
IHE
JAPAN
Integrating
the Healthcare
Enterprise
IHE Japan Connectathon joint event
EHDS & EEHRxF Workshop for Japanese participants
by IHE Catalyst and IHE Japan
2025/10/19(Sun) in Asakusa Tokyo and WebEX

Date Time	2025/10/19(Sun) 1pm - 5pm JST
Venue	Tokyo Metropolitan World Trade Center Taito-kan, Asakusa Tokyo Room: 9th Floor, #3 meeting room
Online	WebEX
Theme	EHDS and EEHRxF Overview & QA
Speaker	Prof. Henrique Martins (ISCTE, IHE-Catalyst)
Moderator	Yasunari Shiokawa (Deputy Director or IHE-Japan)
Participants	IHE Connectathon & Plugathon participants and ordinary guests who are interested in EHDS and EEHRxF
Fee	IHE Connectathon & Plugathon participants are free. Ordinary guests are ¥1,000-.

Agenda

1:00 - 1:10 **Welcome and Introduction** *Yasunari Shiokawa (IHE-Japan)*
1:10 - 2:10 **EHDS Overview** *Prof. Henrique Martins (ISCTE)*
2:10 - 2:20 *Break*
2:20 - 3:20 **EEHRxF Overview** *Prof. Henrique Martins (ISCTE)*
3:20 - 3:30 *Break*
3:30 - 4:30 **EEHRxF Specification Overview** *Giorgio Cangioli (HL7 EU) & Diogo Martins (i2X)*
4:30 - 4:45 **Overview of Japan EHR Information Exchange Service** *Yasunari Shiokawa (IHE-Japan)*
4:45 - 4:50 *Closing Yasunari Shiokawa (IHE-Japan)*

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Henrique Martins, MD, PhD, MLaw, FIAHSI

Associate Professor in Health Management and Leadership at FCS-UBI, ISCTE-IUL
iH10 General Secretary (SMC); IHE Catalist Ambassador for the GlobalEHR
Independent consultant (www.henriquemartins.eu)

Professor with 20+years of experience in teaching and researching in Digital Health, Leadership and Management education for Medical Students and Health Professionals. He is past president of Portugal's Digital Health Agency (7 years), and former Member States co-chair of the EU eHealth Network, the highest policy body on eHealth in the Union. Currently he works as an Academic, on individual consulting projects in Digital Health. He is the Director of BRU-DHI at Iscte University and coordinator of the recently-ended XpanDH and recently-started XiA and i2X projects, among other initiatives such as the General-Secretariat for iH10 initiative (collaborating under Samsung Medical Center) and IHE Catalist Ambassador for the Global EHR

Digital Health Systems

Vision…

- **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



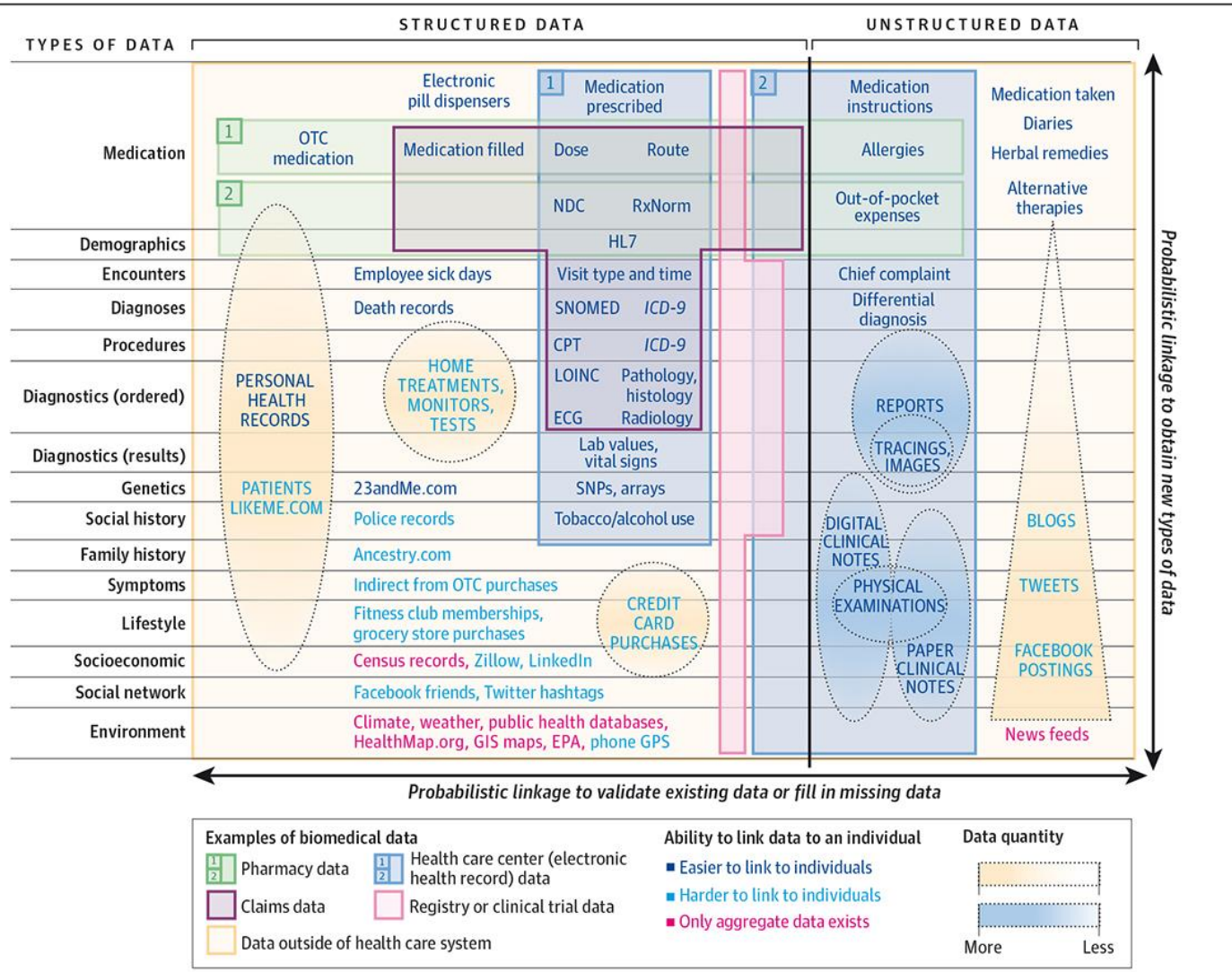
Health Data…

- Data about the individual's health
- Secondary use data
  - National Registries
  - Data about health professionals ca
- Public Health Data / Indicators
- World/Regional level data that is
  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/

Digital Therapeutics

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)

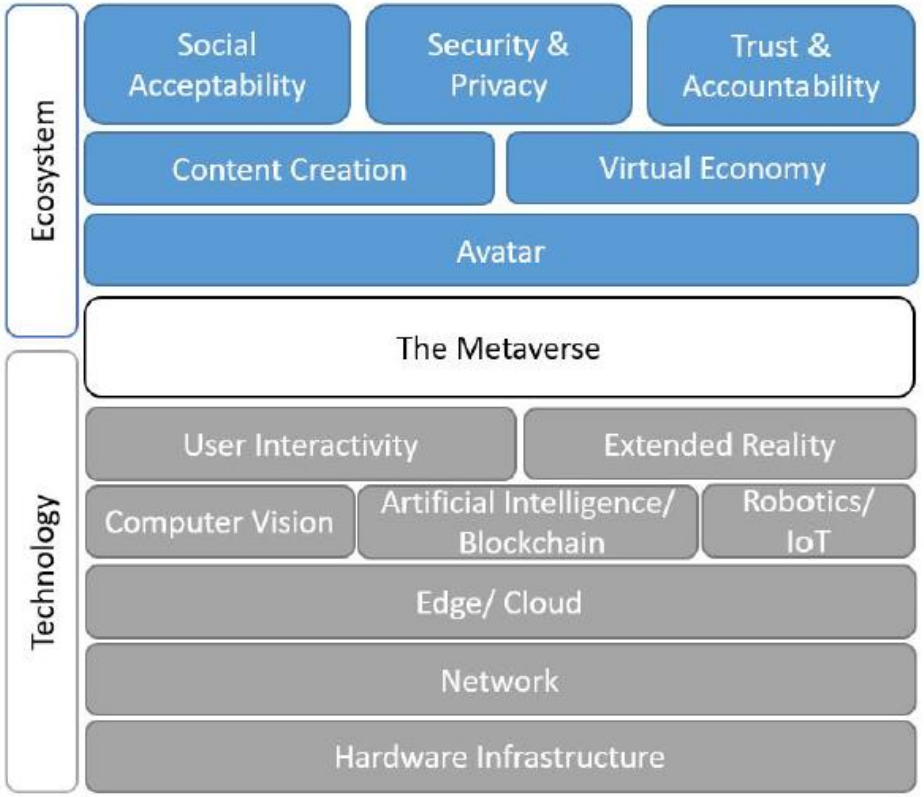
The addition of reSET-O to treatment-as-usual resulted in increased treatment retention rates (82% vs. 68%) and a more than two-fold increase in abstinence rate (40% vs. 18%) (Christensen et al. 2014). Users finishing the KAIA- COPD program (Rassouli et al. 2018) reduced their COPD assessment test scores (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®)

Metaverse: What is it?

JOURNAL OF LATEX CLASS FILES, VOL. 14, NO. 8, SEPTEMBER 2021

All One Needs to Know about Metaverse: A Complete Survey on Technological Singularity, Virtual Ecosystem, and Research Agenda

Lik-Hang LEE, Tristan Braud, Pengyuan Zhou, Lin Wang, Dianlei Xu, Zijun Lin, Abhishek Kumar, Carlos Bermejo, and Pan Hui, *Fellow, IEEE,*



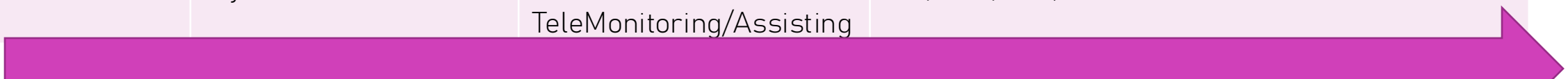
…we consider the metaverse as a virtual environment blending physical and digital, facilitated by the convergence between the Internet and Web technologies, and Extended Reality (XR).

…In the metaverse, all individual users own their respective avatars, in analogy to the user's physical self, to experience an alternate life in a virtuality that is a metaphor of the user's real worlds.

https://tuhat.helsinki.fi/ws/portalfiles/portal/169348619/METAVERSE.pdf

The mHealth telehealth metaHealth continuum

Descriptors	mHealth	teleHealth	metaHealth
Data vs Communication	Access to data/ information/ knowledge	Communication/interaction Access to data;	Data rich environment supports both communication and access to data
Context of clinical interaction	Physical – spacial mobility	Digital – contextual mobility	Phygital (physical+digital)/fully/partial immersive
Mobility Scenario (Pat-Prof/Org)	Patient moves to professional/Org	Prof/Org "reaches" out to Patient… Patient does not "need to move"	Real-to-virtual (virtual allows to enrich/move out); real-in-virtual (representation of absent human/objects) and virtual in real (projection of non-human actors in virtual or "near real")
Data	Moves with patient/professional	Moves across time/space	Represents reality/augments reality – digital twin of patients/professionals/ facilities/equipment
Therapeutic	Drugs/Intervention (physical prescriptions)	ePrescriptions; "telemonitoring", etc	Digital Therapeutics (DTx)/Immersive therapy + Augmented (mix physical and digital therapy)
Example of Techs	mAPP for focused disease (oncology etc) mySNS Wallet	Doc-Doc teleconsultation Prof-Pat teleconsultation TeleMonitoring/Assisting	VR for Dementia cognitive tranning AR/VR/MR for Neurosurgery MetaClinic for Mental Health (several Pat/Prof/DTx)



