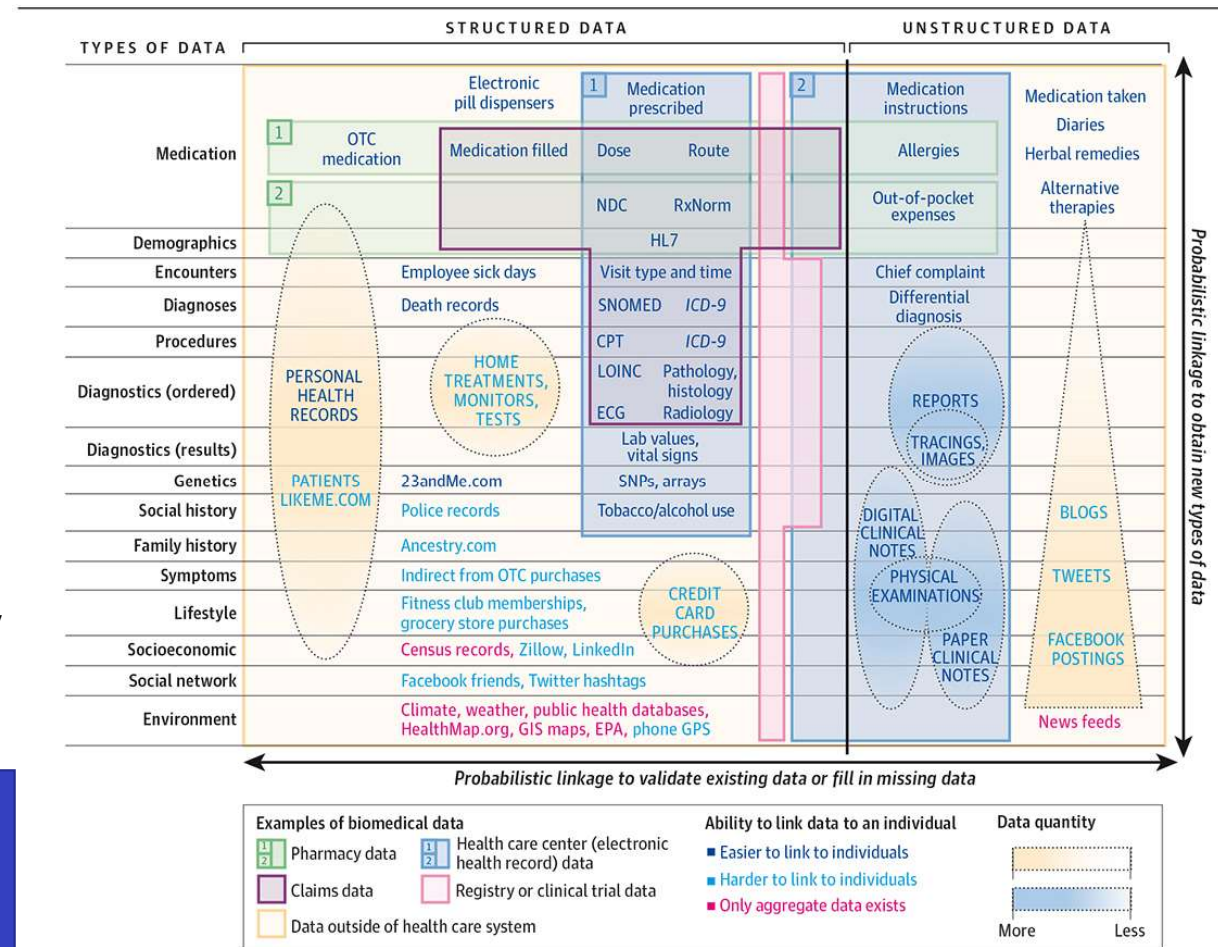
Health Data...

- Data about the individual's health and care
- Secondary use data
 - National Registries
 - Data about health professionals capacity/system capacity
- Public Health Data / Indicators
- World/Regional level data that is necessary for health policy, cross-border healthcare, world health

DATA LEVEL *Broad (public health) Data Types*

- *Data on Communicable Disease (DCD)
- *Data on Non-Communicable Disease (DNCD)
- *Data on Health System (DHS)
- *Data with Public Health Relevance (DPHR)

in H.Martins STOA European Parliament Report

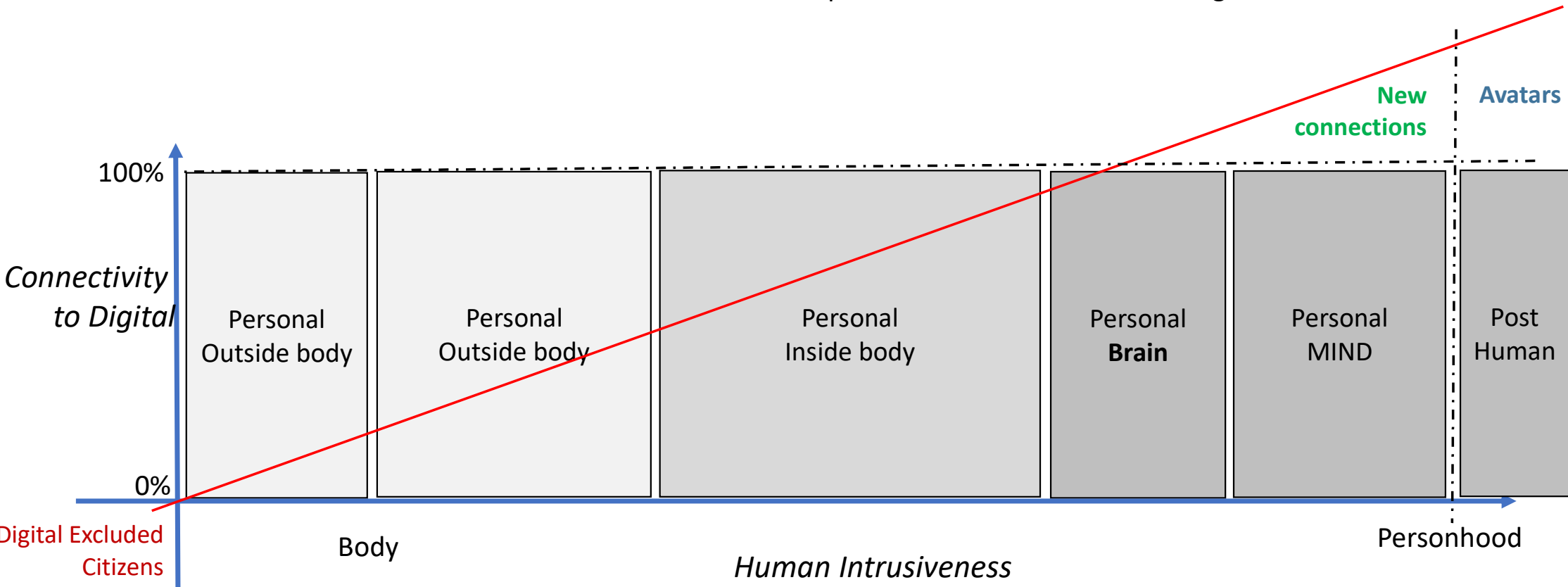


Source: <https://www.openaccessgovernment.org/european-infrastructure-and-health-data-space/83393/>

Technology embodied and embrained

Wellness → Prevention → Diagnosis → Treatment *and Digital Therapeutics*

Portals/www -> mAPPs -> Wearables -> Devices -> Implantables -> MicroRobots -> Cognitive NanoBots -> Artif.Life



What is Digital Therapeutics (DTx)?

Digital therapeutics, a new subdomain of digital health and a new category of therapeutics, will assume an important role in the medical practice.

It delivers interventions that normally only trained professionals know how, or it helps patients adhere to their medication.

If there are limitations to existing conventional pharmacotherapy methods, or when rehabilitation is needed, or there is an unmet need for medical treatment, DTx can be an efficient instrument for the medical industry¹.

Digital Therapeutics (DTx) are evidence-based therapeutic interventions driven by software to prevent, manage, or treat a medical disorder or disease. In other words, DTx are patient-facing software applications that help patients treat, prevent, or manage a disease, and have a proven clinical benefit.

1. Kim HS. Apprehensions about Excessive Belief in Digital Therapeutics: Points of Concern Excluding Merits. *J Korean Med Sci.* 2020;35(45):1-8. doi:10.3346/jkms.2020.35.e373

Digital Therapeutics (DTx) Classification?



1) Treat a disorder (by replacing medication)

In RCT, users of Daybreak and Vorvida (Tait et al. 2019; Jördis et al. 2019) reduced by half their use of alcohol, and in a single-arm study, half of Clickotine users (Iacoviello et al 2017) show 7-day abstinence of smoking tobacco

2) Prevent and manage a disorder (by preventing medication)

Neurotrack's virtual cognitive health program (Kumar et al. 2018, Bott et al. 2019) showed improvements in cognitive function, depression, and anxiety in older patients with subjective cognitive decline. Participation on the program of Omada Health (Su et al. 2018) suggests a reduction in diabetes incidence by 30% to 33% and stroke by 11% to 16% over 5 years, and a ROI break-even point of 3 years.

3) Optimize medication (by reducing medication)

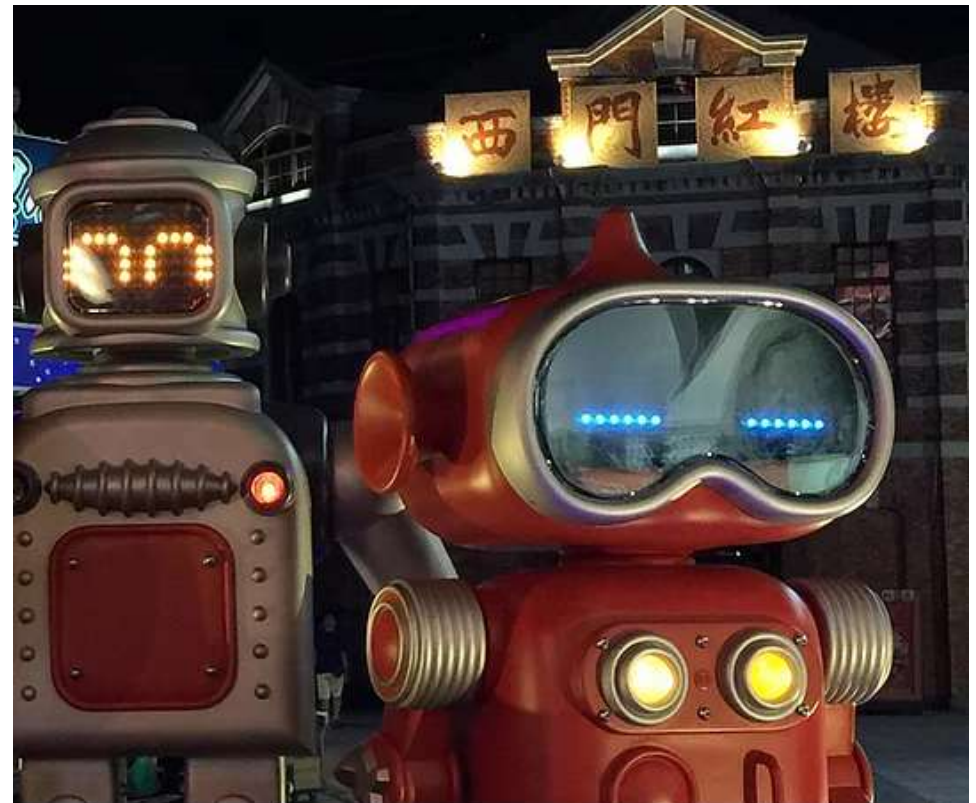
An RCT (Toelle et al. 2019) found that Kaia, a software program that digitizes and delivers back health tools based on multimodal rehabilitation, was more effective at treating lower back pain than traditional physical therapy and education. With BlueStar by Welldoc, patients experienced a drop in HbA1c of 1.7 to 2 points on average, improved medication adherence, and better glucose control (Quinn et al. 2008, Quinn et al. 2011). Better Therapeutics, a 12-week prescription cognitive behavioural therapy program, made participants with an average HbA1c of more than 6.5 percent reduced it by 0.8 percent (Berman et al. 2018).