SUMMARY SLIDE: Personal Health Data Space: mHealth; teleHealth; metaHealth

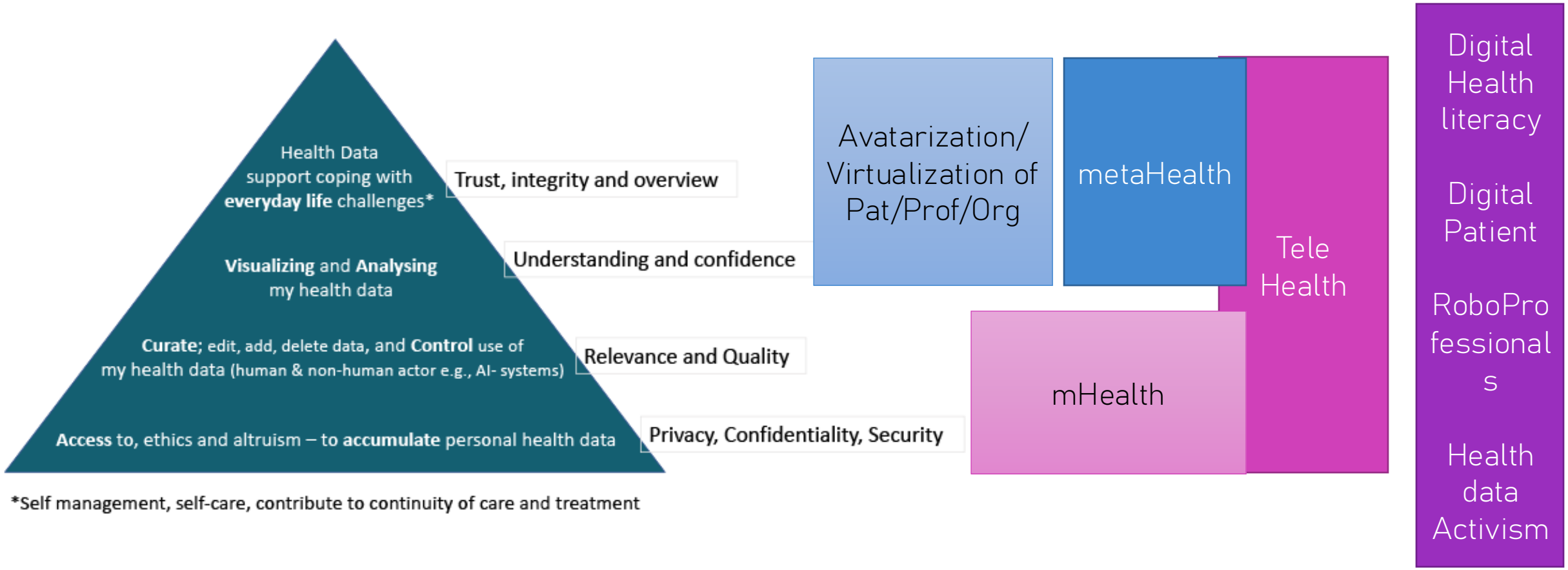


Figure 1.: Personal Health Data Space

People Centric Model to Harness User Value

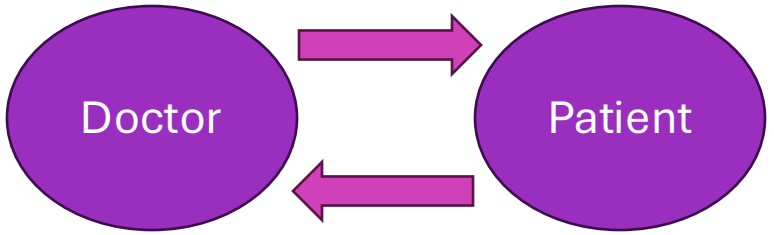
Reflection on Personal Data Spaces in Transformation of Health and Care

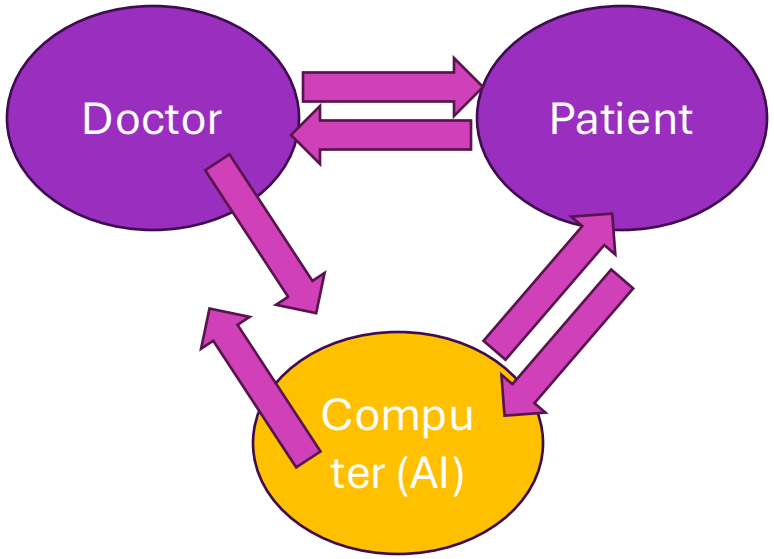
Anne Moen I Professor I University of Oslo and Norwegian Center for eHealth Research I Norway
Catherine Chronaki | Secretary General I HL7 Europe I Belgium
Henrique Martins I Associate Professor I ISCTE Business School I ISCTE-IUL, Lisbon I Faculty of Health Sciences I Universidade da Beira Interior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

PROF. DR. HENRIQUE MARTINS, MD, PHD, FCS-UBI ISCTE-IUL – WWW.HENRIQUEMARTINS.EU | HENRIQUE@HENRIQUEMARTINS.EU

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

AI, Robotics, the “Computer in the room” and Medical Paradigm





- As with traditional clinical activity, patient safety must remain paramount and **AI must be developed in a regulated way in partnership between clinicians and computer scientists.** However, regulation cannot be allowed to stifle innovation
- **Clinicians can and must be part of the change** that will accompany the development and use of AI. This will require **changes in behaviour** and attitude including rethinking many aspects of **doctors’ education and careers**. More doctors will be needed who are as well versed in data science as they are in medicine
- **Artificial intelligence should be used to reduce**, not increase, **health inequality – geographically, economically and socially.**



Academy of Medical Royal Colleges, Artificial Intelligence in Healthcare (2019)

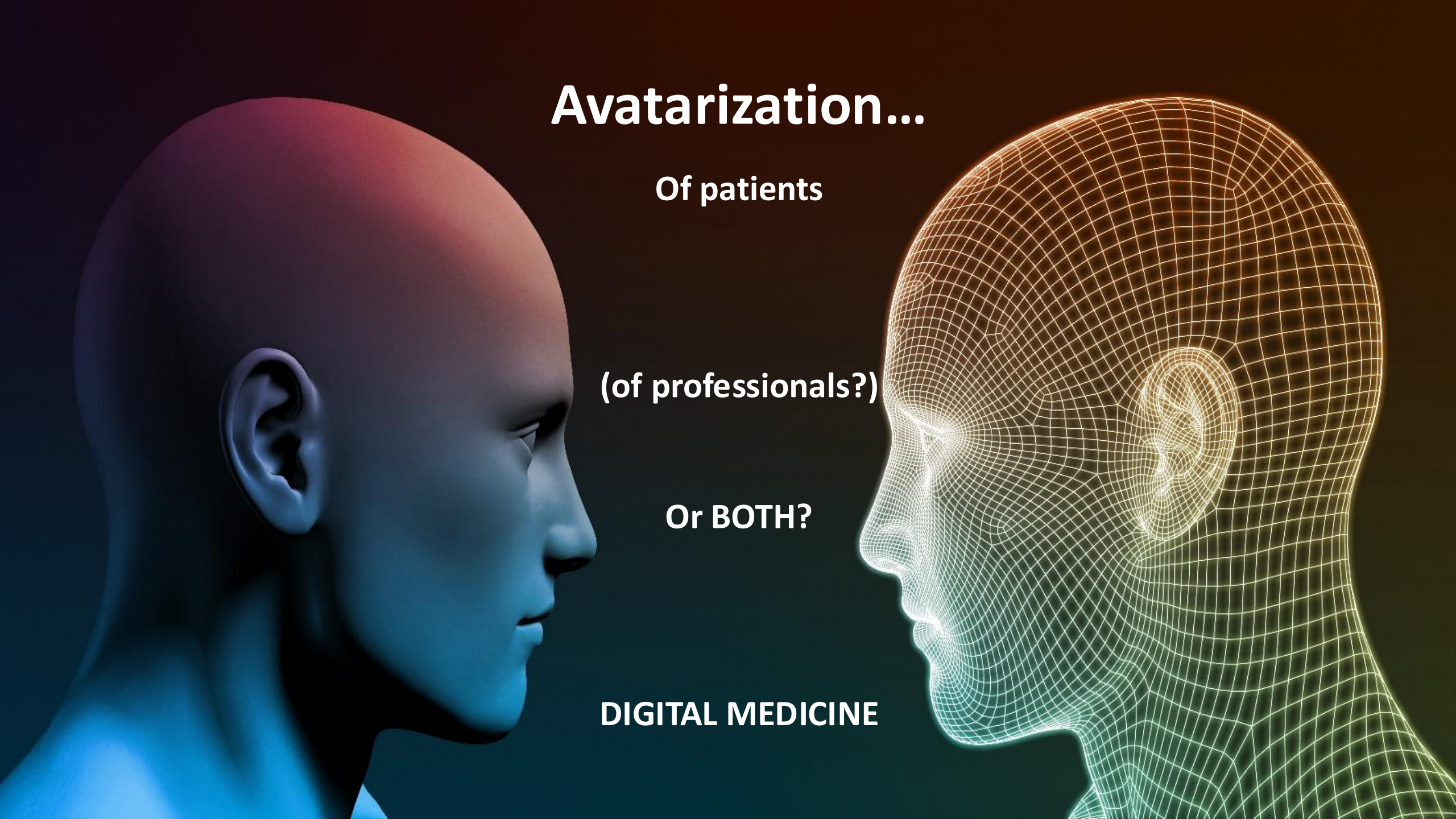
Avatarization…

Of patients

(of professionals?)

Or BOTH?

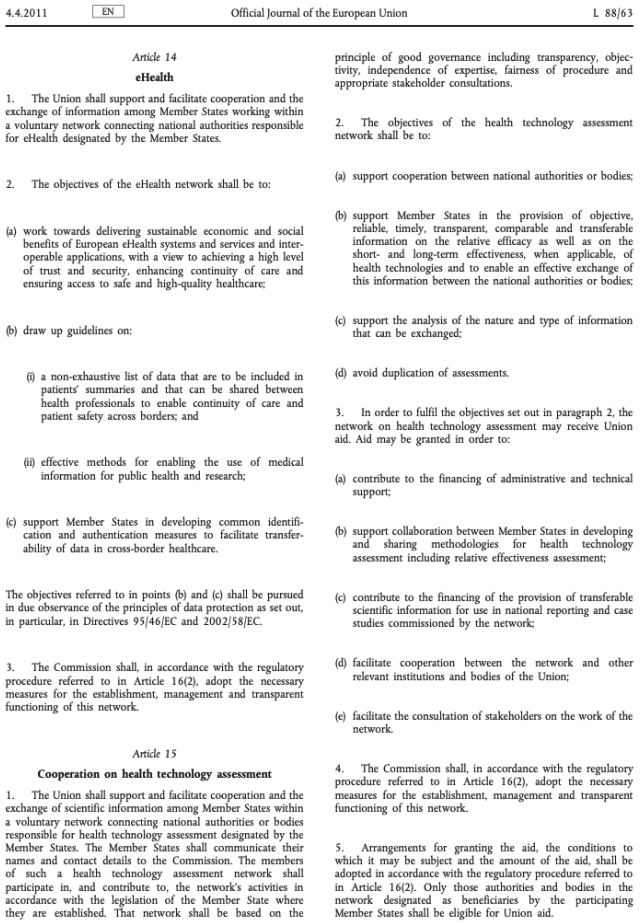
DIGITAL MEDICINE



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EUROPEAN DIRECTIVES (2011) & EC COMMUNICATION (2018)



4.4.2011 EN Official Journal of the European Union L 88/63

Article 14

eHealth

1. The Union shall support and facilitate cooperation and the exchange of information among Member States working within a voluntary network connecting national authorities responsible for eHealth designated by the Member States.

2. The objectives of the eHealth network shall be to:

(a) work towards delivering sustainable economic and social benefits of European eHealth systems and services and interoperable applications, with a view to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and high-quality healthcare;

(b) draw up guidelines on:

(i) a non-exhaustive list of data that are to be included in patients' summaries and that can be shared between health professionals to enable continuity of care and patient safety across borders; and

(ii) effective methods for enabling the use of medical information for public health and research;

(c) support Member States in developing common identification and authentication measures to facilitate transferability of data in cross-border healthcare.

The objectives referred to in points (b) and (c) shall be pursued in due observance of the principles of data protection as set out, in particular, in Directives 95/46/EC and 2002/58/EC.

3. The Commission shall, in accordance with the regulatory procedure referred to in Article 16(2), adopt the necessary measures for the establishment, management and transparent functioning of this network.

Article 15

Cooperation on health technology assessment

1. The Union shall support and facilitate cooperation and the exchange of scientific information among Member States within a voluntary network connecting national authorities or bodies responsible for health technology assessment designated by the Member States. The Member States shall communicate their names and contact details to the Commission. The members of such a health technology assessment network shall participate in, and contribute to, the network's activities in accordance with the legislation of the Member State where they are established. That network shall be based on the principle of good governance including transparency, objectivity, independence of expertise, fairness of procedure and appropriate stakeholder consultations.

2. The objectives of the health technology assessment network shall be to:

(a) support cooperation between national authorities or bodies;

(b) support Member States in the provision of objective, reliable, timely, transparent, comparable and transferable information on the relative efficacy as well as on the short- and long-term effectiveness, when applicable, of health technologies and to enable an effective exchange of this information between the national authorities or bodies;

(c) support the analysis of the nature and type of information that can be exchanged;

(d) avoid duplication of assessments.

3. In order to fulfil the objectives set out in paragraph 2, the network on health technology assessment may receive Union aid. Aid may be granted in order to:

(a) contribute to the financing of administrative and technical support;

(b) support collaboration between Member States in developing and sharing methodologies for health technology assessment including relative effectiveness assessment;

(c) contribute to the financing of the provision of transferable scientific information for use in national reporting and case studies commissioned by the network;

(d) facilitate cooperation between the network and other relevant institutions and bodies of the Union;

(e) facilitate the consultation of stakeholders on the work of the network.

4. The Commission shall, in accordance with the regulatory procedure referred to in Article 16(2), adopt the necessary measures for the establishment, management and transparent functioning of this network.

5. Arrangements for granting the aid, the conditions to which it may be subject and the amount of the aid, shall be adopted in accordance with the regulatory procedure referred to in Article 16(2). Only those authorities and bodies in the network designated as beneficiaries by the participating Member States shall be eligible for Union aid.

Directive 2011/24/EU Article: 14



Communication from the Commission to the European Parliament, The Council, the European Economic and Social Committee of the regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society.

Brussels, 25.4.2018

The Communication contains a package of legislative & non-legislative proposals with the aim of supporting Member States action on eHealth to:

1 Access and Sharing of Eletronic Health Records for citizens

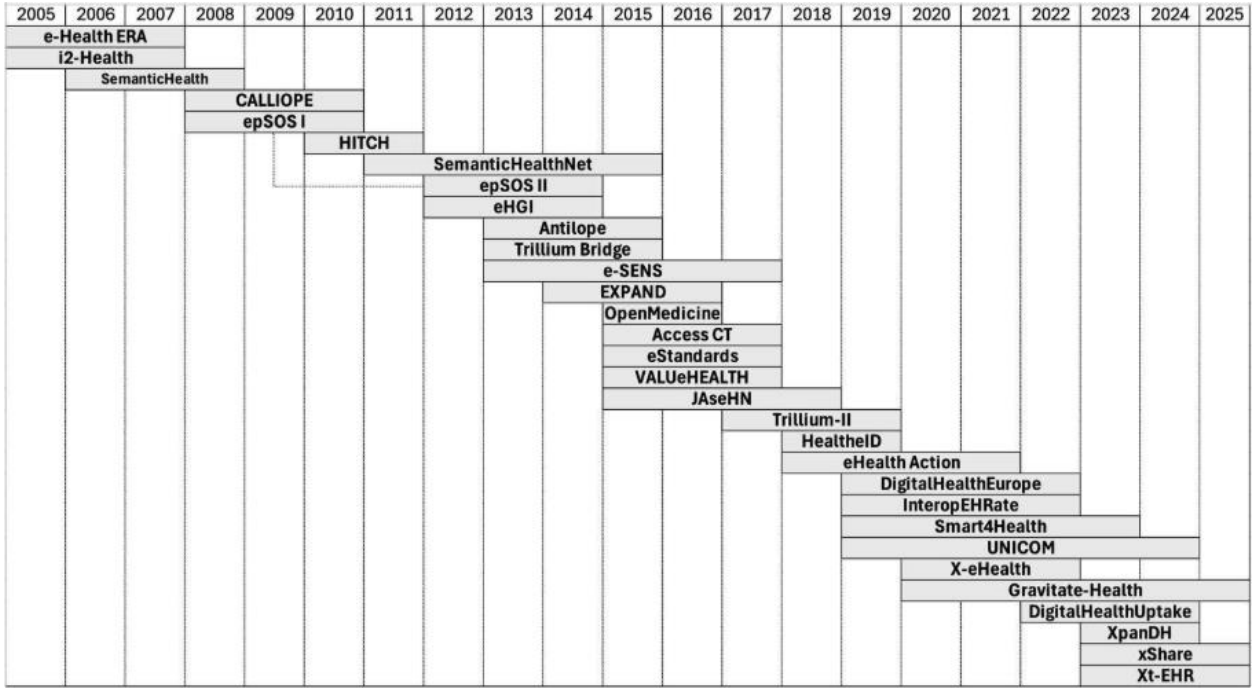
2 Connected health data to advance research, prevention and personalised health and care

3 Digital tools to foster citizen empowerment and person-centred care

The Value:

The trajectory of European projects in recent years shows a gradual consolidation of primary-use health data exchange under the framework of the European Electronic Health Record Exchange Format (EEHRxF) and its deployment through MyHealth@EU.

Between 2021 and 2025, the emphasis has shifted from specification work to real-world adoption, with projects not only defining standards but also operationalising them through testing strategies and demonstrators



A lot of collaboration happen on the voluntary basis before the EHDS

EU Service and Infrastructure for Primary use of Health data
2020- present

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

Primary use of Health data
2019-present

X-eHealth
Exchanging Electronic Health Records in a common framework

XpanDH
Expanding Digital Health through a pan-European EHRxF-based Ecosystem

Voluntary Networks
&
MS Collaboration

European Reference Networks

eHAction
Joint Action supporting the eHealth Network

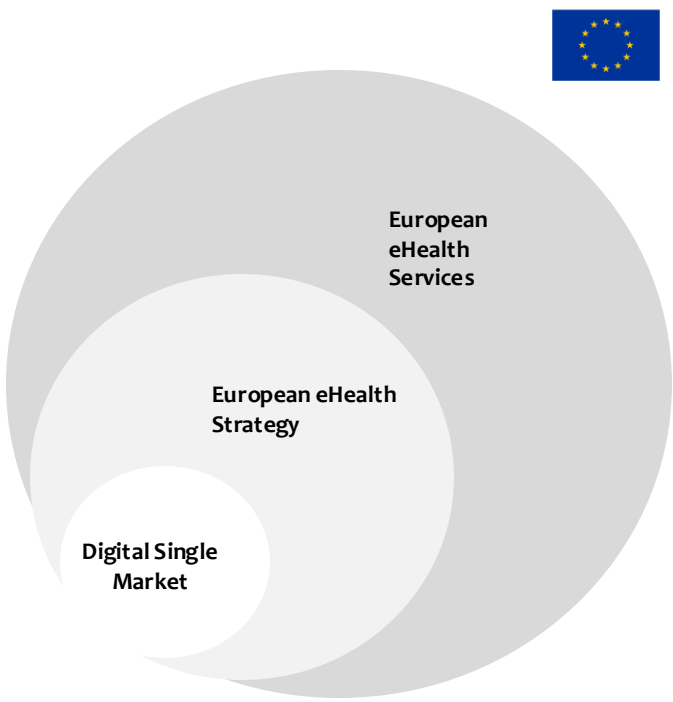
Smart4Health
Enables EU citizens to manage and bridge their own health data in different ways.



Xt EHR @dataspace

TEHDAS
Towards European Health Data Space

TEHDAS2



Secondary use of Health data
2021-present

EU landscape





Governance: A system of checks, balances and established norms

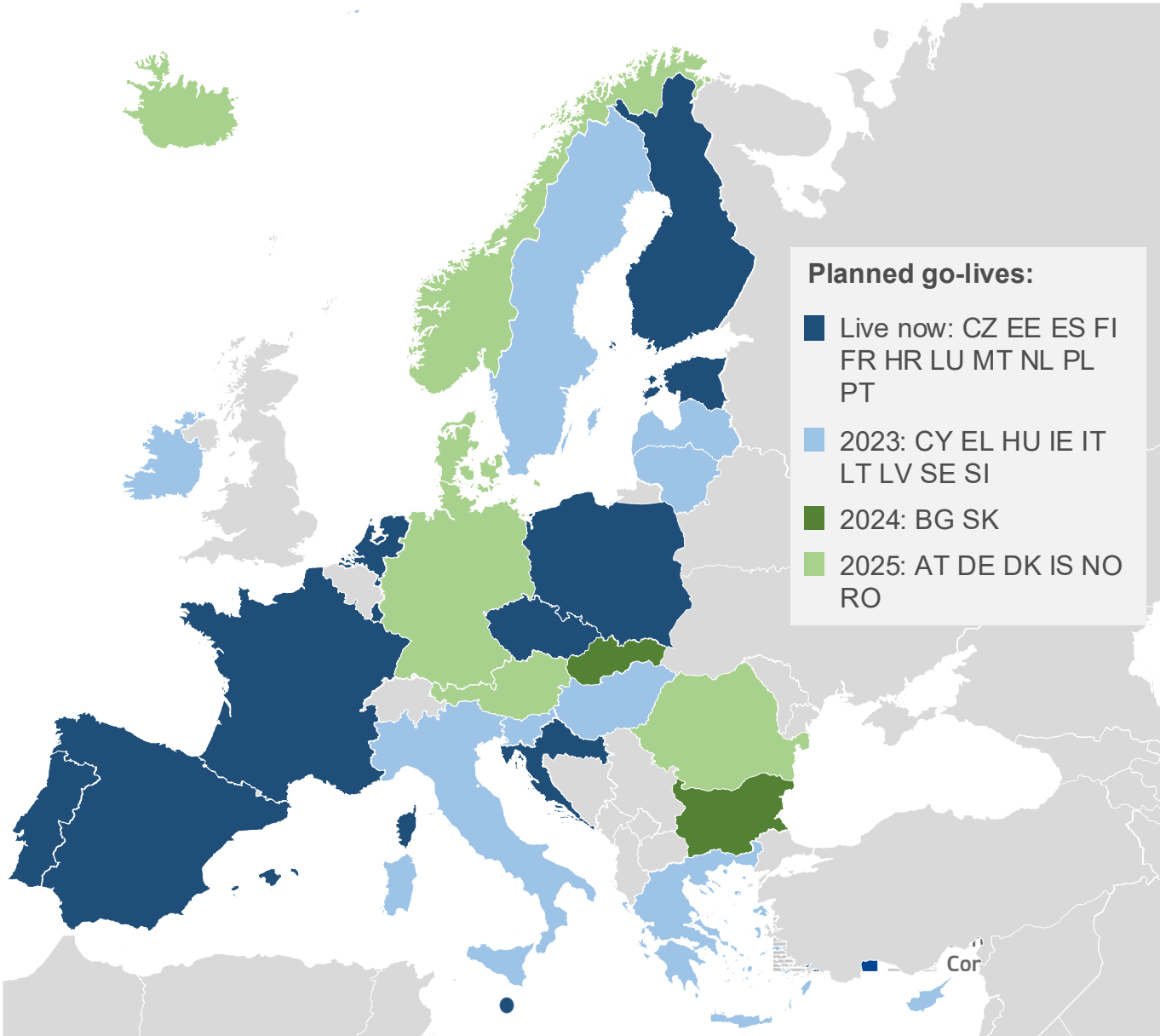
... ranging from formal institutions to informal processes, governing the interactions between major entities through to the expectations and performance of individuals.

MyHealth@EU state of play

MyHealth@EU is the existing infrastructure that connects healthcare providers in 11 Member States.

It allows them to exchange health data such as Patient Summaries and ePrescriptions.

These services will be expanded to include lab results and other types of health data.