4) Add value to/Complement medication (by improving medication outcomes)

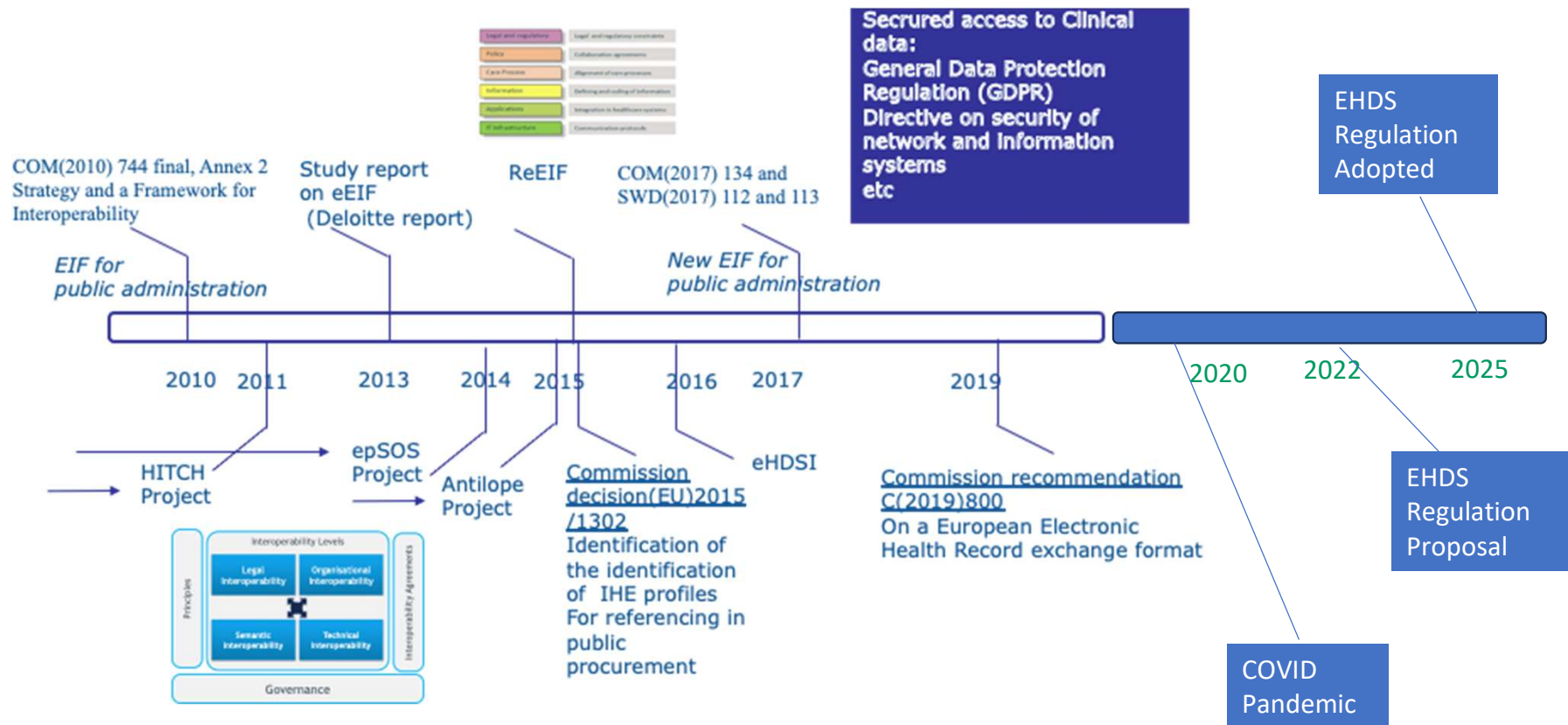
The addition of reSET-O to treatment-as-usual resulted in increased treatment retention rates (82% vs. 68%) and a more than two-fold increase in abstinence rate (40% vs. 18%) (Christensen et al. 2014). Users finishing the KAIA- COPD program (Rassouli et al. 2018) reduced their COPD assessment test scores (mean 2.5 units). In a meta-analysis (Twomey et al. 2020) of twelve Deprexis-specific RCT the effectiveness of deprexis, a tailored, integrative digital CBT intervention, was confirmed for depression reduction at post-intervention. (Deprexis by Gaia®)

Agenda for our Keynote...

- Digital Health Systems
- European Health Data Space
- Projects that help understand/prepare for the EHDS and the EuropeanEHRxFormat



Background



The Refined eHealth European Interoperability Framework (ReEIF)



Legal and Regulatory	Legal and regulatory constraints
Policy	Collaboration agreements
Care Process	Alignment of care processes
Information	Defining and coding information
Applications	Integration in healthcare systems
IT Infrastructure	Communication Protocols

Agreement between National Authorities or National Organisations responsible for National Contact Points for eHealth

The organisational Framework

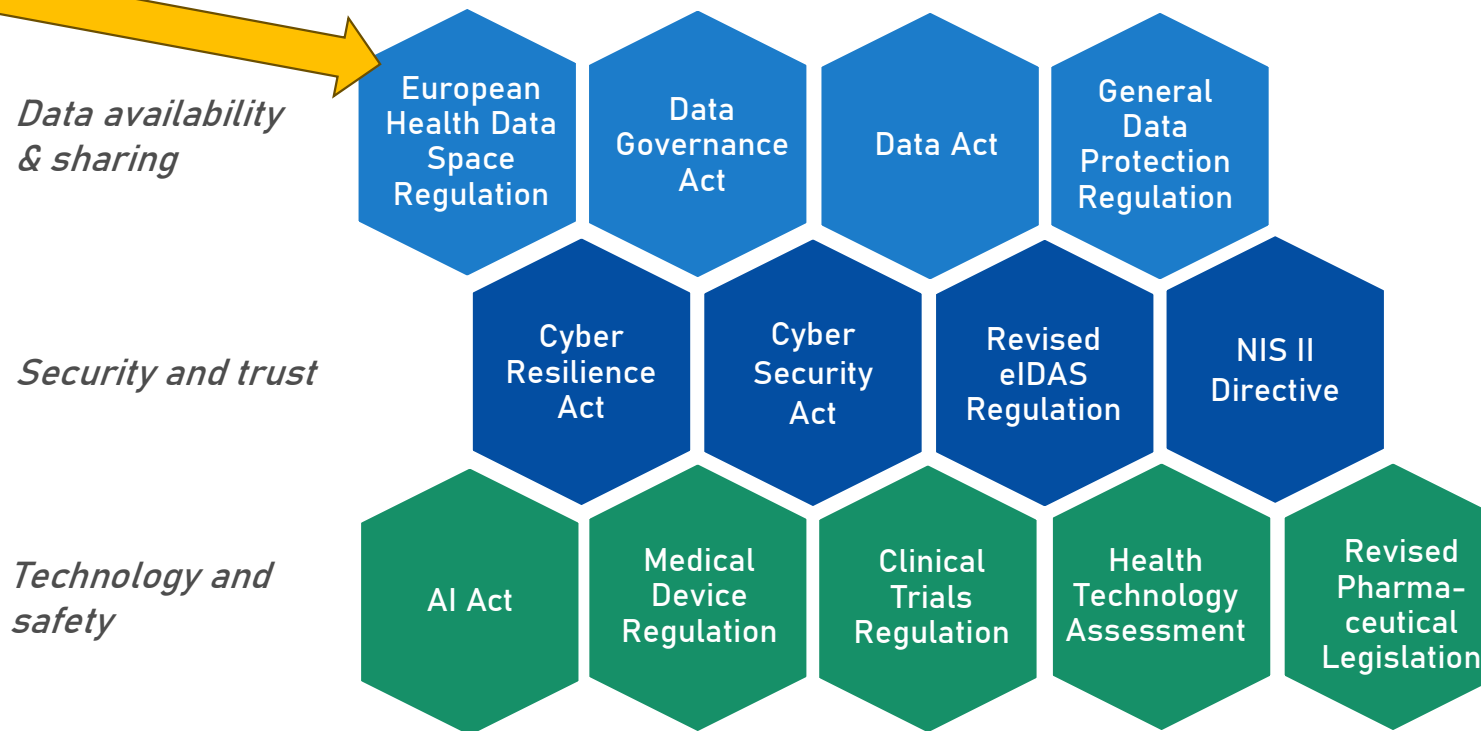
The Semantic Specifications and Master Value Set Catalogue (and Master Translation Catalogue) as well as the semantic catalogues' governance procedures

The technical specifications and OpenNCP reference implementation

The Refined eHealth European Interoperability Framework for managing interoperability and standardization challenges in the eHealth domain

<https://ec.europa.eu/research/participants/documents/downloadPublic?documentIds=080166e5b56dffdc&appId=PPGM52S>

Digital transformation of healthcare: the building blocks



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

Source: Konstantin Hyppönen, European Commission

EHDS in a Nutshell

Sharing of health data for healthcare

Problems

- Limited control of patients over their health data
- Limited interoperability between health care providers

Areas of work

- Control of patients over their data
- Interoperability
- Role of e-health agencies
- Reinforced EU governance (eHealth Network)
- Reinforced MyHealth@EU

Access to health data for research, policy making

Problems

- Low re-use of health data
- Cumbersome cross-border access to health data
- Fragmented digital infrastructures

Areas of work

- Governance and rules for access to health data
- Data FAIR-ification
- Digital infrastructure (EHDS2)

Single market for digital health services

Problems

- Uneven legislative framework
- Uneven quality framework
- Uneven procedures for prescriptions, reimbursement, liability

Areas of work

- Eliminate barriers to free movement
- Labelling
- Interoperability
- Reimbursement
- Liability

AI

Problems

- Limited provision of data for training of AI
- Difficulties for regulators to evaluate AI algorithms
- Uncertainty on AI liability in health

Areas of work

- Support for development and rollout of AI
- Data for AI
- Support for regulators

AI- Friendly and AI- Ready Healthcare Organizations

Data Readiness

- **Enterprise architecture**
 - Process mapping
 - Process representation
 - Data collection points
 - Data lists – “META DATA CATALOGUES”
 - types of data available (date and quality);
 - what does it represent
- **Interoperability: including Semantics – local tables/data sets**
-

AI- Friendly and AI- Ready Healthcare Organizations

AI-Friendliness – Culture; Legal and ethics Structures (Professionals and Leadership skills)

- E-soft-skills
- Data culture – and patient safety/quality culture
- Sub-committees and teams – complex decisions about the use and adoption of AI, and AI-based decisions

AI- Friendly and AI- Ready Healthcare Organizations

AI-Readiness – Data, Digital Infrastructure, Computing and technical capacity (IT-staff skills)

- **Data sources** – rich and of high quality (semantics, proper use of IT tools by humans)
- **Data infrastructures** (centralized, federated, shared and interoperable)
- **Computing power** (Cloud; Quantum; On-prem/On-cloud)
- ***Cybersecurity***
- **Software and sophisticated applications**
- **Paperless**, and healthcare processes (procedures and datafication)

2024 EU AI Act - Evaluation of Risk

Risk-Based Categorisation:

- **Minimal Risk:** AI systems with minimal risk, such as spam filters and video games, are largely unregulated.
- **Limited Risk:** Systems with limited risk require transparency measures to inform users about their interaction with AI.
- **High Risk:** High-risk systems, including medical devices and AI used in recruitment, must meet strict criteria before accessing the EU market.
- **Unacceptable Risk:** AI systems posing unacceptable risks, such as those manipulating decisions or exploiting vulnerabilities, are banned entirely.

Direct mentions of health

- Recitals 1, 4, 7, 8, 9, 20, 29, 46, 47, 48, 52, 53, 55, 58, 64, 65, 66, 67, 68, 72, 96, 110, 130, 140, 155, 157, 171, 176.
- Chapter 1: Art.1, Art.3 (14, 49, 65).
- Chapter III: Art.6 (3, 6,7,8), Art.7 (1b, 2e, 2i, 3a, 3b), Art.9 (2.a), Art.10 (2f), Art.13 (3.b.iii), Art.14 (2), Art.36 (7.e, 8.a, 9.a), Art.43 (6), Art.46 (1).
- Chapter VI: Art.57 (6, 11), Art.58 (4), Art. 59 (1.a.i)
- Chapter VII: Art.70 (3), Art.79 (1), Art.82 (1), Art.86 (1)
- Chapter XIII: Art.112 (10)
- Annex III (5.a, 5.c, 5.d, 7.b)
- Annex IV (3)

Source: AI Act (EN) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202401689

LIABILITY IMPLICATIONS OF ARTIFICIAL INTELLIGENCE USE IN HEALTH: FAULT AND RISK IN PUBLIC SECTOR HEALTHCARE

by Henrique Manuel Gil Martins

Under the supervision of: Prof Rui Medeiros



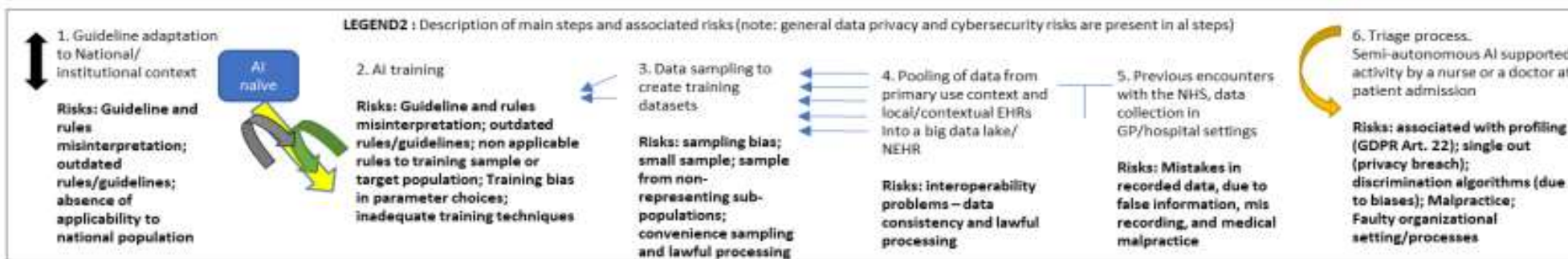
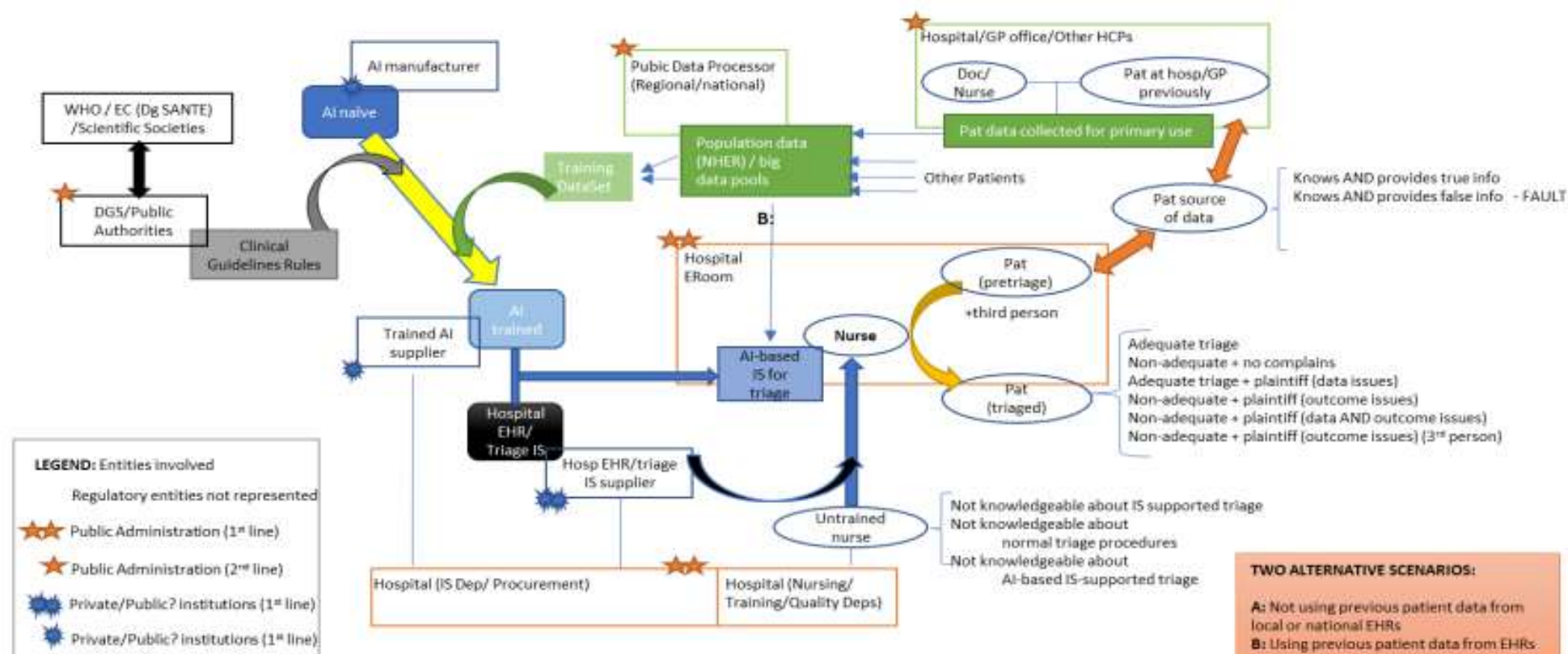
Mestrado em Direito Administrativo - Faculdade de Direito de Lisboa

UNIVERSIDADE CATÓLICA PORTUGUESA

3.2 Causes of malfunctioning

- A non-exhaustive list include:
 - 1) Maybe the information system received incorrect data about the present status of the patient because:
 - a. the patient did not provide correct information;
 - b. the nurse did not formulate the right questions;
 - c. the nurse mis-recorded the information received from the patient;
 - d. any other working environment issue or working procedures in the ER;
 - 2) The AI algorithm was improperly integrated with the display software, hence eventually correct results were misrepresented to the nurse;
 - 3) The AI-based system produces an erroneous result because it has been tampered with as a result of a cyber incident (or by malicious behaviour);
 - 4) Maybe the system received incomplete, wrong (from another patient) historical patient data;
 - 5) The AI algorithm was trained using an inappropriate training data set (bias, selection, not statistically representative of the target population); was inappropriately feed with right scientific evidence; or has errors, programming errors or in its mathematics basis.

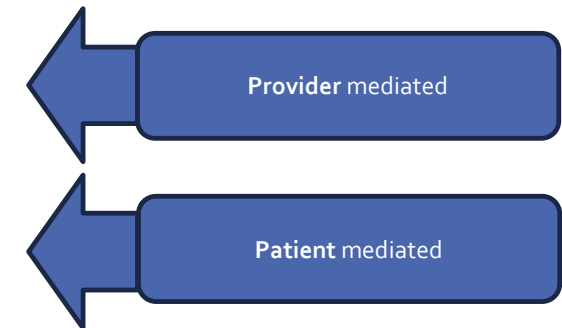
Hospital Emergency Room AI-based IS-Supported Triage Process (with/without previous patient data)



EHDS in a Nutshell –what is it about?



1. Primary use = use of data for the delivery of healthcare
 - Improving patients' access to their health data;
 - Ensuring seamless exchanges for continuity of healthcare – also across borders
2. Secondary use = use of data for research and public interest purposes
 - Making data available for research, policy-making etc. in a safe and secure way - also across borders
3. Requirements for electronic health record (EHR) systems
 - Creating a single market for electronic health records systems, supporting both primary and secondary use.



My health @ EU
eHealth Digital Service Infrastructure
A service provided by the European Union

HealthData@EU

Priority categories

Group 1

- Patient summaries
- Electronic prescriptions
- Electronic dispensations



Detailed specifications for the European Electronic Health Record Exchange Format (EEHRxF) via implementing act, building on work done following 2019 recommendation, several projects etc. => strong Member State involvement

Group 2

Articles 14, 15

- Medical imaging studies and related imaging reports
- Medical test results, including laboratory test and related reports
- Discharge reports

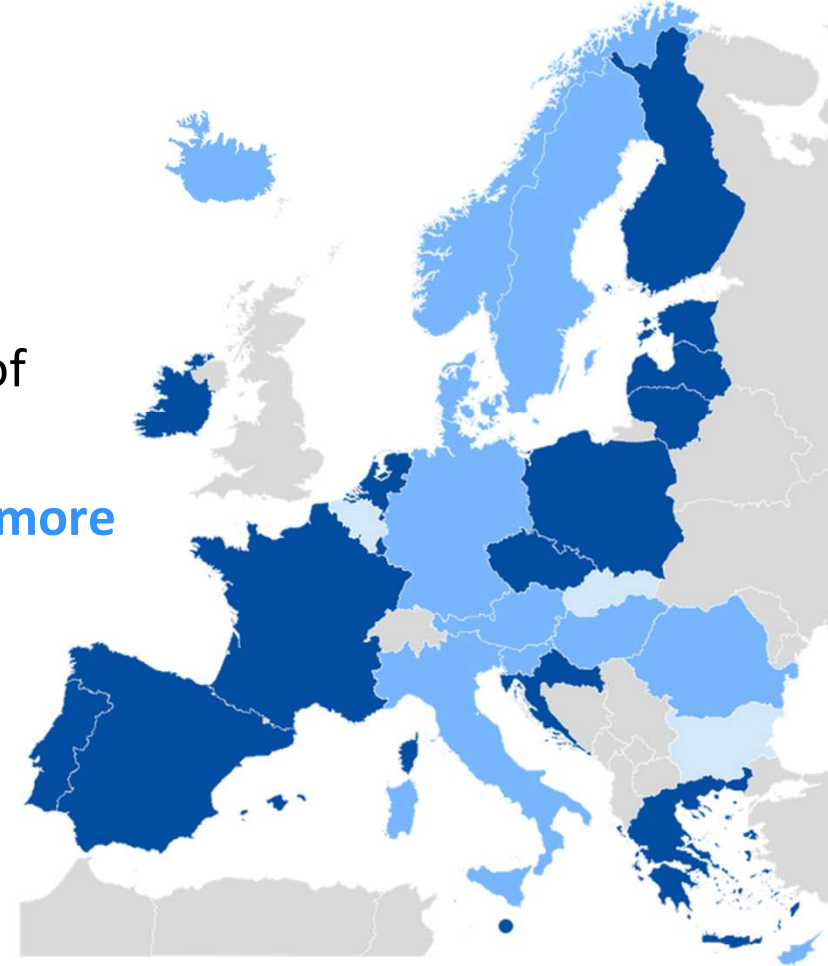
Building on existing cooperation

MyHealth@EU under Cross-border Healthcare Directive

- Voluntary system for exchanging
 - patient summaries,
 - E-prescriptions and E-dispensations (= first group of priority categories)
 - **18 countries** live with at least one service, up to **7 more** expected to go live with first service(s) next year

Evolution of MyHealth@EU for the EHDS

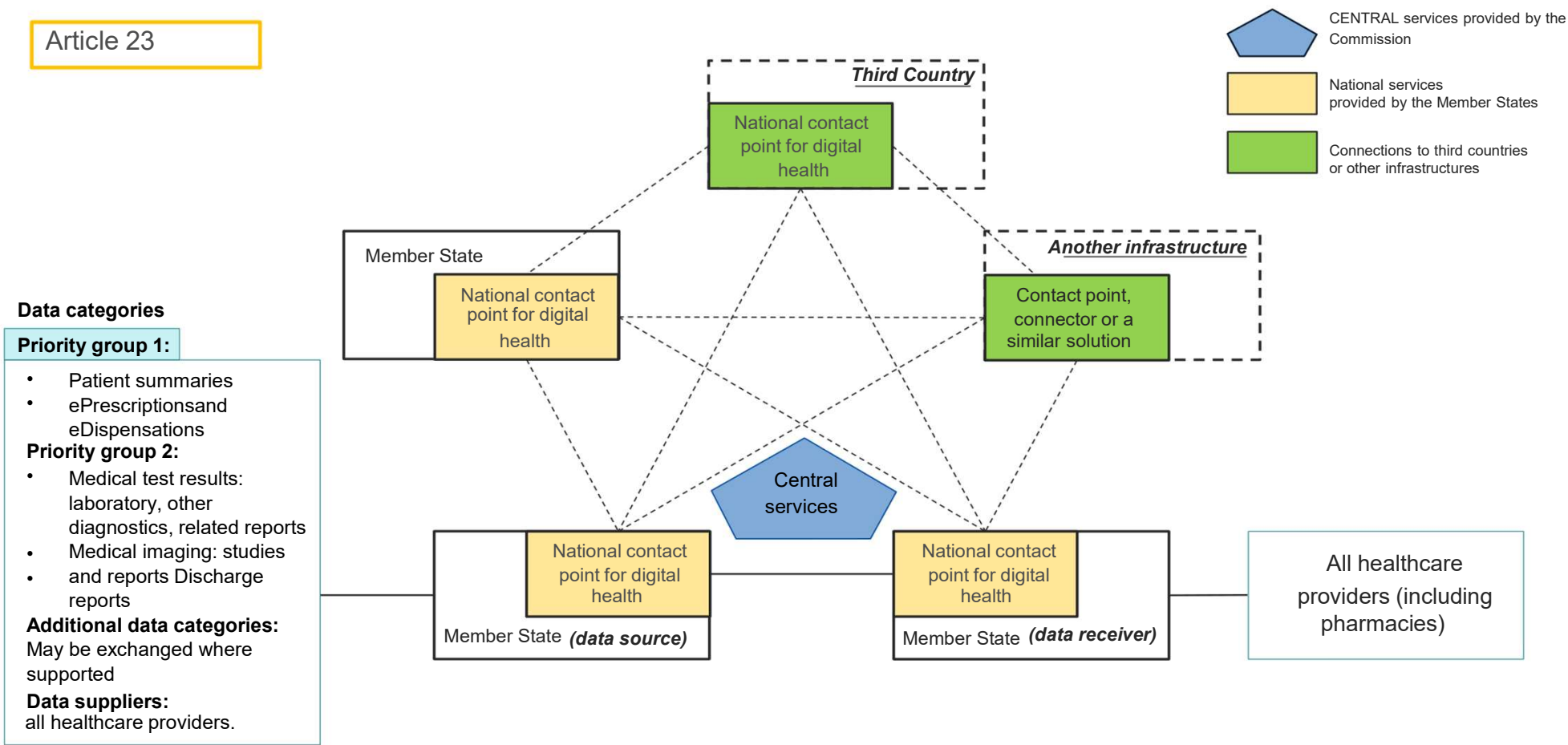
- Voluntary => mandatory
- New services
- New data categories