Cross-border e-Prescription in action

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



Illustration based on materials from: THL/FI

MyHealth@EU timeline (olde slide; voluntary adoption)

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

ePrescription

EE HR FI PT

IT LT LU RO HU SE BG ES EL CY SI AT DK PL CZ IE LV NO

W1	W2	W3	W4	W5	W6	W7	W8
2018-2019	2019-2020	2020-2021	2021-2022	2022-2023	2023-2024	2024-2025	2025-2026

PT CZ HR LU MT

FR ES NL HU EL IE EE FI IT CY

LV LT SI BG

NO IS SK DK DE

Patient Summary

Timelines are approximate and subject to change

Digital Transformation of Health and Care Objectives

1. Citizens' secure access to and sharing of health data across borders
2. Better data to advance research, disease prevention and personalised health and care
3. Digital tools and data for citizen empowerment and person-centred care



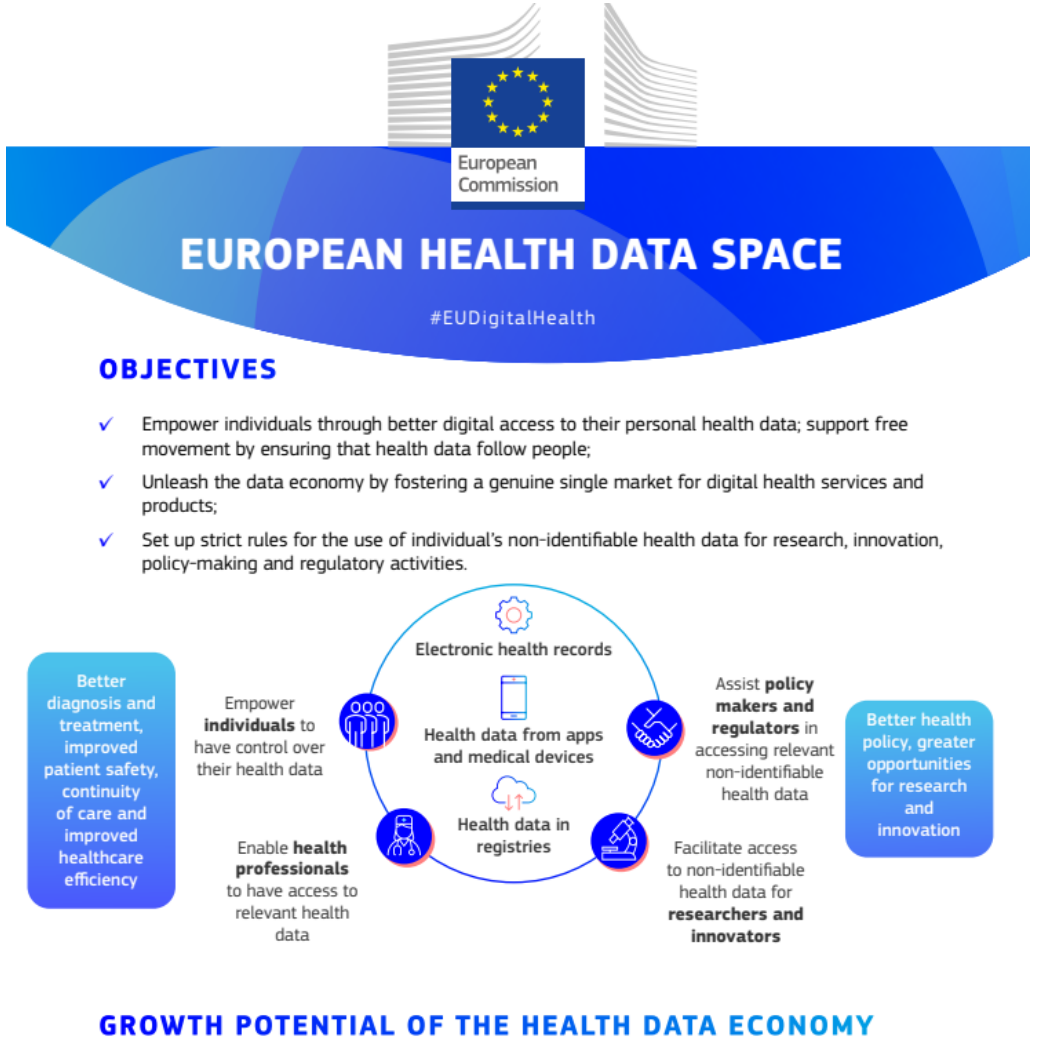
Efficiency of health and care systems, better outcomes, personalised medicine, integrated care, well-being, citizens empowerment

European Commission

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

European Context

The EHDS proposal also builds on the requirements that have been imposed on software through the Medical Devices Regulation and the proposed Artificial Intelligence Act. Medical device software already needs to be certified under the Medical Devices Regulation and AI-based medical devices and other AI systems would also need to comply with the requirements of the Artificial Intelligence Act once in force. However, a regulatory gap has been identified when it comes to information systems used in the health domain, also called electronic health record systems ('EHR systems'). The focus is therefore on these EHR systems that are intended to be used to store and share electronic health data of natural persons. Therefore, the EHDS sets essential requirements specifically for EHR systems in order to promote interoperability and data portability of such system, which would allow natural persons to control their electronic health data more effectively.



Funded by the European Union

The European Health Data Space is a health specific ecosystem comprised of rules, common standards and practices, infrastructures and a governance framework

EHDS Proposal published 03/05/2022

Funded by the European Union

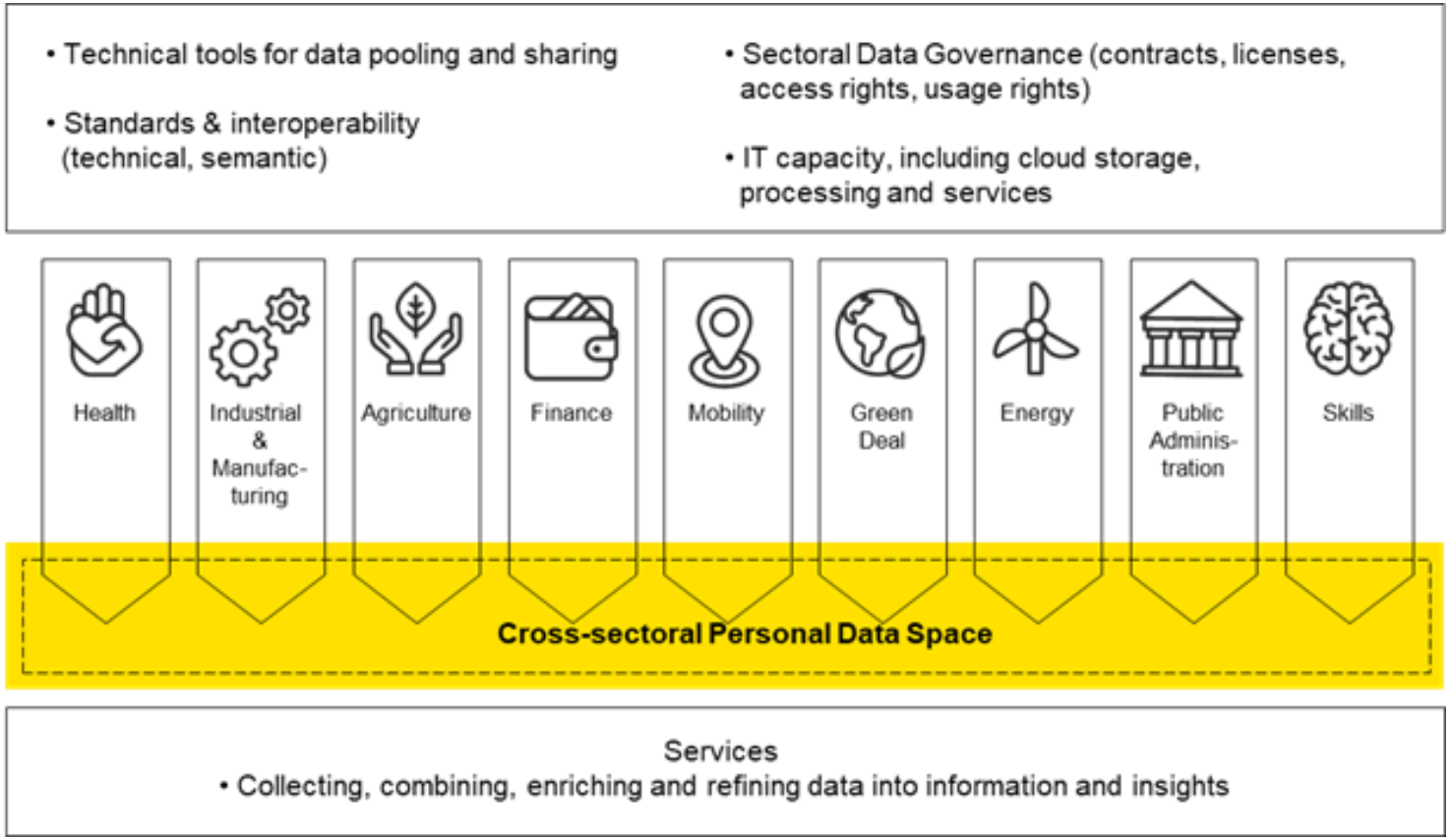
EU data strategy and Data Spaces

Rich pool of data (varying degree of accessibility)

Free flow of data across sectors and countries

Full respect of GDPR

Horizontal framework for data governance and data access



Funded by the European Union

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.



Scope of EHDS Regulation

Strengthens the rights of individuals in relation to greater control over their electronic health data:



Access, share health data with health professionals nationally or cross-border, add information, rectify errors, restrict access, know what health professional accessed data, issue and accept health data in a common European format, strengthen interoperability.

Rules for electronic health record systems (EHR systems)

Rules and mechanisms supporting the secondary use of electronic health data

Mandatory cross-border infrastructures for primary and secondary use of health data

- MyHealth@EU
- HealthData@EU

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

European Commission

The EHDS – Chapter I; Article 1

Subject matter and scope

1. This Regulation establishes the European Health Data Space ('EHDS') by providing for common rules, standards, infrastructures and a governance framework with a view to facilitating access to electronic health data for the purposes of primary and secondary use of these data.

2. This Regulation:

(a) specifies and complements the rights laid down in Regulation (EU) 2016/679 of natural persons in relation to the primary and secondary use of their personal electronic health data;

(b) lays down common rules for electronic health records systems ('EHR systems') in relation to two mandatory software components, namely the 'European interoperability component for EHR systems' and the 'European logging component for EHR systems' as defined in Article 2(2), points (nc) and (nd), and wellness applications that claim interoperability with EHR systems in relation to those two components in the Union for primary use;

(c) lays down common rules and mechanisms for primary and secondary use of electronic health data;

(d) establishes a cross-border infrastructure enabling the primary use of personal electronic health data across the Union;

(e) establishes a cross-border infrastructure for the secondary use of electronic health data;

(f) establishes governance and coordination on national and European level for both primary and secondary use of electronic health data.

The EHDS – Chapter I; Article 1

Subject matter and scope

3. This Regulation applies to:

(a)manufacturers and suppliers of EHR systems and wellness applications placed on the market and put into service in the Union and the users of such products;

(b)controllers and processors established in the Union processing electronic health data of Union citizens and third-country nationals legally residing in the territories of Member States;

(c)controllers and processors established in a third country that has been connected to or are interoperable with MyHealth@EU, pursuant to Article 12(5);

(d)data users to whom electronic health data are made available by data holders in the Union.

4. This Regulation shall be without prejudice to other Union legal acts regarding access to, sharing of or secondary use of electronic health data, or requirements related to the processing of data in relation to electronic health data, in particular Regulations (EU) 2016/679, (EU) 2018/1725, (EU) 536/2014(27), No223/2009(28), (EU) 2022/868 and (EU) 2023/2854 and Directives 2002/58/EC(29) and (EU) 2016/943(30).

4a. References to the provisions of Regulation (EU) 2016/679 shall be understood also as references to the corresponding provisions of Regulation (EU) 2018/1725, where relevant.

5. This Regulation shall be without prejudice to Regulations (EU) 2017/745, (EU) 2017/746 and […] [AI 2021/0106(COD)], as regards the security of medical devices, in vitro diagnostic medical devices and AI systems that interact with EHR systems.

6. This Regulation shall be without prejudice to Union or national law regarding electronic health data processing for the purposes of reporting, complying with access to information requests or demonstrating or verifying compliance with legal obligations or Union or national law regarding the granting of access to anddisclosure of official documents.

6a. This Regulation shall be without prejudice to specific provisions in Union or national law providing for access to electronic health data for further processing by public bodies of the Member States, Union institutions, bodies and agencies, or by private entities entrusted under Union or national law with a task of public interest, for the purpose of carrying out such task.
6b. This Regulation shall not affect access to electronic health data for secondary use agreed in the framework of contractual or administrative arrangements between public or private entities.