MyHealth@EU high-level architecture

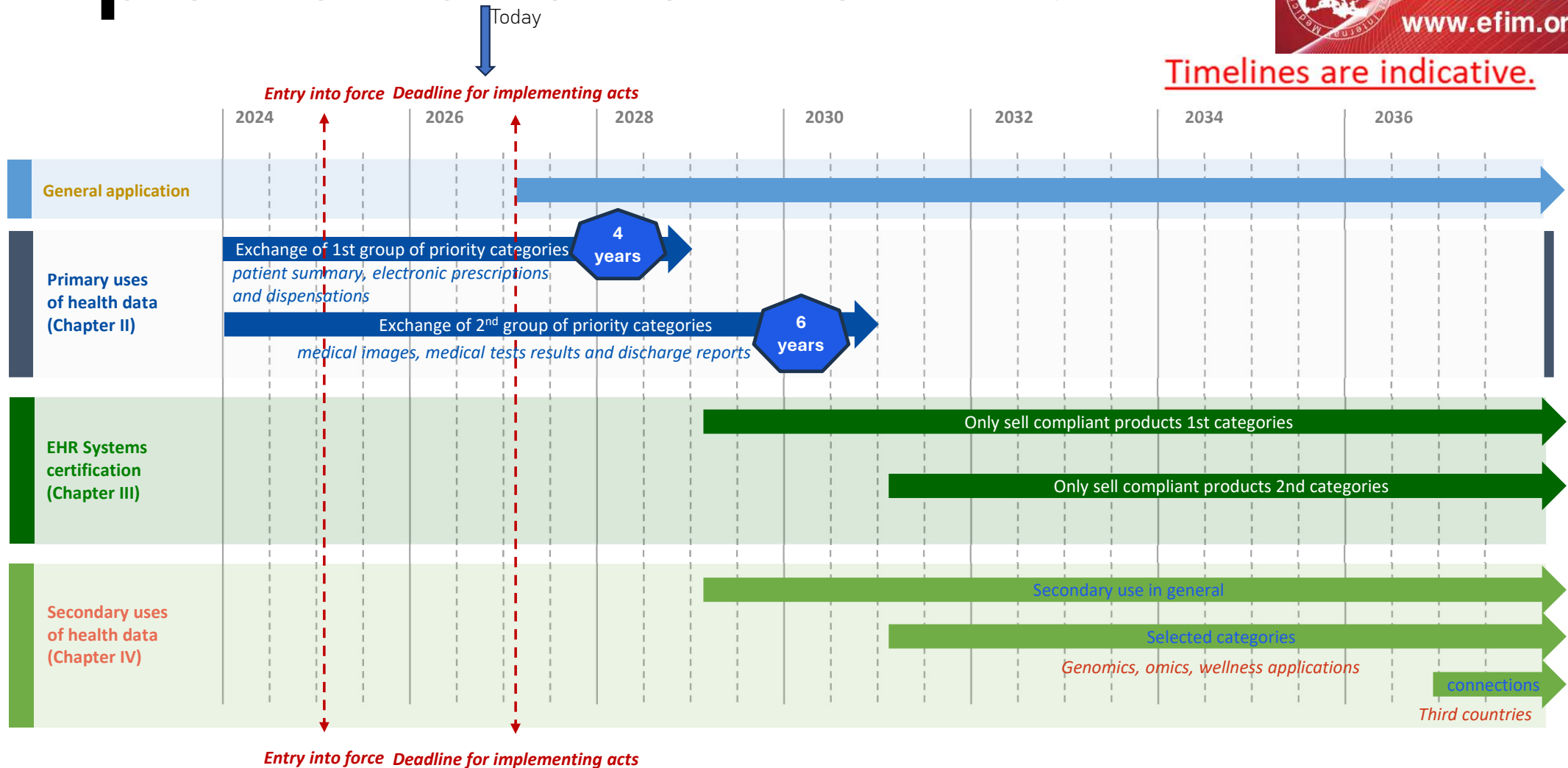


Article 23

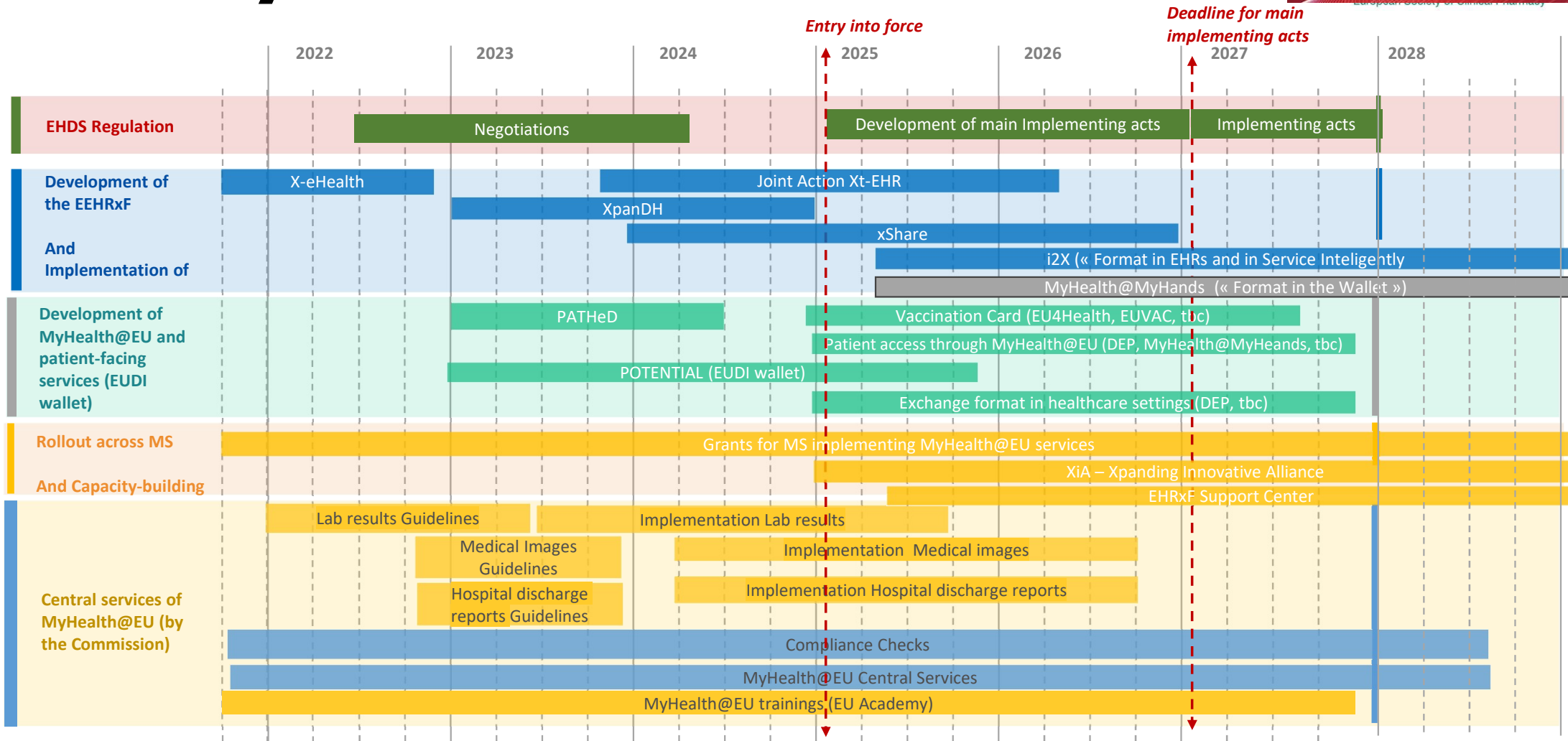


Implementation of the EHDS

Timelines are indicative.

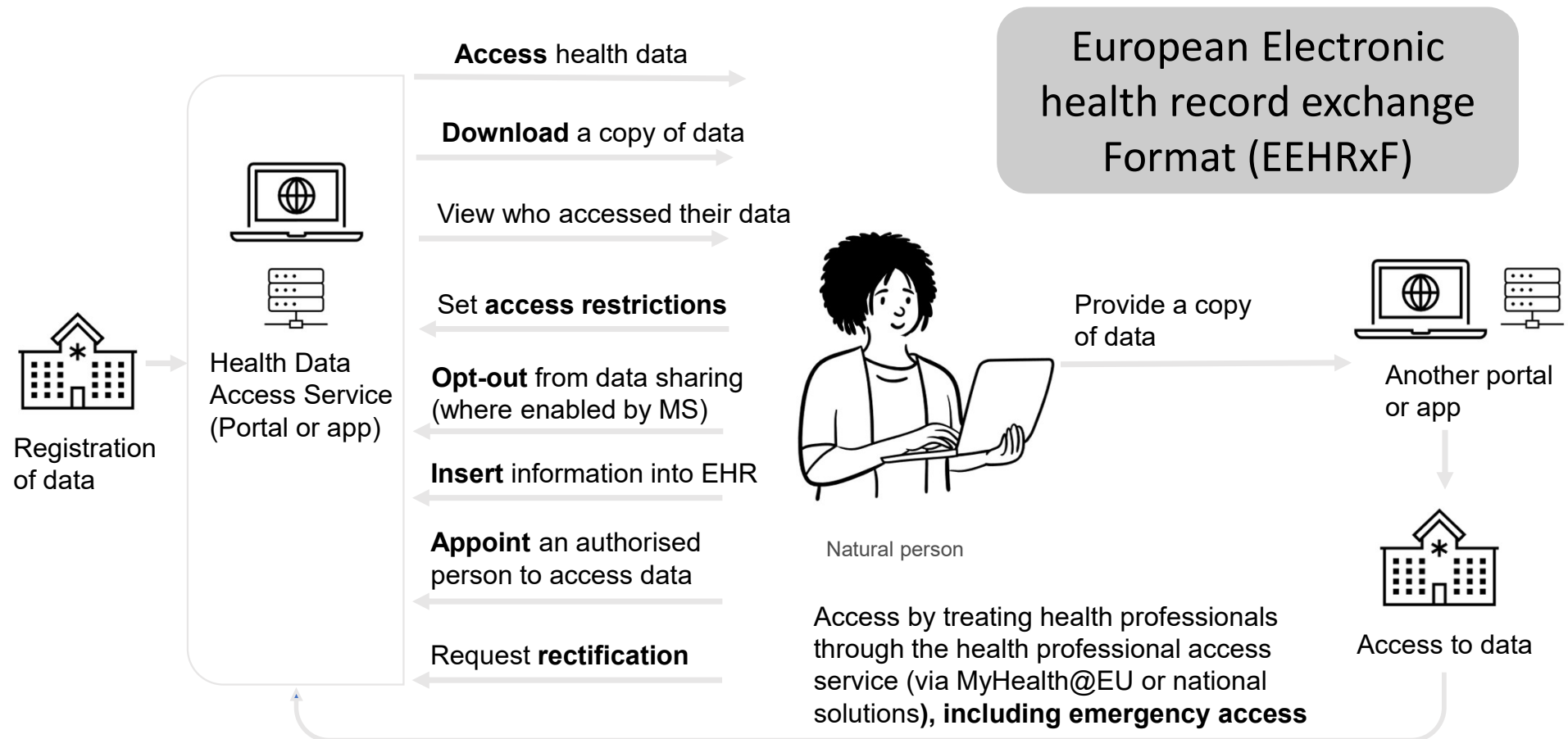


Primary use of health data: (adapted from EC)



NEW DIGITAL HEALTH RIGHTS – Citizen at the center of health data sharing

- Rights of natural persons in primary use



Sources and slides Courtesy of DG SANTE: European Commission. (2025). European Health Data Space Regulation (EHDS) slide deck i2X kickoff meeting;

"Digital Health for all and around the world"



Personal Health Data Space



People Centric Model to Harness User Value

Reflection on Personal Data Spaces in Transformation of Health and Care

Anne Moen | Professor | University of Oslo and Norwegian Center for eHealth Research | Norway
Catherine Chronaki | Secretary General | HL7 Europe | Belgium
Henrique Martins | Associate Professor | ISCTE Business School | ISCTE-IUL, Lisbon | Faculty of Health Sciences | Universidade da Beira Interior | Covilhã, Portugal
Giovanna Ferrari | Regional Labeling Lead | Global Regulatory Affairs | Global Product Development | Pfizer Limited | UK

Figure 1.: Personal Health Data Space

*Source: H. Martins 2020:

<https://healthmanagement.org/c/healthmanagement/issuearticle/digital-health-diplomacy-in-chained-globalised-health-context>

<https://healthmanagement.org/c/healthmanagement/issuearticle/people-centric-model-to-harness-user-value-personal-data-spaces-in-transformation-of-health-care>

Prof. Dr. Henrique Martins, MD, PhD, FCS-UBI ISCTE-IUL – www.henriquemartins.eu | Henrique@henriquemartins.eu

xShare vision:

Everyone can share their health data in EEHRxF with a click-of-a-button.



Global Standards



European Health Data Space



button



industry label

Industry Driven



Global Digital Health Partnership

- Build the European EHRxF Standards and Policy Hub sustainable by design.
- Examine feasibility of the xShare industry label indicating EEHRxF capability



Co-funded by
the European Union

DOMAIN/CATEGORY:

**IPS-Subject = CDISC-Demographics (DM)
Subject Characteristics (SC)**

- Subject Characteristic /Demographic Item
- Subject Characteristic/Demographic Result
- Collection Date

Demographics/Subject Characteristics – Specific Requested Items:

- **Research Subject Identifier**
- **Research Study Identifier**
- Age
 - Age Units
- Birth Date
- Gender/Sex*
- Death
 - Death Date
 - Death Time
- Subject Death Flag

*Terms not precisely defined

DOMAIN/CATEGORY:

**IPS Diagnostic Results= CDISC- Laboratory Results (LB)
Microbiology Results (MB); Body Systems Findings****

- **Diagnostic/Laboratory/Micro Test Name**
 - Diagnostic/Lab/Micro Result in Original Units Value
 - Diagnostic/Lab/Micro Original Units
 - Diagnostic/Lab/Micro Specimen Collection Date
 - Diagnostic/Lab/Micro Specimen Collection Time
 - Diagnostic/Lab/Micro Specimen Type
 - Diagnostic/Lab Fasting Status
 - Diagnostic/Lab/Micro Specimen/Reference ID
 - Lab Ref Range Lower Limit in Original Unit
 - Lab Ref Range Upper Limit in Original Unit
 - Diagnostic/Lab/Micro Specimen Collection Location
 - Diagnostic/Lab/Micro Method of Test/Exam
- **Microbiology Examination Detail**

**Body Systems Findings each have specific domain with the same variables (e.g., CVTEST/CVORRES for Cardiovascular).

PS-Data Element = Adverse Event**

CDISC- Adverse Events (AE)

Allergies and Intolerances

- Start Date
- End Date
- Reaction
- Manifestation
- Severity

➤ **Adverse Event Term**

- Adverse Event Start Date
- Ongoing Adverse Event
- Adverse Event End Date
- Adverse Event Severity
- Serious Criteria Met
 - AE Result in Death
 - Death Date
 - AE Life Threatening
 - AE Hospitalization
 - AE Disability or Permanent Damage
 - AE Congenital Anomaly or Birth Defect
 - AE Needs Intervention to Prevent Impairment
 - AE Other Serious Important Medical Event
- Action Taken with Study Treatment
- Outcome

**Category Not in HL7 FHIR IPS IG

Essential to research – likely not found in health care records

IPS-Problem List = CDISC- Medication History (MH)**

- Problem/Condition/Medical History Reported Term
- Medical History Event Collection Date
- Medical History Event Start Date
- Medical History Event End Date
- Hypertension
- Diabetes
- Chronic obstructive pulmonary disease
- Alcohol Abuse
- Drug Abuse
- Allergy

DOMAIN/CATEGORY:

IPS-Medication Summary = CDISC- Concomitant Meds (CM)

- **Medication/Drug/Product Name**
 - Medication Start Date
 - Medication End Date
 - Dose
 - Dose Units
 - Dose Form
 - Dose Frequency
 - Route of Administration
- Medication Indication

IPS-Vital Signs = CDISC- Vital Signs (VS)

- Vital Signs Test Name
- Vital Signs Date
- Vital Signs Time
- Vital Signs Result of Finding in Original Units
- Vital Signs Original Units

IPS- Pregnancy status + history summary =

CDISC- Reproductive Findings (RP)

- Pregnancy Status
- Reproductive Finding Name
- Reproductive Result or Finding in Original Units
- Reproductive Original Units
- Reproductive System Finding Date
- There are a number of discrete pregnancy related outcomes that were mapped to CDISC SDTM since there were discrete data elements in IPS (code system/code/label) available – potential public health use case

IPS-History of Procedures = CDISC- Procedures (PR)

- Name of Procedure
- Procedure Start Date
- Procedure Indication
- Ongoing Procedure
- Procedure End Date

IPS-Social History = CDISC- Substance Use (SU)

- Tobacco Use (Smoking Status)
- Alcohol Use
- Name of Substance
- Never/Current/Former Usage
- Substance Dose
- Substance Dose Units
- Substance Use Frequency
- Substance Use Start Date
- Substance Use End Date
- Substance Use Duration
- Substance Use Duration Unit

DOMAIN/CATEGORY:

IPS-Data Element = CDISC- Healthcare Encounters (HO)

- **Hospital Stay**
 - Admission Date
 - Discharge Date
- **Healthcare Encounter**
 - Reason for Healthcare Encounter
 - Reported Term for Healthcare Encounter
 - Healthcare Encounter Start Date
 - Healthcare Encounter End Date

Category Not in HL7 FHIR IPS IG

ISO IPS and IPS IHE have discharge summary information

DOMAIN/CATEGORY:

**IPS-Subject = CDISC-Demographics (DM)
Subject Characteristics (SC)**

- Subject Characteristic /Demographic
- Subject Characteristic/Demographic
- Collection Date

Demographics/Subject Characteristics
Requested Items:

- **Research Subject Identifier**
- **Research Study Identifier**
- Age
 - Age Units
- Birth Date
- Gender/Sex*
- Death
 - Death Date
 - Death Time
- Subject Death Flag

*Terms not precisely defined



IPS+

Research Subject Identifier

Research Study Identifier

Hospital Stay

Admission Date

Discharge Date

Healthcare Encounter

Reason for Healthcare Encounter

Reported Term for Healthcare Encounter

Healthcare Encounter Start Date

Healthcare Encounter End Date

DOMAIN/CATEGORY:

**IPS Diagnostic Results= CDISC- Laboratory Results (LB)
Microbiology Results (MB); Body Systems Findings****

PS-Data Element = Adverse Event**

CDISC- Adverse Events (AE)

Allergies and Intolerances

- Start Date
- End Date
- Reaction
- Manifestation
- Severity

Adverse Event Term

- Adverse Event Start Date
- Ongoing Adverse Event
- Adverse Event End Date
- Adverse Event Severity
- Serious Criteria Met
 - AE Result in Death
 - Death Date
 - AE Life Threatening
 - AE Hospitalization
 - AE Disability or Permanent Damage
 - AE Congenital Anomaly or Birth Defect
 - AE Needs Intervention to Prevent Impairment
 - AE Other Serious Important Medical Event
- Action Taken with Study Treatment
- Outcome

**Category Not in HL7 FHIR IPS IG

Essential to research – likely not found in health care records

IPS-Problem List = CDISC- Medication

- Problem/Condition/Medical History Reason
- Medical History Event Collection Date
- Medical History Event Start Date
- Medical History Event End Date
- Hypertension
- Diabetes
- Chronic obstructive pulmonary disease
- Alcohol Abuse
- Drug Abuse
- Allergy

IPS-History of Procedures = CDISC- Procedures (PR)

- Name of Procedure
- Procedure Start Date
- Procedure Indication
- Ongoing Procedure
- Procedure End Date

IPS- Pregnancy status + history summary =

CDISC- Reproductive Findings (RP)

- Pregnancy Status
- Reproductive Finding Name
- Reproductive Result or Finding in Original Units
- Reproductive Original Units
- Reproductive System Finding Date
- There are a number of discrete pregnancy related outcomes that were mapped to CDISC SDTM since there were discrete data elements in IPS (code system/code/label) available – potential public health use case

IPS-Social History = CDISC- Substance Use (SU)

- Tobacco Use (Smoking Status)
- Alcohol Use
- Name of Substance
- Never/Current/Formal Usage
- Substance Dose
- Substance Dose Units
- Substance Use Frequency
- Substance Use Start Date
- Substance Use End Date
- Substance Use Duration
- Substance Use Duration Unit

DOMAIN/CATEGORY:

Data Element = CDISC- Healthcare Encounters (HO)

- Hospital Stay
 - Admission Date
 - Discharge Date
- Healthcare Encounter
 - Reason for Healthcare Encounter
 - Reported Term for Healthcare Encounter
 - Healthcare Encounter Start Date
 - Healthcare Encounter End Date

Category Not in HL7 FHIR IPS IG

ISO IPS and IPS IHE have discharge summary information

Note: Items in black are proposed to add to IPS to support secondary use.

HL7 International Patient Summary

HL7

International

International Patient Summary Implementation Guide

1.1.0 - STU 1 Update 1

HL7 FHIR

Home

Table of Contents

General Principles and Design

The "IPS"

FHIR Artifacts

Downloads

Copyrights

Table of Contents > International Patient Summary Implementation Guide

This page is part of the International Patient Summary Implementation Guide (v1.1.0: STU1 Update 1) based on FHIR R4. This is the current published version. For a full list of available versions, see the [Directory of published versions](#).

1 International Patient Summary Implementation Guide

Official URL: <http://hl7.org/fhir/uv/ips/implementationguide/hl7-uv-ips>

Version: 1.1.0

IG Standards status: Trial-use

Maturity Level: 2

Computable Name: InternationalPatientSummaryIG

Page standards status: Informative

An International Patient Summary (IPS) document is an electronic health record extract containing essential healthcare information about a subject of care. As specified in EN 17269 and ISO 27269, it is designed for supporting the use case scenario for "unplanned, cross border care", but it is not limited to it. It is intended to be international, i.e., to provide generic solutions for global application beyond a particular region or country.

The IPS dataset is minimal and non-exhaustive; specialty-agnostic and condition-independent; but still clinically relevant.

The IPS document is composed by a set of robust, well-defined and potentially reusable sets of core data items (indicated as IPS library in the figure below). The tight focus of the IPS on unplanned care is in this case not a limitation, but, on the contrary, facilitates their potential re-use beyond the IPS scope.

Figure 1: The IPS product and by-products

• Purpose

• Project Background

• Project Scope

• Relationships with Other Projects and Guidelines

• Ballot Status

• Dependencies

• Cross Version Analysis

• Global Profiles

• Authors and Contributors

The "IPS"

Medications

Problems

Medications

Vaccinations

Results

Procedures

.....

Allergies

Problems

Medications

Vaccinations

Results

Procedures

.....

IPS Library

xShare IPS+ provides tools to implement the HL7 IPS for clinical research and public health

Implementer's will start with IPS

And use the IPS+ as a guide to enhance the specification for research

Share

xShare Project Yellow Button

0.1.0 - ci-build 150

Home

Table of Contents

X-Bundle registry

Get Started

Business

Application

Data

Technology

About

Table of Contents > Home

xShare Project Yellow Button

0.1.0 - ci-build 150

Home

Table of Contents

Business

Application

Data

Technology

Downloads

About

1 Home

Official URL: <http://hl7.org/fhir/ig/xshare-ips-plus/implementationguide/hl7-eu.fhir.xshare-ips-plus>

Version: 0.1.0

Draft as of 2025-06-02

Computable Name: XshareipsplusIg

The specification herewith documented is a working specification. No liability can be inferred from the use or misuse of this specification, or its consequences.

Contents:

• Scope

• Purpose

• How to read

1.1 Scope

This guide provides instructions to help you understand and implement your product in accordance with the xShare IPS+, facilitating in the access and adoption of the selected specifications.

1.2 Purpose

This FHIR Implementation guide is designed to assist users in implementing the International Patient Summary for secondary data purposes, such as clinical research and public health. The xShare specification informs the FHIR International Patient Summary and this is referred to as IPS+. The aim is to solve the existing challenge created by the variability and semantic differences in health data. Addressing this issue successfully will help create a consistent and reliable health data system, improving public health and wellness and to enable clinical research, the results of which can inform healthcare decisions in a learning health system. It will also give individuals greater control over their own health data and support seamless data exchange for both primary and secondary use.

1.3 Guid

The overarching purpose of this guide is to outline how to use the International Patient Summary for secondary data purposes, such as clinical research and public health. This will improve the usability, the quality, and the timing of the data availability for these purposes. It is important to use secondary data efficiently to improve the processes and reduce documentation burden. This guide provides detailed instructions for implementing business use cases, interoperability specifications aligned with international standards, and a standardized core data element set for use across healthcare, population health, and clinical research. To ensure consistency with existing terminologies, we include preferred value sets and code lists.