7. This Regulation does not apply to the processing of personal data:
(a) in the course of an activity which falls outside the scope of Union law;
(b) by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security.

The EHDS – Chapter I; Article 2

Definitions

1. For the purposes of this Regulation, the following definitions shall apply:
   (a) the definitions of 'personal data', 'processing', 'pseudonymisation', 'controller', 'processor', 'third party', 'consent', 'genetic data', 'data concerning health', 'international organisation' pursuant to Article 4, points (1), (2), (5), (7), (8), (10), (11), (13), (15) and (26), of Regulation (EU) 2016/679;

   (b) the definitions of 'healthcare', 'Member State of affiliation', 'Member State of treatment', 'health professional', 'healthcare provider', 'medicinal product' and 'prescription', pursuant to Article 3, points (a), (c), (d), (f), (g), (i) and (k), of Directive 2011/24/EU;

   (c) the definitions of 'data', 'access', 'data altruism', 'public sector body' and 'secure processing environment', pursuant to Article 2, points (1), (13), (16), (17) and (20), of Regulation (EU) 2022/868;

   (d) the definitions of 'making available on the market', 'placing on the market', 'market surveillance', 'market surveillance authority', 'non-compliance', 'manufacturer', 'importer', 'distributor', 'economic operator', 'corrective action', 'recall' and 'withdrawal', pursuant to Article 2, points (1), (2), (3), (4), (7), (8), (9), (10), (13), (16), (22) and (23), of Regulation (EU) 2019/1020;

   (e) the definitions of 'medical device', 'intended purpose', 'instructions for use', 'performance', 'health institution' and 'common specifications', pursuant to Article 2, points (1), (12), (14), (22), (36) and (71), of Regulation (EU) 2017/745;

   (f) the definitions of 'electronic identification', 'electronic identification means' and 'person identification data' pursuant to Article 3, points (1), (2) and (3), of Regulation (EU) No 910/2014;

   (g) the definition of 'contracting authorities' pursuant to Article 2(1), point (1), of Directive 2014/24/EU of the European Parliament and of the Council(31);

   (h) the definition of 'public health' pursuant to Article 3, point (c), of Regulation (EC) No 1338/2008 of the European Parliament and of the Council(32).

The EHDS – Chapter I; Article 2

Definitions

2. In addition, for the purposes of this Regulation the following definitions shall apply:

(a) 'personal electronic health data' means data concerning health and genetic data as defined in Article 4, points (13) and (15), of Regulation (EU) 2016/679, processed in an electronic form;

(b) 'non-personal electronic health data' means electronic health data other than personal electronic health data, encompassing both data that has been anonymised so that it no longer relates to an identified or identifiable natural person and data that has never related to a data subject;

(c) 'electronic health data' means personal or non-personal electronic health data;

(d) 'primary use of electronic health data' means the processing of electronic health data for the provision of healthcare to assess, maintain or restore the state of health of the natural person to whom that data relates, including the prescription, dispensation and provision of medicinal products and medical devices, as well as for relevant social , administrative or reimbursement services;

(e) 'secondary use of electronic health data' means the processing of electronic health data for purposes set out in Chapter IVof this Regulation, other than the initial purposes for which they were collected or produced;

(f) 'interoperability' means the ability of organisations as well as software applications or devices from the same manufacturer or different manufacturers to interact , involving the exchange of information and knowledge without changing the content of the data between these organisations, software applications or devices, through the processes they support;

(g) 'European electronic health record exchange format' means a structured, commonly used and machine-readable format that allows transmission of personal electronic health data between different software applications, devices and healthcare providers;

(h) 'registration of electronic health data' means the recording of health data in an electronic format, through manual entry of data, through the collection of data by a device, or through the conversion of non-electronic health data into an electronic format, to be processed in an EHR system or a wellness application;

(i) 'electronic health data access service' means an online service, such as a portal or a mobile application, that enables natural persons not acting in their professional role to access their own electronic health data or electronic health data of those natural persons whose electronic health data they are legally authorised to access;

(j) 'health professional access service' means a service, supported by an EHR system, that enables health professionals to access data of natural persons under their treatment;

The EHDS – Chapter I; Article 2

Definitions

(m) 'EHR' (electronic health record) means a collection of electronic health data related to a natural person and collected in the health system, processed for the purpose of the provision of healthcare ;

(n) 'EHR system' (electronic health record system) means any system where the appliance or software allows to store, intermediate, export, import, convert, edit or view personal electronic health data that belongs to the priority categories of personal electronic health data as referred to in Article 5(1) of this Regulation and is intended by the manufacturer to be used by healthcare providers in providing patient care or by patient to access to their health data;

(na) 'putting into service' means the first use, for its intended purpose, in the Union, of an EHR system covered by this Regulation;

(nb) 'software component' or 'component' means a discrete part of software which provides specific functionality or performs specific functions or procedures and which can operate independently or in conjunction with other components;

(nc) 'European interoperability component for EHR systems' (or 'the interoperability component') means a software component of the EHR system which provides and receives personalelectronic health data referred to in Article 5 in the format referred to in Article 6 of this Regulation; The European interoperability component is independent of the European logging component;

(nd) 'European logging component for EHR systems' (or 'the logging component') means a software component of the EHR system which provides logging information relating to accesses of health professionals or other individuals to personal electronic health data referred to in Article 5, in the format defined in Annex II.3.4 of this Regulation; the European logging component is independent of the European interoperability component;

(p) 'CE marking of conformity' means a marking by which the manufacturer indicates that the EHR system is in conformity with the applicable requirements set out in this Regulation and other applicable Union legislation providing for its affixing pursuant to Regulation (EC) No 765/2008 of the European Parliament and of the Council(33);

(pa) 'risk' means the combination of the degree of severity of a harm and the probability of an occurrence of a hazard causing the harm to health, safety or information security;

(q) 'serious incident' means any malfunction or deterioration in the characteristics or performance of an EHR system made available on the market that directly or indirectly leads, might have led or might lead to any of the following:

(i) the death of a natural person or serious damage to a natural person's health or serious prejudice to a natural persons rights;

(ii) a serious disruption of the management and operation of critical infrastructure in the health sector;

(xa) 'care' means a professional service for the purpose of which is to address the specific needs of a person who, on account of impairment or other physical or mental conditions requires assistance, including preventive and supportive measures, to carry out essential activities of daily living in order to support their personal autonomy;

The EHDS – Chapter I; Article 2

Definitions

(y) 'health data holder' means any natural or legal person, public authority, agency or other body in the healthcare or the care sectors; including reimbursement services when needed as well as any natural or legal person developing products or services intended for the health, healthcare or care sectors; developing or manufacturing wellness applications; performing research in relation to the healthcare or care sectors; or acting as a mortality registry; as well as any Union institution, body, office or agency; who has either:

(a) the right or obligation, in accordance with applicable Union law or national legislation, to process personal electronic health data for the provision of healthcare or care or for public health, reimbursement, research, innovation, policy making, official statistics, patient safety or regulatory purposes, in its capacty as a controller or joint controller; or

(b) the ability to make available, including to register, provide, restrict access or exchange non-personal electronic health data, through control of the technical design of a product and related services.

(z) 'health data user' means a natural or legal person, including Union institutions, bodies or agencies, which has been granted lawful access to electronic health data for secondary use pursuant to a data permit, data request or an access approval by an authorized participant in Health Data @ EU;

(aa) 'data permit' means an administrative decision issued to a health data user by a health data access body to process certain electronic health data specified in the data permit for specific secondary use purposes based on conditions laid down in Chapter IV of this Regulation;

(ab) 'dataset' means a structured collection of electronic health data;

(aba) 'datasets of high impact for the secondary use of electronic health data' means datasets the re-use of which is associated with important benefits because of their relevance for health research;

(ac) 'dataset catalogue' means a collection of datasets descriptions, which is arranged in a systematic manner and consists of a user-oriented public part, where information concerning individual dataset parameters is accessible by electronic means through an online portal;

(ad) 'data quality' means the degree to which the elements of electronic health data are suitable for their intended primary and secondary use;

(ae) 'data quality and utility label' means a graphic diagram, including a scale, describing the data quality and conditions of use of a dataset;

(aea) 'wellness application' means any appliance or software intended by the manufacturer to be used by a natural person for processing electronic health data specifically for providing information on the health of individual persons, or the delivery of care for other purposes than the provision of healthcare.

The EHDS – Chapter II; Article 3

Rights of natural persons in relation to the primary use of their personal electronic health data

The Commission shall, by means of implementing acts, determine the requirements for the technical implementation of the rights set out in this Section.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68(2).

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Source EP text approved 24.4.2024: https://www.europarl.europa.eu/doceo/document/TA-9-2024-04-24_EN.html#sdocta18

The EHDS – Chapter II; Article 3

Rights of natural persons in relation to the primary use of their personal electronic health data

7.Member States shall ensure that, when exercising the right to rectification under Article 16 of Regulation (EU) 2016/679, natural persons can easily request rectification online through the electronic health data access services referred to in paragraph 5, point (a), of this Article.

8.Natural persons shall have the right to give access to or request a data holder from the health or social security sector to transmit their electronic health data to a data recipient of their choice from the health or social security sector, immediately, free of charge and without hindrance from the data holder or from the manufacturers of the systems used by that holder.

Natural persons shall have the right that, where the data holder and the data recipient are located in different Member States and such electronic health data belongs to the categories referred to in Article 5, the data holder shall transmit the data in the European electronic health record exchange format referred to in Article 6 andthe data recipient shall read and accept it.

By way of derogation from Article 9 of Regulation […] [Data Act COM/2022/68 final], the data recipient shall not be requiredto compensate the data holder for making electronic heath data available.

Natural persons shall have the right that, where priority categories of personal electronic health data referred to in Article 5 are transmitted or made available by the natural person according to the European electronic health record exchange format referred to in Article 6, such data shall be read and accepted by other healthcare providers.

9.Notwithstanding Article 6(1), point (d), of Regulation (EU) 2016/679, natural persons shall have the right to restrict access of health professionals to all or part of their electronic health data. Member States shall establish the rules and specific safeguards regarding such restriction mechanisms.

10.Natural persons shall have the right to obtain information on the healthcare providers and health professionals that haveaccessed their electronic health data in the context of healthcare. The information shall be provided immediately and free of charge through electronic health data access services.

11.The supervisory authority or authorities responsible for monitoring the application of Regulation (EU) 2016/679 shall alsobe responsible for monitoring the application of this Article, in accordance with the relevant provisions in Chapters VI, VII and VIII of Regulation (EU) 2016/679. They shall be competent to impose administrative fines up to the amount referred to in Article 83(5) of that Regulation. Those supervisory authorities and the digital health authorities referred to in Article 10 of this Regulation shall, where relevant, cooperate in the enforcement of this Regulation, within the remit of their respective competences.

12.The Commission shall, by means of implementing acts, determine the requirements concerning the technical implementation ofthe rights set out in this Article. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).

The EHDS – Chapter II; Article 4

Access by health professionals to personal electronic health data

Where they process data in an electronic format, health professionals shall:

(a)have access to the electronic health data of natural persons under their treatment, irrespective of the Member State of affiliation and the Member State of treatment;

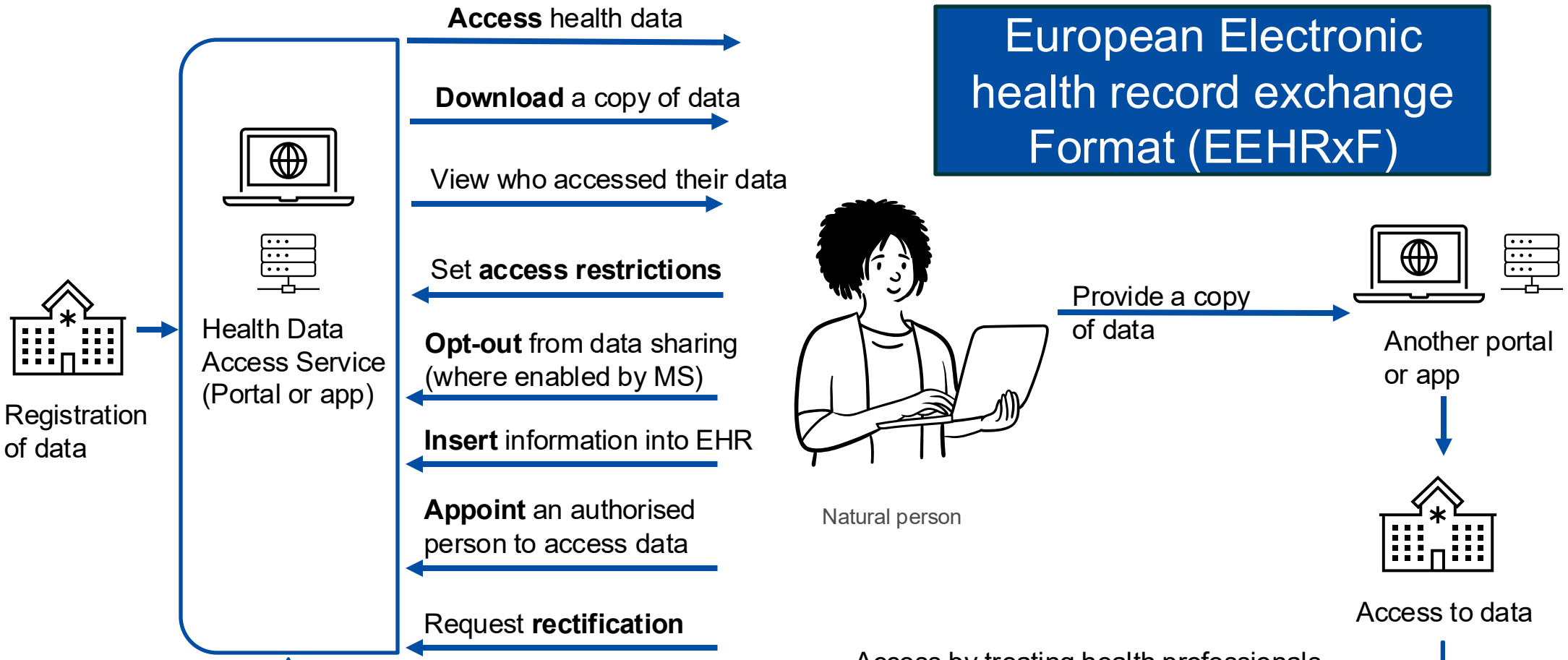
(b)ensure that the personal electronic health data of the natural persons they treat are updated with information related to the health services provided.

2.In line with the data minimisation principle provided for in Regulation (EU) 2016/679, Member States may establish rules providing for the categories of personal electronic health data required by different health professions. Such rules shall not be based on the source of electronic health data.

3.Member States shall ensure that access to at least the priority categories of electronic health data referred to in Article 5 is made available to health professionals through health professional access services. Health professionals who are in possession of recognised electronic identification means shall have the right to use those health professional access services, free of charge.

4.Where access to electronic health data has been restricted by the natural person, the healthcare provider or health professionals shall not be informed of the content of the electronic health data without prior authorisation by the natural person, including where the provider or professional is informed of the existence and nature of the restricted electronic health data. In cases where processing is necessary in order to protect the vital interests of the data subject or of another natural person, the healthcare provider or health professional may get access to the restricted electronic health data. Following such access, the healthcare provider or health professional shall inform the data holder and the natural person concerned or his/her guardians that access to electronic health data had been granted. Member States' law may add additional safeguards.

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;

EU Regulations applied

1. Regulations Already in Force (or Effective by 2025):

General Data Protection Regulation (GDPR) - 2016/679

Medical Devices Regulation (MDR) - 2017/745

In Vitro Diagnostic Medical Devices Regulation (IVDR) - 2017/746

Clinical Trials Regulation (Regulation 536/2014)

2. Regulations Already in Force (until 2031):

European Health Data Space (EHDS) regulation

Artificial Intelligence Act (AI Act)

Data Governance Act (DGA) OR Digital Markets Act (DMA) and Digital Servies Act (DSA)

3. Relevant Technical Standards and Guidelines

ISO 13485 (Quality Management Systems for Medical Devices):

IEC 62304 (Medical Device Software):

HL7 FHIR (Fast Healthcare Interoperability Resources):

Key Considerations

1. Interoperability

Interoperability will be a major focus in the coming years, with regulations like the EHDS requiring healthcare software systems to comply with European standards.

2. Security and Privacy

The GDPR and AI Act will require software developers to ensure the security and privacy of health data, incorporating features like encryption, anonymization, and access control

3. Technical Compliance

Technical standards, such as IEC 62304 and ISO 13485, will be essential to ensure medical software meets regulatory requirements

Agenda

1:00 - 1:10 **Welcome and Introduction** *Yasunari Shiokawa (IHE-Japan)*
1:10 - 2:10 **EHDS Overview** *Prof. Henrique Martins (ISCTE)*
2:10 - 2:20 *Break*
2:20 - 3:20 **EEHRxF Overview** *Prof. Henrique Martins (ISCTE)*
3:20 - 3:30 *Break*
3:30 - 4:30 **EEHRxF Specification Overview** *Giorgio Cangioli (HL7 EU) & Diogo Martins (i2X)*
4:30 - 4:45 **Overview of Japan EHR**
Information Exchange Service *Yasunari Shiokawa (IHE-Japan)*
4:45 - 4:50 *Closing Yasunari Shiokawa (IHE-Japan)*

Scope of harmonisation

EHR systems must contain **two harmonised components**, starting 2028/2030 depending on which kind of data they process:

Interoperability component

- Provides capability to import/ export data in EEHRxF

Logging component

- Provides capability to generate the logs of access

Member States remain free to have requirements on other parts of EHR systems, provided they do not interfere with the harmonised components

The exchange format (EEHRxF) – Art. 15

Article 15

European electronic health record exchange format

1. 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 elements:

   (a) 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;

   (b) coding systems and values to be used in datasets containing electronic health data;

   (c) technical interoperability specifications for the exchange of electronic health data, including its content representation, standards and profiles.

   The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 98(2).

2. The Commission shall, by means of implementing acts, provide regular updates of the European electronic health record exchange format to integrate relevant revisions of the healthcare coding systems and nomenclatures. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).

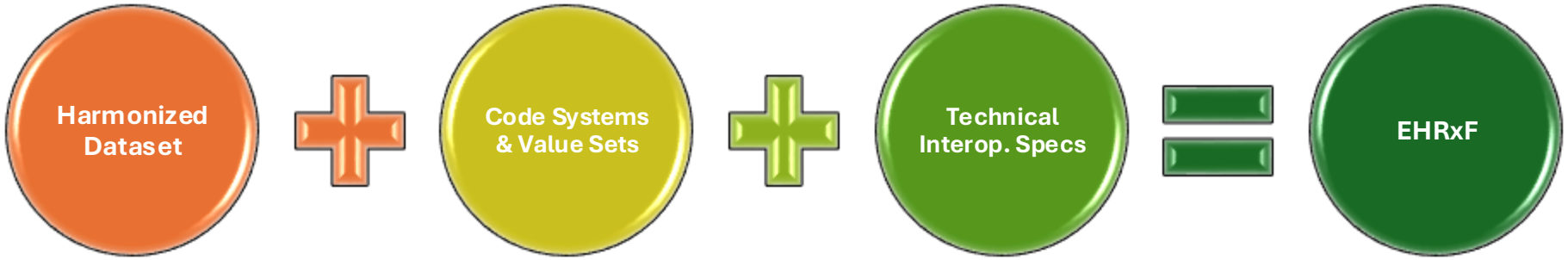
3. The Commission may, by means of implementing acts, lay down technical specifications to extend the European electronic health record exchange format to additional categories of personal electronic health data referred to in Article 14(1), third subparagraph. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).

4. Member States shall ensure that the priority categories of personal electronic health data referred to in Article 14 are issued in the European electronic health record exchange format referred to in paragraph 1 of this Article. Where such data are transmitted by automated means for primary use, the receiving provider shall accept the format of the data and be able to read them.

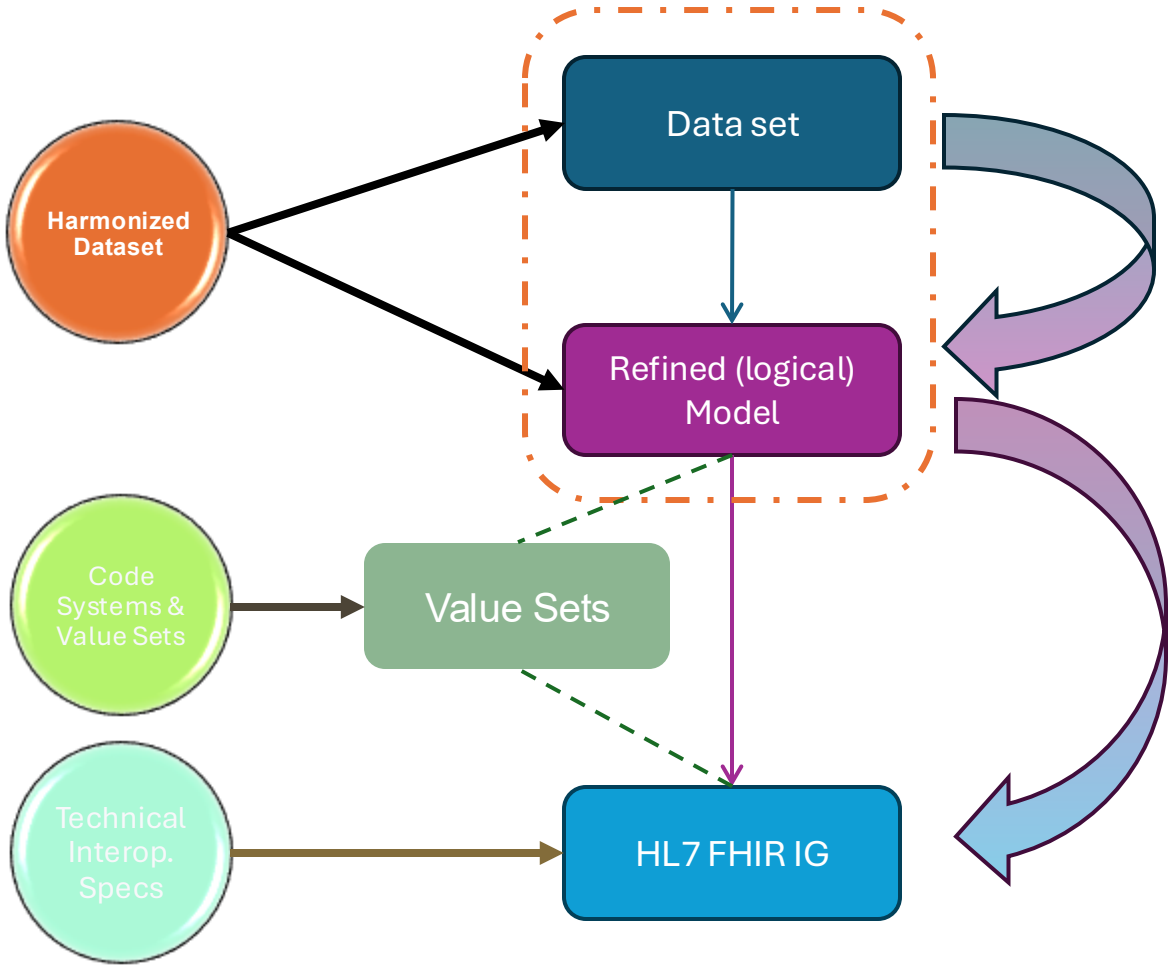
E-EHRxF (art. 15)

*"Such format shall be **commonly used**, **machine-readable** and allow **transmission** of personal electronic **health data** between different software applications, devices and healthcare providers.*

*The format should support transmission of **structured** and **unstructured** health data."*



EEHRxF (art. 15): content



Formal model mapping

How is the data set realized in the refined model ?

Formal model mapping

How is the refined model realized in the Tech. specs ?