This FHIR Implementation Guide is primarily in the form of downloadable informational materials, spreadsheets, mappings and documents to aid functionalities related

Tools in IPS+			
FHIR to CDISC Map	Core Harmonized Dataset	Valueset alignment	Workflow to Trigger IPS+

IPS+

- xShare Core Harmonized Data Elements
- Maps from FHIR to CDISC in support of the Core Harmonized Data Elements metadata
- Valueset alignment for routine laboratory and microbiology tests (public health)
- Workflow to trigger for IPS+
- Guidance for HL7 FHIR IPS for research
- Sources of HL7 FHIR IGs for research
- Sources for CDISC standards content



Clinical Research Supports Public Health

-  CDISC has Therapeutic Area User Guides (TAUGs) that provide example case report forms (CRFs) and guidance on how to use the standards for the core elements for a particular disease, including metadata standards and terminology

Infectious Disease

COVID-19

Ebola

Hepatitis C

HIV

Influenza

Malaria

Tuberculosis

Chronic Disease

Asthma

Cardiovascular

COPD

Diabetes

Kidney

Depression

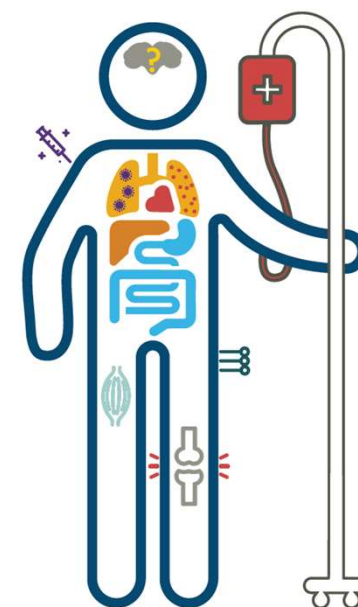
Rare Diseases

Paediatrics

Vaccines

Virology

Traumatic Brain Injury



All TAUGs are available for download in multiple formats at:

www.cdisc.org/standards/therapeutic-areas



Co-funded by
the European Union



Project Overview & Insights

Cyprus Presidency 2026, Limassol – Cyprus
30th April 2026



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 AI-powered and standards-based tools
- **Support** healthcare providers in adapting to the EEHRxF
- **Capture** real-world evidence and cost-benefit of structured data implementation
- **Empower** patients to access, share, and manage their health information
- **Contribute** to policy alignment, standardization, and EU-wide interoperability

At a Glance





12
EU Member
States



1,200+
healthcare
professionals
engaged



3+ million
citizens
impacted



32+
healthcare
systems
adapted



5
priority data
domains:
Patient
Summaries,
ePrescriptions,
Lab Reports,
Imaging,
Discharge
Summaries



14
healthcare
settings



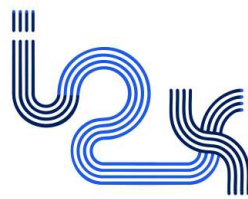
40+
partners



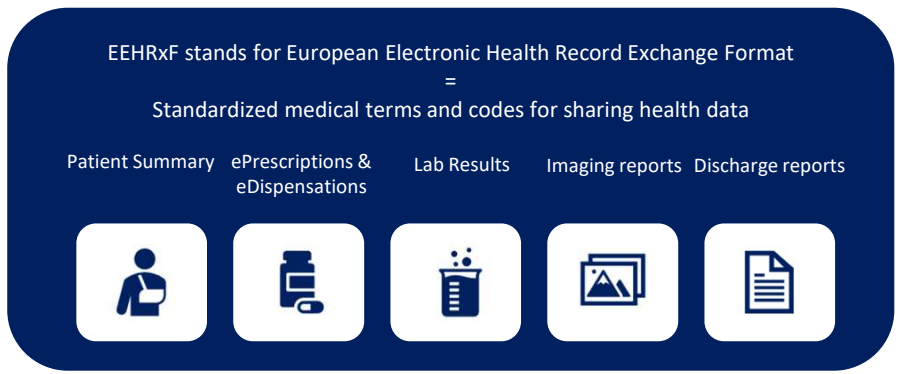
5
AI-driven
technologies
integrated



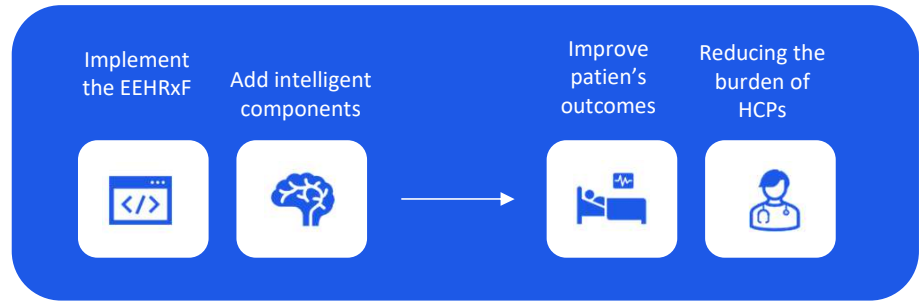
i2X is an 8M EU-funded project that aims to implement EEHRxF in an intelligent way, involving 38 partners across 12 different EU Member States in the next 4 years



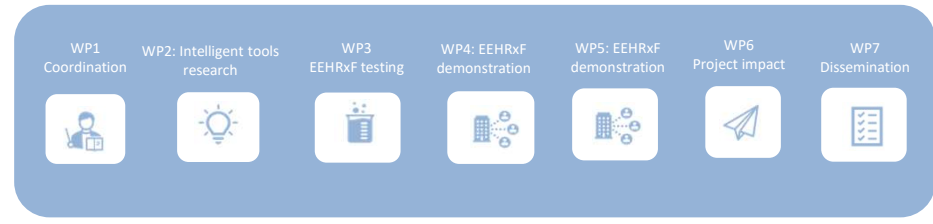
 What is the EEHRxF?



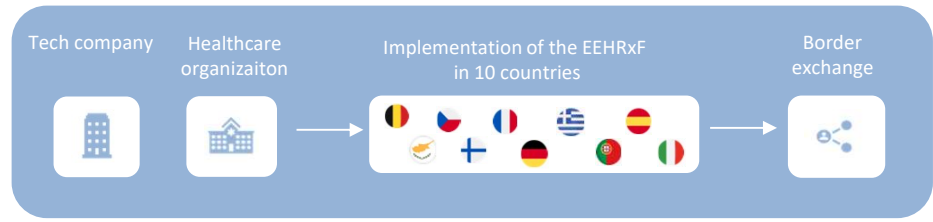
 What is the purpose of i2X?



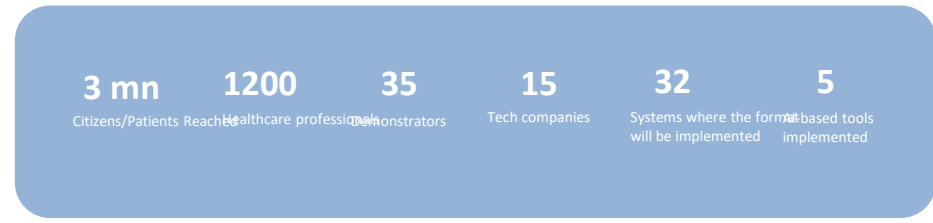
 How will i2X implement the EEHRxF?



STRUCTURE



DEMONSTRATION



IMPACT

Expansion – Outreach & Ecosystem Engagement



Expansion of entities and early adopters



Co-create and validate standards in real-world settings

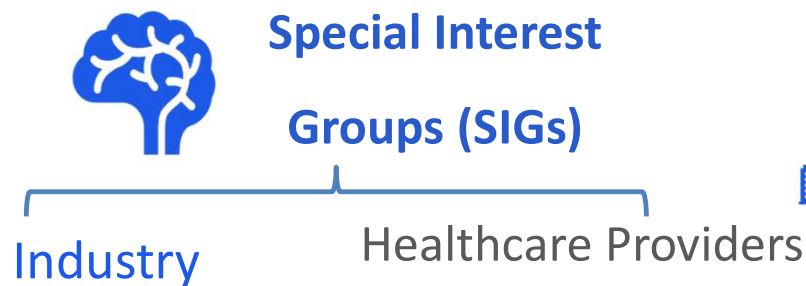


Drive adoption and ensure alignment with European Strategies



Foster sustainability and open Innovation

Why it matters: Expanding beyond the consortium allows i2X to validate EEHRxF implementation readiness, test interoperability in real clinical settings, and ground adoption in operational reality.



Engaging Networks



X-net Industry



38 + 11 i2X Partners

<https://i2xhealth.eu/partners/>

New Partners: Expanding beyond the consortium allows i2X to validate EEHRxF implementation in YOUR INSTITUTION

P39 – IHE Europe – BEN – WP3 and WP6

P40 – CatSalut (SERVEI CATALÀ DE LA SALUT) – AP – WP3

P41 – ChipSoft (ChipSoft b.v.) – AP – WP3 and WP4

P42 – FDA (Finnish Diabetes Association) – AP – WP6

P43 – FYRSTAIN – AP – WP2, WP3 and WP6

P44 – CVTT-ISCTE – AP – WP6

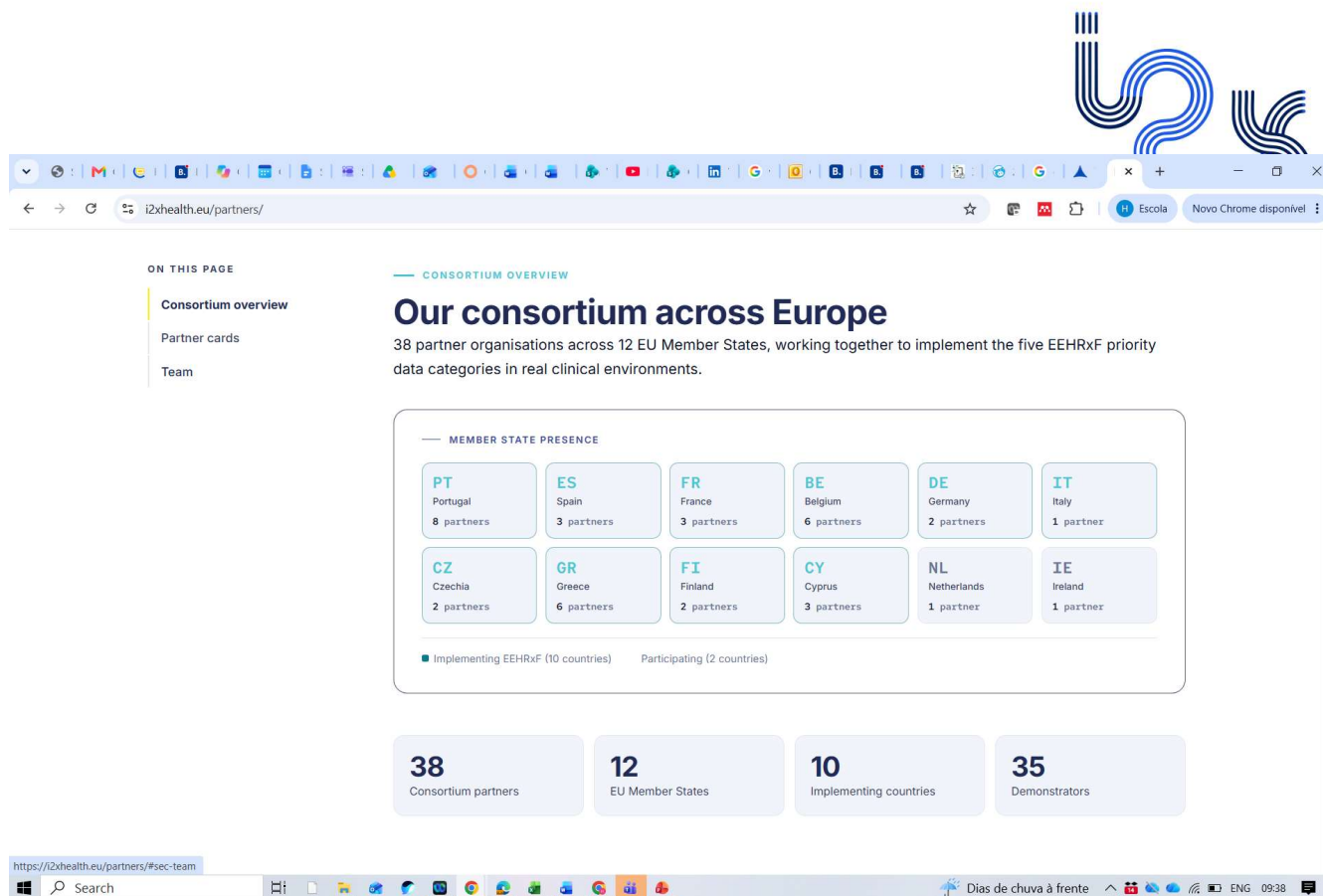
P45 – MEDCOM (MEDCOM)– AP – WP3 and WP4

P46 – MISAN (MINISTERIO DE SANIDAD) – AP – WP2 and WP6

P47 – THL (TERVEYDEN JA HYVINVOINNIN LAITOS) – AP – WP4 and WP5

P48 – VYSOCINA KRAJ – AP – WP4 and WP5

P49 – ULS Alto Alentejo (Unidade Local de Saúde do Alto Alentejo, EPE) – AP – WP2, WP3, WP4 and WP5





A hybrid implementation model

How we Work and what we accomplish in 1Y: From specification to real-world deployment across 12 Member States

01 SPECIFY

WP2 + WP3

- Needs & challenges baseline
- AI tools: NLP, NER, LLM for unstructured data
- IHE profiles: PDQm, MHD, IUA, ATNA
- Gazelle validation platform
- Alignment with HL7, IHE, openEHR

02 TEST

WP3 + iT2

- IHE Plugathon 2026 (Brussels) - completed
- i2Xathon - Pisa, October 2026
- Multi-profile FHIR validation
- Common use-case testing framework
- Online Testing Lab (2-day format)

03 DEPLOY

WP4 + WP5

- 16 implementers, 8 countries
- Three-action approach per site
- MVPs targeting September 2026 (M18)
- T4.2 patient summary: fortnightly cadence
- 35+ use cases across 5 data categories

WP1 · Coordination

WP2 · Tools

WP3 · Testing

WP4 · Implementation I

WP5 · Implementation II

WP6 · Evidence

WP7 · Dissemination

i2X implementation for the 5 EEHRxF priority categories



WP4 - Demonstrators for first group of priority categories

Lead: UNL | Gnomon



Patient summaries



ePrescription / eDispensation



Medical test results



Medical imaging and reports



Discharge reports

WP5 - Demonstrators for second group of priority categories

Lead: FTGM | Gnomon

T4.1 X-Format Adoption: Baseline and Requirements and specifications for demonstrators Lead: NOVA

T4.2 Demonstrating the use of Patient Summary: Deployment and execution Lead: UpHill

T4.3 Demonstrating the use of ePrescription/ eDispensation: Deployment and execution Lead: FTSS

T4.4 Hybrid eXchange demonstrators Lead: Gnomon/ Co Lead: FTGM

T5.1 Demonstrating the use of Laboratory Exams Results Lead: Gnomon

T5.2 Demonstrating the use of Imaging studies and reports Lead: UTH

T5.3 Demonstrating the use of Discharge reports Lead: FTGM

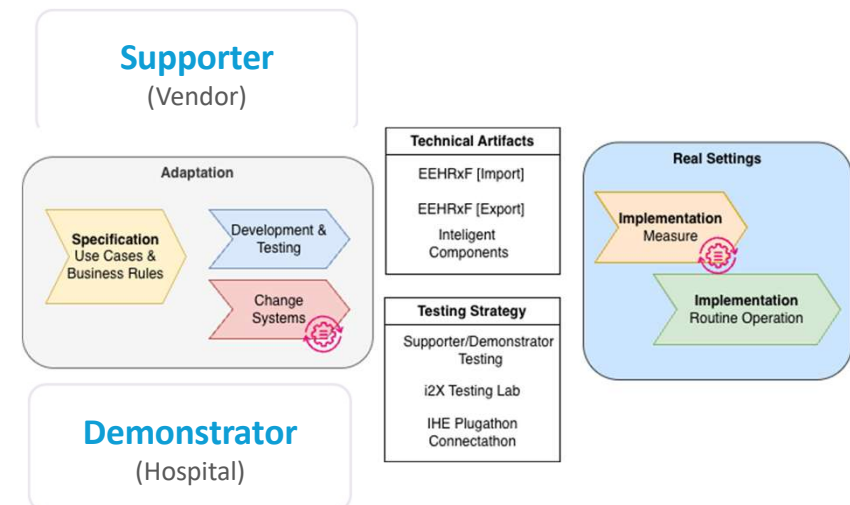
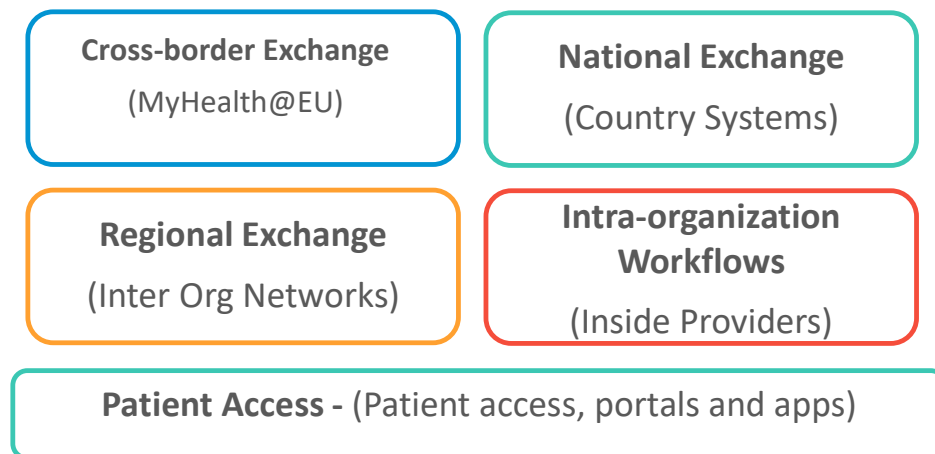
i2X Implementation Scenarios & Use Cases



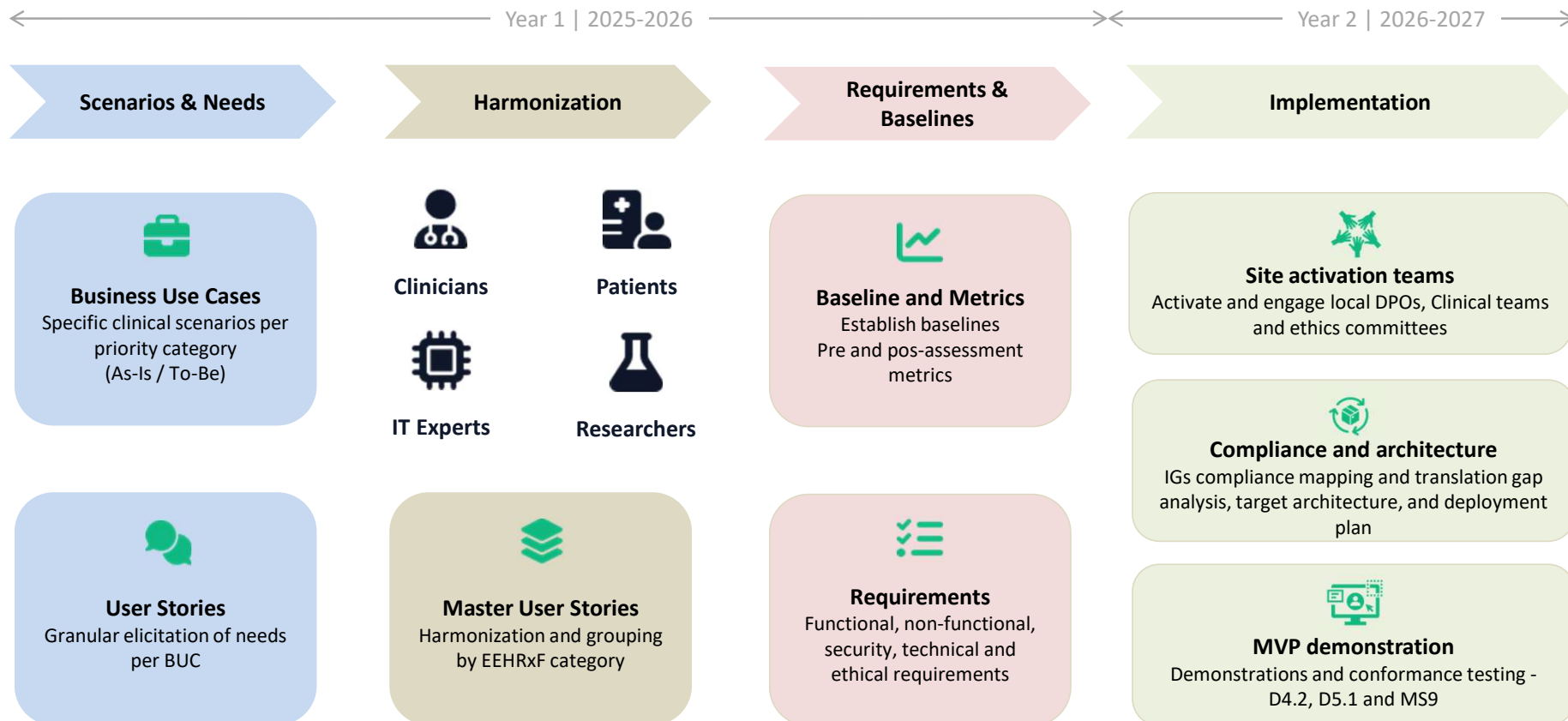
High-Level Areas of Work:

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



WP4&WP5 Implementation methodology



IHE Plugathon Results Analysis – March 2026

i2X partners | EU FHIR IG validation and exchange testing | 25 March 2026



By partner

Partner	IPS	Lab	HDR	EU Exch.
UpHill	✓	✓	—	~
Amaron	✓	✓	—	✓
CYENS	✓	✓	—	✓
FTGM	—	✓	✓	—
VirtualCare (*)	✓	✓	—	✓
FTSS	✓	—	—	—
Sensotrend	✓	—	—	—
SESARAM/SRS	✓	—	—	—

✓ Complete ~ Partial — Not started — N/A; (*) external

HoF / i2X-a-thon

Testar use case ULS COIMBRA c/ UpHill:

- ULS Coimbra produção de dados sintéticos, e partilha
- UpHill, consumo de dados de saúde



Key observations

IPS - validated and exchanged across 6 partners (L1, L2, and L3 peer-to-peer). **Lab exchange** : 4 partners perform peer-to-peer exchange (some of them -2x using MHD profile)

MyH testing participation: 2 entities engaged on testing the wallet

Xt-HER use cases still lowest completion - 25%, but this reflects Gazelle registration gaps rather than real capability.



i2X Use Cases Landscape

35 Business Use Cases · 16 implementers · 9 Member States · 5 EEHRxF Priority Categories



Patient Summary	Lab Results	Discharge Reports	ePrescription / eDispensation	Medical Imaging
HIGH	HIGH	MEDIUM	MEDIUM	STARTING
11 implementers 69 user stories	10 implementers 59 user stories	9 implementers 50 user stories	6 implementers 25 user stories	6 implementers 31 user stories
PT CY GR FI ES DE BE CZ	PT CY GR IT FI DE BE CZ	PT CY IT ES BE CZ	PT CY GR ES	PT CY GR IT
From pre-operative consultation prep and remote patient monitoring, to regional patient access and sharing, national platform integration via NCP, cross-border emergency access, and patient-held digital summaries. Use cases span clinician decision support, patient empowerment, and EHDS-aligned cross-border care continuity.	From intra-hospital pre-op and cardiology lab workflows, to national platform exchange via NCP, cross-border organ donation coordination, and patient-controlled access via wallet apps and diabetes aggregators. Use cases cover structured reporting, longitudinal trending, abnormal value alerts, and LOINC-coded export.	From automated post-surgical report generation using NLP, to remote monitoring continuity, regional patient access via viewer apps, AI-assisted free-text structuring, and cross-border NCP exchange. Central challenge: converting unstructured clinical notes into EEHRxF-compliant FHIR bundles.	From QR-code hospital dispensation and physician assistant pre-preparation workflows, to regional prescribing and dispensation platforms, and cross-border dispensation already operational via MyHealth@EU. Use cases cover the full medication lifecycle: structured prescribing, pharmacist retrieval, and patient medication view.	From patient-controlled wallet export of imaging studies, to regional sharing and second-opinion access, national NCP-connected exchange, and AI-assisted tumour board summaries and discharge automation. Core blockers: DICOM-FHIR metadata synchronisation pipeline and zero-footprint viewer integration. Not yet Plugathon-ready at scale.
FHIR IPS profile aligned, evolve to EUPS	LOINC 73% adoption baseline	NLP pipeline dependencies	NCP connector operational	DICOM-FHIR sync pending

i2X Use Cases Landscape



Evidence from 35 use cases across 16 implementers

Most Common Standards

ICD-10 (93%): Nearly all implementers use ICD-10 for disease and health condition coding, it remains the most stable baseline for health condition coding.

SNOMED CT (73%): There is a robust adoption of SNOMED CT for clinical terminology, which is a critical pillar for the EEHRxF.

LOINC (73%): Used by the majority for laboratory results and clinical observations, reflecting a high maturity in diagnostic data management.