Priority categories

- Group 1
  - Patient summaries
  - Electronic prescriptions
  - Electronic dispensations

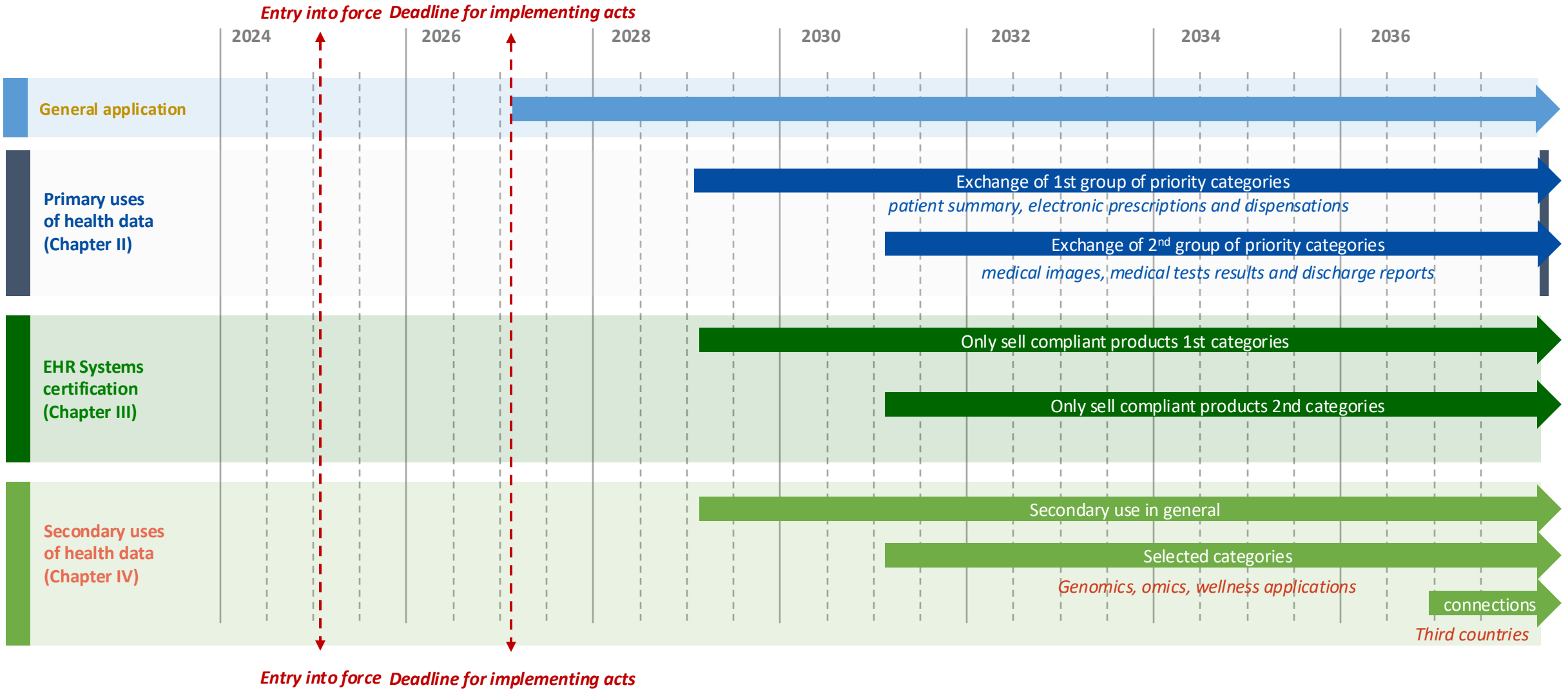


- Group 2
  - Medical imaging studies and related imaging reports
  - Medical test results, including laboratory test and related reports
  - Discharge reports

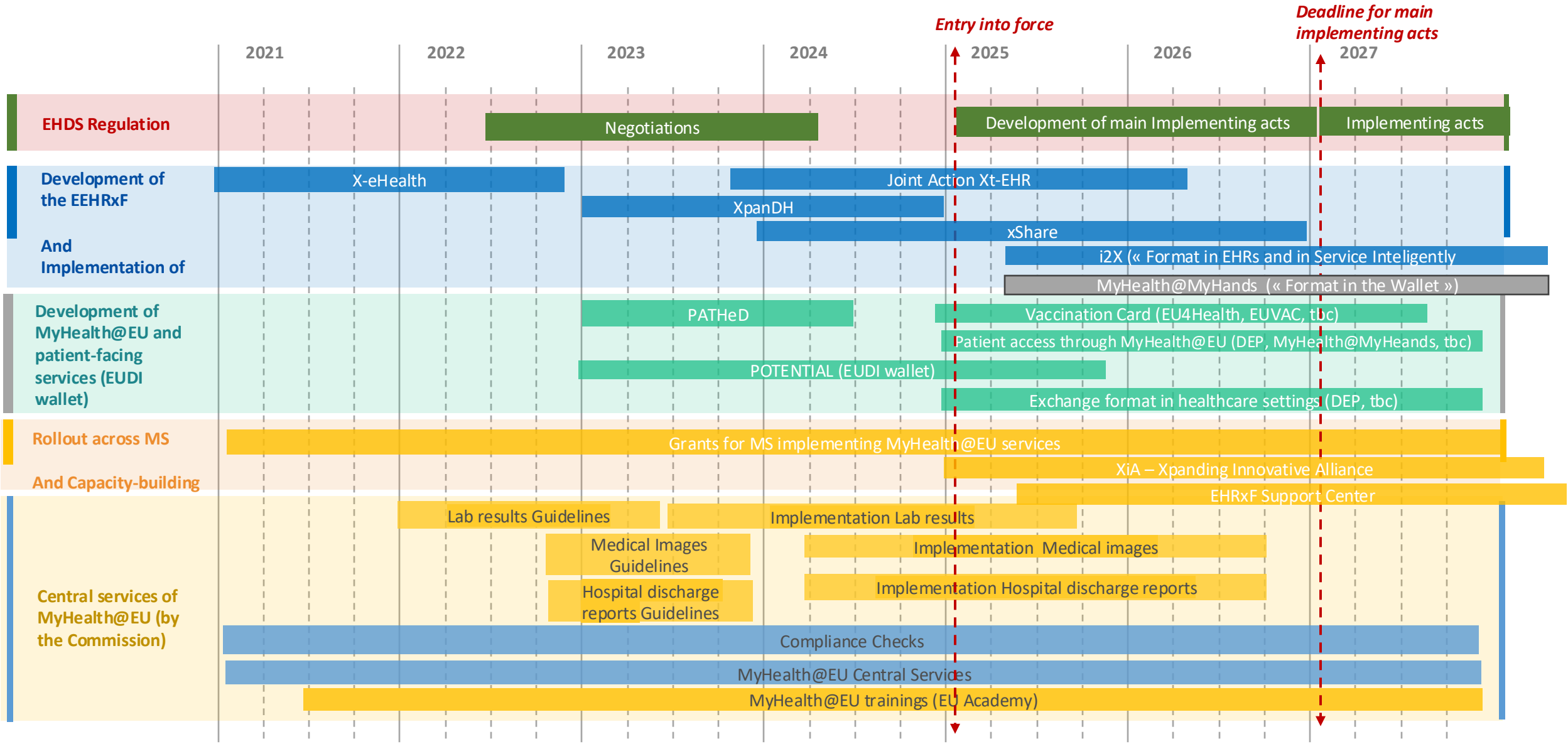


Implementation of the EHDS Regulation

Timelines are indicative.



Primary use of health data: Implementation (adapted from EC)



The EHDS – Chapter II; Article 14 n.1

Priority categories of personal electronic health data for primary use

1. For the purposes of this Chapter, where data is processed in electronic format, the priority categories of personal electronic health data shall be the following ▌:

(a) patient summaries;
(b) electronic prescriptions;
(c) electronic dispensations;
(d) medical imaging studies and related imaging reports;
(e) medical test results, including laboratory and other diagnostic results and related reports;
(f) discharge reports.

The main characteristics of the priority categories of personal electronic health data▌ shall be as set out in Annex I.

Member States may provide by virtue of national law that additional categories of personal electronic health data shall be accessed and exchanged for primary use pursuant to this Chapter. The Commission may, by means of implementing acts, lay down cross-border specifications for these data categories pursuant to Article 6(-1a) and Article 12(8).

(2022 PROPOSED TEXT). (d)medical images and image reports; (e) Laboratory results;

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Source EP text approved 24.4.2024: https://www.europarl.europa.eu/doceo/document/TA-9-2024-04-24_EN.html#sdocta18

The EHDS – ANNEX I

Main characteristics of **priority categories of personal** electronic health data **for primary use**

Electronic health data category	Main characteristics of electronic health data included under the category
1. Patient summary	Electronic health data that includes important clinical facts related to an identified person and that is essential for the provision of safe and efficient healthcare to that person. The following information is part of a patient summary: 1. Personal details 2. Contact information 3. Information on insurance 4. Allergies 5. Medical alerts 6. Vaccination/prophylaxis information, possibly in the form of a vaccination card 7. Current, resolved, closed or inactive problems ***including in an international classification coding*** 8. Textual information related to medical history 9. Medical devices and implants 10. ***Medical or care*** procedures 11. Functional status 12. Current and relevant past medicines 13. Social history observations related to health 14. Pregnancy history 15. Patient provided data 16. Observation results pertaining to the health condition 17. Plan of care 18. Information on a rare disease such as details about the impact or characteristics of the disease
2. Electronic prescription	Electronic health data constituting a prescription for a medicinal product as defined in Article 3(k) of Directive 2011/24/EU.
3. Electronic dispensation	Information on the supply of a medicinal product to a natural person by a pharmacy based on an electronic prescription.
4. Medical image and image report	Electronic health data related to the use of or produced by technologies that are used to view the human body in order to prevent, diagnose, monitor, or treat medical conditions.
5. Laboratory result	Electronic health data representing results of studies performed notably through in vitro diagnostics such as clinical biochemistry, haematology, transfusion medicine, microbiology, immunology, and others, and including, where relevant, reports supporting the interpretation of the results.
6. Discharge report	Electronic health data related to a healthcare encounter or episode of care and including essential information about admission, treatment and discharge of a natural person.

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Source EP text approved 24.4.2024: https://www.europarl.europa.eu/doceo/document/TA-9-2024-04-24_EN.html#sdocta18

The EHDS – Chapter II; Article 14 n.2

Priority categories of personal electronic health data for primary use

2. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend ▌ Annex I by adding, modifying or removing the main characteristics of the priority categories of personal electronic health data as referred to in paragraph 1. The amendments shall satisfy the following **cumulative** criteria:

(a) the characteristic is relevant for healthcare provided to natural persons;

(b) the characteristic as modified is used **in the majority of** Member States according to the most recent information;

(c) the changes are aimed to adapt the priority categories to the **technical evolution and international standards**.

(2022 PROPOSED TEXT). The categories of electronic health data added through such delegated acts shall satisfy the following criteria:

(a)the category is relevant for health services provided to natural persons;

*(b)according to the most recent information, the category is used in **a significant number** of EHR systems used in Member States;*

(c)international standards exist for the category that have been examined for the possibility of their application in the Union.

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Source EP text approved 24.4.2024: https://www.europarl.europa.eu/doceo/document/TA-9-2024-04-24_EN.html#sdocta18

Role of implementing acts for EHRxF adoption

1. **Detailed Provisions**: Implementation acts will provide specific details and technical specifications necessary for the regulation's effective execution. This includes defining standards, formats, and procedures to ensure interoperability and secure data exchange across the EU.
2. **Operational Guidelines**: They will offer operational guidelines for the functioning of EHDS entities, such as data access bodies and health data access points. This ensures a harmonised approach across member states, promoting consistent and efficient data usage.
3. **Compliance and Monitoring**: Implementation acts will establish mechanisms for monitoring compliance with the EHDS regulation. They will set up procedures for regular reporting, auditing, and evaluation to ensure that the objectives of the EHDS are being met.
4. **Adaptability**: These acts allow for the regulation to be updated and adapted in response to technological advancements and emerging challenges. This ensures that the EHDS remains relevant and effective over time.

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Implementing acts related to the EHDS

Act	EHDS article #	Scope / Title	Date
Data Governance Act COM/2020/767 final	1	**European data governance** (Data Governance Act)	25.11.2020
Data Act COM/2022/68 final	1; 3	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on **harmonised rules on fair access to and use of data** (Data Act)	23.2.2022
AI Act COM/2021/206 final	1	**LAYING DOWN HARMONISED RULES ON ARTIFICIAL INTELLIGENCE** (ARTIFICIAL INTELLIGENCE ACT) AND AMENDING CERTAIN UNION LEGISLATIVE ACTS	21.4.2021

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Foreseen implementing acts to come

EHDS Regulation	Aims & scope
Article 3	Determine the requirements for the technical implementation of the rights set out in Section 1.
Article 14	Lay down cross-border specifications for mentioned data categories. To amend Annex I by adding, modifying or removing the main characteristics of the priority categories
Article 15	Lay down the technical specifications for the priority categories of personal electronic health data setting out the European EHRxF.
	Provide regular updates of the European EHRxF to integrate relevant revisions of the healthcare coding systems and nomenclatures.
	Lay down technical specifications that **extend the European EHRxF to additional categories** of electronic health data.
Article 16	Determine data quality requirements, including semantics, uniformity, consistency of data registration, accuracy and completeness, for the registration of personal electronic health data in EHR system.
Article 17	Lay down the technical specifications to ensure the interoperability of the proxy services of the Member States.