Moderate Adoption

HL7 FHIR (60%): Currently, the majority of the consortium has already [begun the transition to FHIR](#). The i2X project serves as the essential catalyst to bring the remaining 40% into this modern ecosystem.

Internal Databases and National Standards (approx. 47%): Roughly [half of the project environments still rely on localized systems or proprietary structures](#), requiring significant mapping efforts to reach European interoperability.

Less Common

HL7 CDA (33%): While previously a standard for cross-border exchange, it is now present in only a third of the sites as they move toward more granular data models.

HL7 v2 (27%): This legacy transactional messaging format remains in use for internal hospital communications but is a target for modernization within the i2X framework.



Evidence from 35 Use Cases across 16 implementers

93%

ICD-10 adoption

73%

SNOMED CT

73%

LOINC adoption

60%

HL7 FHIR

1,000+

LinkedIn followers



Use Case Coverage

Patient Summary

11 impl · 59 stories

Lab Results

10 impl · 59 stories

Discharge Reports

9 impl · 50 stories

Medical Imaging

6 impl · 31 stories

ePrescription

6 impl · 25 stories

Countries

PT · CY · GR · IT · FI · DE · BE · CZ



AI Models in Progress

NLP + NER

Unstructured → EEHRxF structured data (3 tools/resources developed)

LLM alignment

T3.6 specification support

Interoperability broker Automation

Features available in Implementors

Voice-to-text

Symptom recognition and EHR ingest

Report structuring

AI-driven Lab & discharge

Ethics

ALTAI: 2 workshops completed



Testing & Standards

IHE Plugathon 2026

Brussels - completed

Gazelle/Testing Tool

IG validator; Online Testing Tool and Central FHIR validation

FHIR & IHE profiles tested

HL7 EU IG; PDQm, MHD,

M12 deliverables

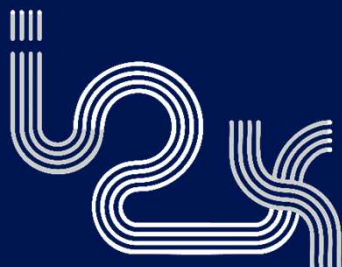
Submitted on schedule

iT2 Technical discussions

IPS & Lab, eID, FHIR vs IHE profiles

Xt-EHR MoU

Signature process done



Co-funded by
the European Union

THANK YOU!



Learn more:

www.i2Xhealth.eu

Don't forget to follow us:



[i2X – Connecting EU Health Data](https://www.linkedin.com/company/i2X-Connecting-EU-Health-Data)



[@i2Xproject](https://twitter.com/i2Xproject)



[@i2Xproject](https://www.youtube.com/channel/UCi2Xproject)



What is XiA?

A European initiative to strengthen interoperability skills
for the European Health Data Space (EHDS)

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the European Education and Culture Executive Agency (EACEA). Neither the European Union nor EACEA can be held responsible for them.



Co-funded by
the European Union

Grant Agreement 101187650

What is XiA?



- The **Xpanding Innovative Alliance (XiA)** is a concrete European response to the question of how to integrate interoperability into education and continuous training.



Pan-European initiative
supporting
EHDS implementation
(2025–2028)

2025 >>> 2028



Co-funded by
the European Union

4-year
EU co-funded project



Consortium that brings
together 42 universities
and interoperability
stakeholders



Co-funded by
the European Union

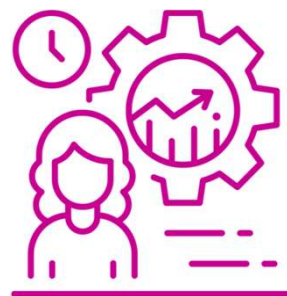
Grant Agreement 101187650

Who is XiA designed for?

XiA aims to bridge the skills gaps in advanced digital health interoperability across healthcare and IT roles



IT/IS specialists
(“Developers”)

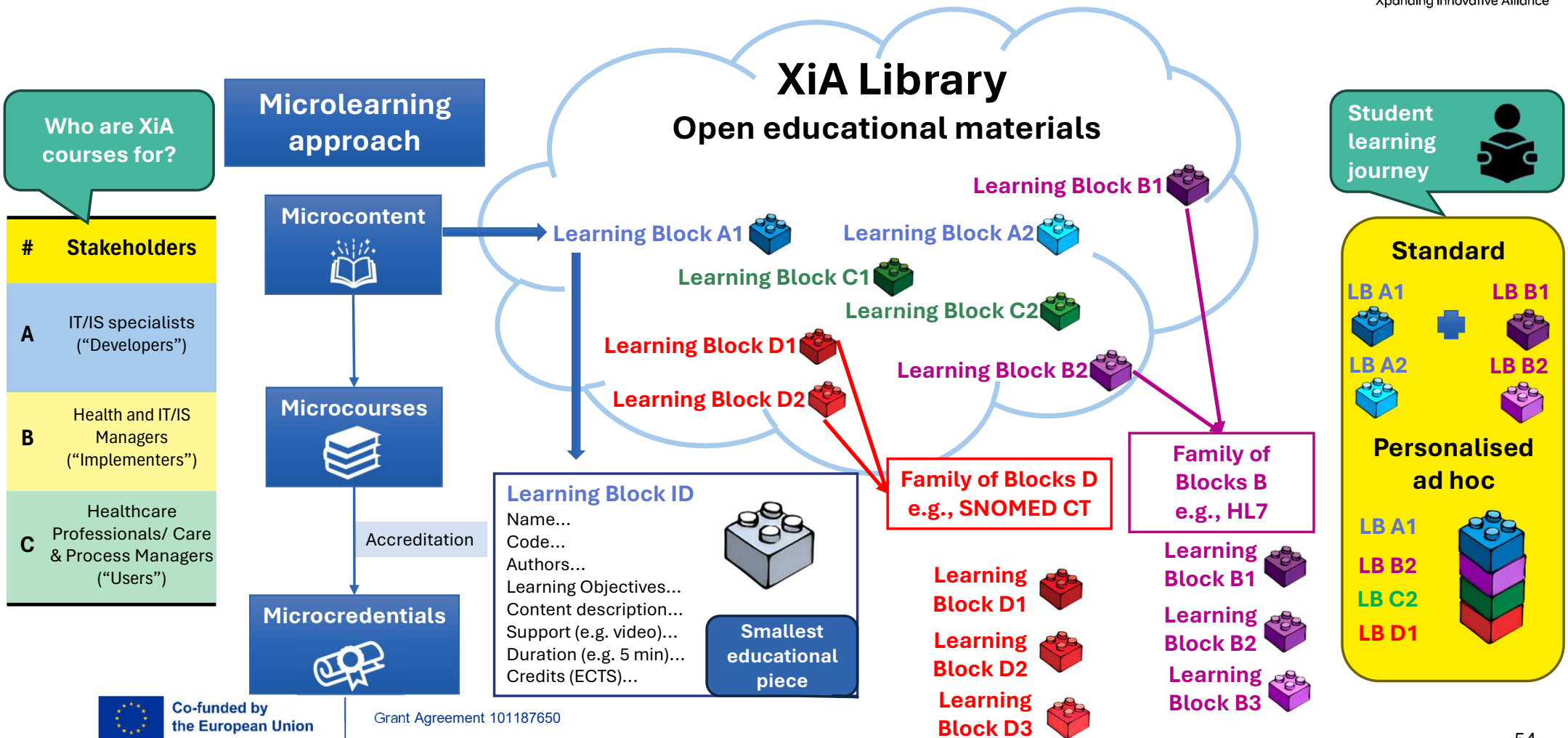


Health and IT/IS Managers
(“Implementers”)



Healthcare Professionals
Care & Process Managers
(“Users”)

The XiA Framework

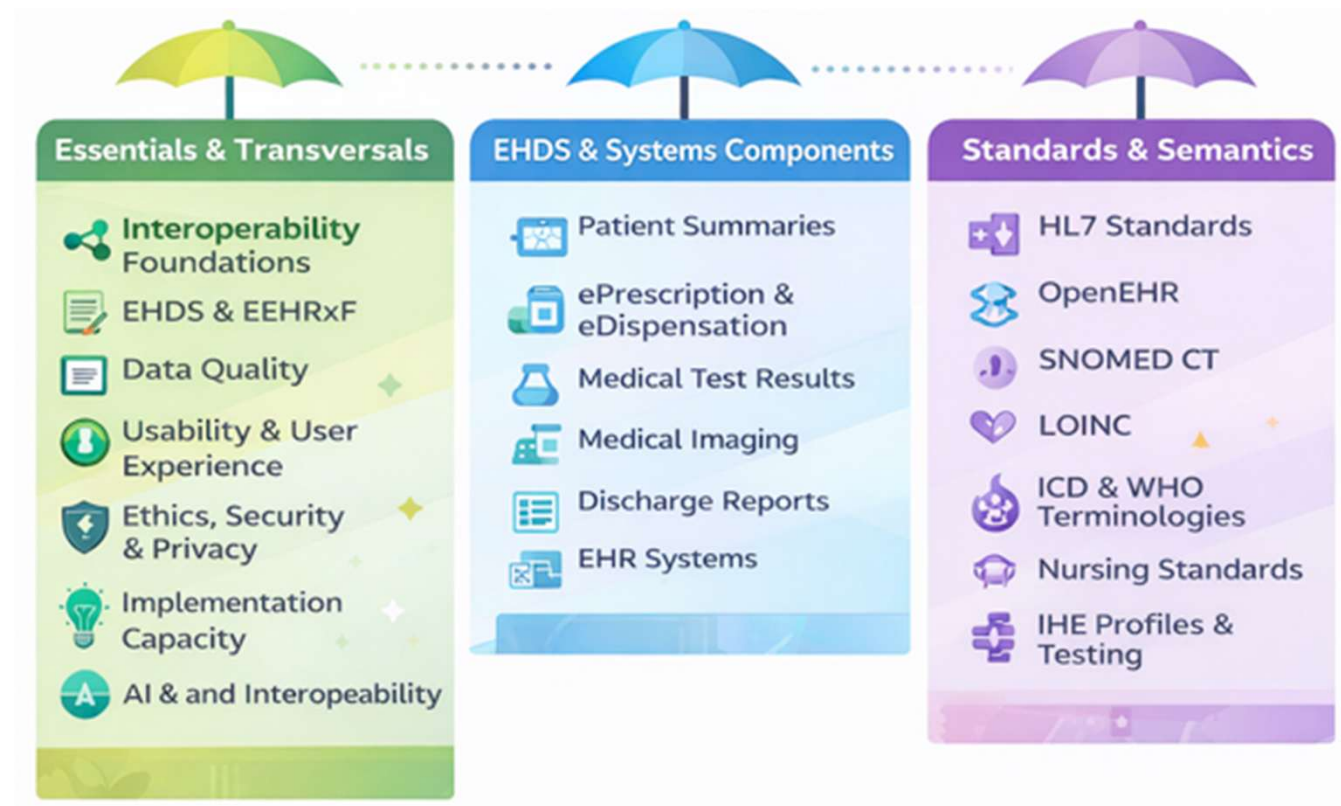




- SNOMED CT: 63,7%
- HL7 FHIR: 64,1%
- HIS Interoperability: 56,3%

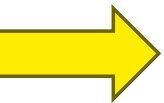
XiA Content Scope

20 Families of Micro-Content Learning Blocks (MCLBs) various topics on Key Advanced Interoperability Standards



XiA Core Stages

Core stages	Status
Needs analysis	Concluded
Learning and curriculum design	Ongoing
Creating educational content	Ongoing
Implementing and evaluating XiA courses	Starts Q3.2026



The XiA Community of Practice

- Already 150+ individuals
- Clustered by language
- Localised kick-off events (France, Slovakia, Italy...)

JOIN TO LEARN AND SHARE 👉



Contacts

Prof. Henrique Martins (Coordinator)

ISCTE – University Institute of Lisbon

Henrique.Manuel.Martins@Iscte-iul.pt

and Simon.Lewerenz@Iscte-iul.pt

Thank you!

Obrigado – Gracias – Ευχαριστώ – Tak – Hvala – Dank u – Děkuji – Danke – Takk –
Kiitos – Köszönöm – Go raibh maith agat – Ďakujem – Köszönöm – Dziękuję – Grazie
– Mulțumesc – Благодаря – Grazzi – Aitäh – Paldies – Ačiū – Merci – Tack



Co-funded by
the European Union

Grant Agreement 101187650

Iscte BRUDHI Digital Health International

Our hub of expertise dedicated to advancing digital health innovation and research.

Our interdisciplinary team comprises global leaders with proven track records in **policy-making, project coordination, and academic research** across Europe and beyond, with individual backgrounds stemming from Portugal, Brazil, France, Germany, Italy, Pakistan, USA, and Ethiopia.

Coordinating



Visit us!

<https://brudhi.iscte-iul.pt/>

bru _ Digital
Health International



Partner of  Share EHR Xchange Format 