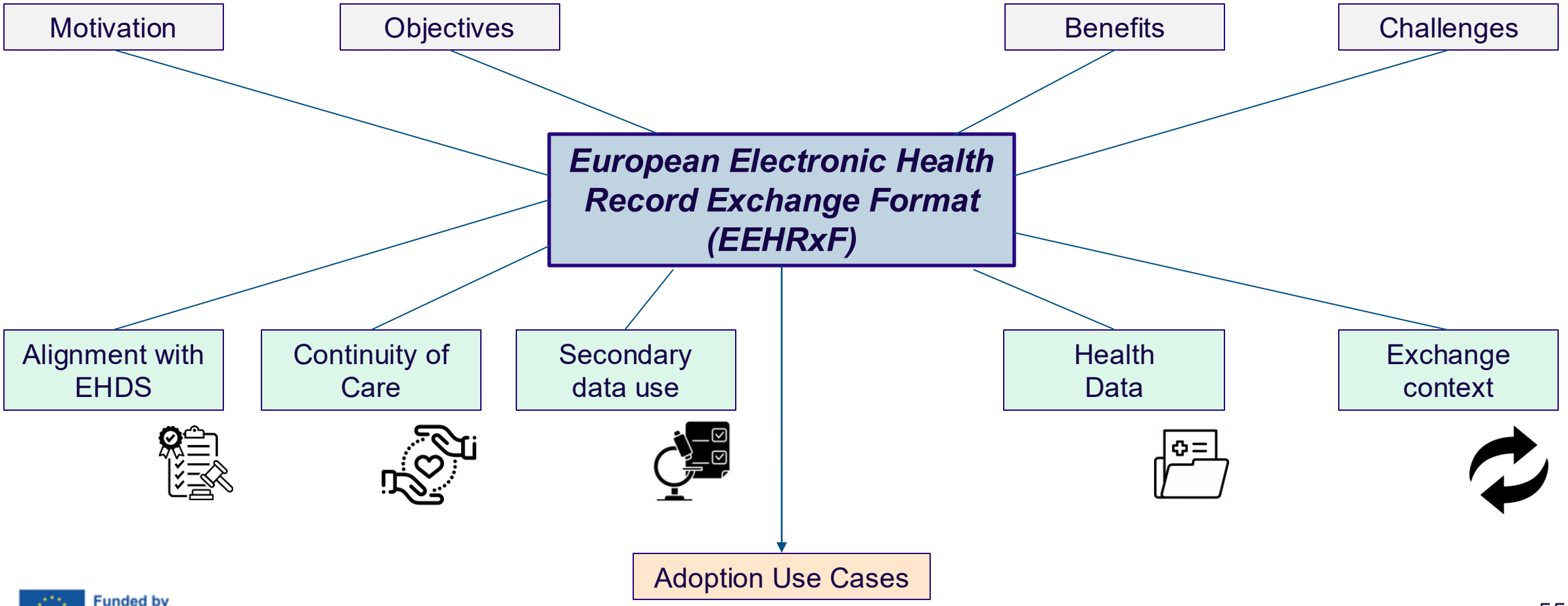
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Foreseen implementing acts to come

EHDS Regulation	Aims & scope
Article 9	Determine the requirements for the interoperable, cross-border identification and authentication mechanism for natural persons and health professionals, to facilitate the cross-border transferability of personal electronic health data.
Article 12	Adopt the necessary measures for the technical development of MyHealth@EU, detailed rules concerning the security, confidentiality and protection of personal eHealth data and the conditions necessary to connect to MyHealth@EU.
	Lay down the rules regarding the requirements of cybersecurity, technical interoperability, semantic interoperability, operations and service management in relation to the processing and responsibilities of the EC towards the NCPeH.
Article 13	Set out the technical aspects of supplementary services that facilitate telemedicine, mHealth, access by natural persons to their translated health data, exchange or verification of health-related certificates, including vaccination card services supporting public health and public health monitoring or digital health systems, services and interoperable applications.
	Set out the technical aspects of the exchange of personal electronic health data with other infrastructures, such as the Clinical Patient Management System or other services or infrastructures in the health, care or social security fields which may become authorised participants to MyHealth@EU.
	Connect or disconnect the NCP of a third country or of a system established at an international level to MyHealth@EU.

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Aspects of adopting the EEHRxF



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Use Case Template

Use Case ID	ID
Priority Category	<PS / eP / eD / Lab Report / Discharge Report / Medical image>
Exchange Scenario	<hospital-to-hospital / hospital-to-patient / patient-to-hospital / hospital-to-national authority / national authority-to-hospital>
Motivation	<why are you interested in EEHRxF>
Target Group	<The main beneficiary of the use case (e.g. patients with a specific condition)>
Stakeholders	<Other Entities with interest in the use case, that may affect it and/or interact with it (e.g. clinicians)>
Context of use	<online consultation / emergency care / continuity care /…>
AS-IS situation	<AS-IS description>
TO-BE situation	<how do you envisage to do it in the future>

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Use Case Template

Use Case ID	ID	
Description	<A description of what will do to move from the AS-IS to the TO-BE (e.g. what kind of technology will be used, what kind of interventions, etc.) >	
Objectives	<The objectives of the use case expressed in a realistic and measurable manner (e.g. collect data on a specific condition)>	
Actors and their Roles	Actor < user or system (e.g. patient, platform, device)>	Role <Role played>
Preconditions	<conditions and factors that need to be present for the use case to be applied (they could be of diverse nature)>	
Trigger	<The criteria for the execution of the use case>	
Flow	<A step-by-step description that indicates the actions that are executed by each Actor to cover the full storyline. May be supported by illustrations, links, schemas, etc. >	
Post conditions	<Conditions that need to be present when the use case is executed (i.e. the outcome of the use case)>	

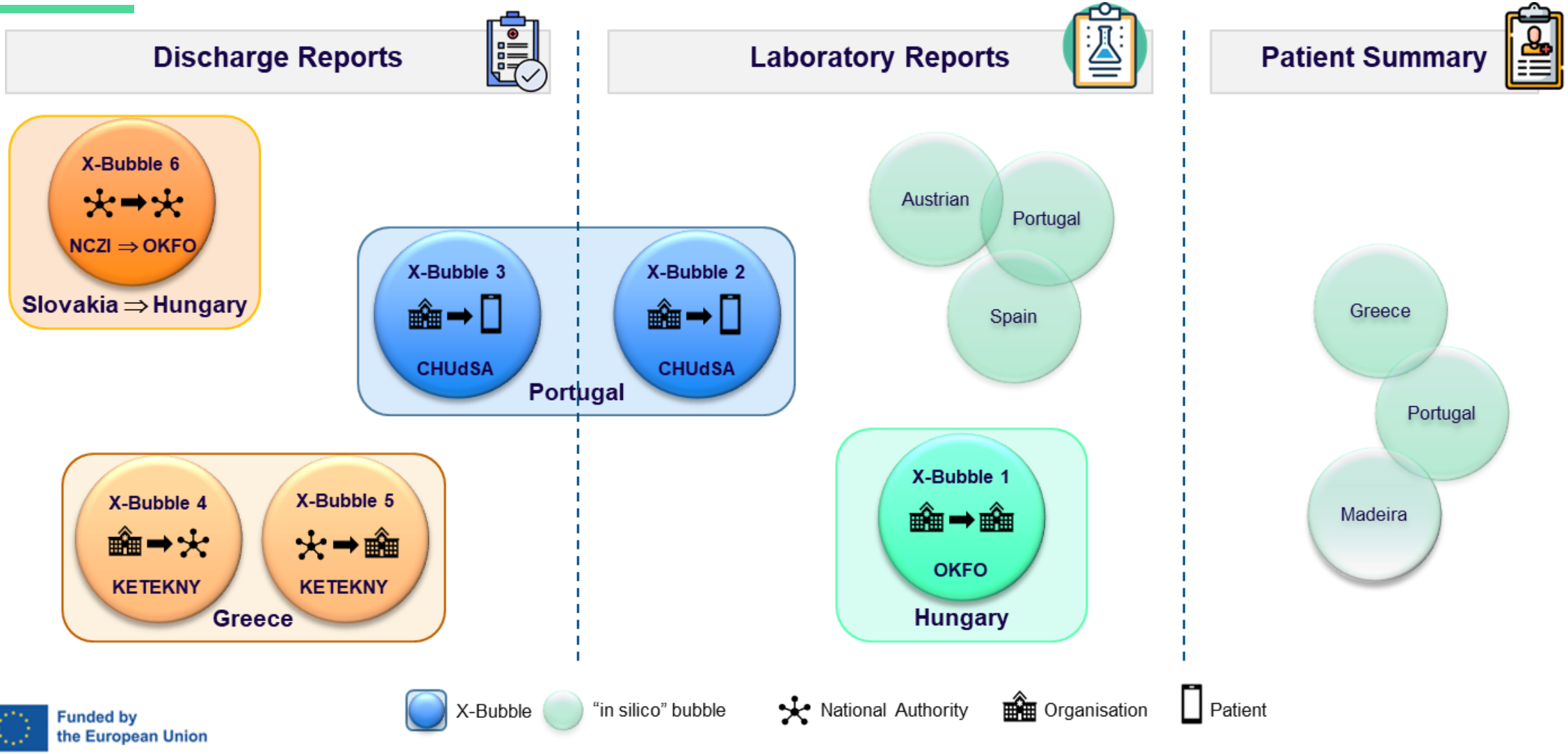
Funded by the European Union

Use Case Template

Use Case ID	ID
Requirements	User requirements <Main functionalities that need to be available for users)> Technical requirements < Basic information such as coding languages, APIs, standards > Operational requirements < What users need to use the solutions? > Ethics requirements < What is needed to comply with EU ethics requirements>
Challenges	<Which difficulties do you foresee? Are there any mitigation measures/work arounds?>
Architecture	<A graphical high level technical architecture, focusing on data flow between system actors>
Alternative flows (optional)	<If there are any other flows that may be followed to execute the Use case>
Exceptions (optional)	<Any conditions that may compromise the result of the use case>
Comments and open issues (optional)	<What is missing? Are there still some open points?>

Funded by the European Union

Bubbles of experimentation



Funded by the European Union

Example of Experimentation in Laboratory Report

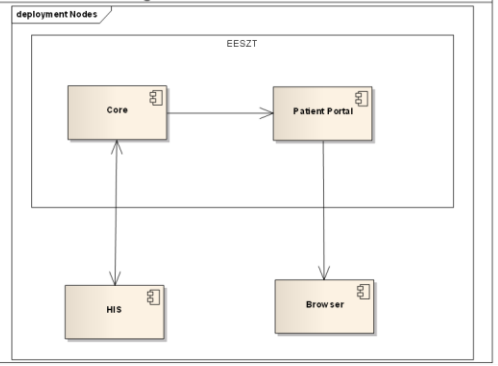
- Organization to Organization – National context

X-Bubble ID	**X-Bubble 1**
Target Group	Diabetes patient
Stakeholders	Clinicians
Context of use	Continuity of care
AS-IS situation	Currently, it is obligator healthcare provider and EESZT to make patient providers treating the his/her data through the Technical specifications: on SOAP for healthcare records pertaining to tl stored as PDF document Semantic elements: Hur ICD-10 for billing purpos Master datasets and providers and heal implementation of ICPM (separate for inpatient and outpatient care), Hungarian implementation of ICD10 and a partial national implementation of LOINC. The PDF is for human use only, no underlying structured document (e.g. EHR according to EN/ISO 13606) is available. The laboratory systems typically use LOINC for internal purposes and use the Hungarian implementation of ICPM for reporting to the health Insurance Fund.

TO-BE situation	Continuity of care for diabetic patients is supported by structured data exchange, saving much time for the physician by providing an integrated view of the patient's condition through time, providing alerts based on the structured data etc.
Description	Necessary steps to move fro 1. The document structu defined. 2. The EESZT interface o has to be updated tc such structured docur 3. The EHR component o validate such structure Note: step 1 is possible withi not be possible.
Objectives and contributions to overall XpanDH objectives	Pilot structured data exchar for diabetic patient.

Objectives and contributions to overall XpanDH objectives	Pilot structured data exchange supporting continuity of care for diabetic patient.
Actors and their Roles	**Actor** Physician Patient Laboratc informat EESZT
Preconditions	• Do • EE • Lal an

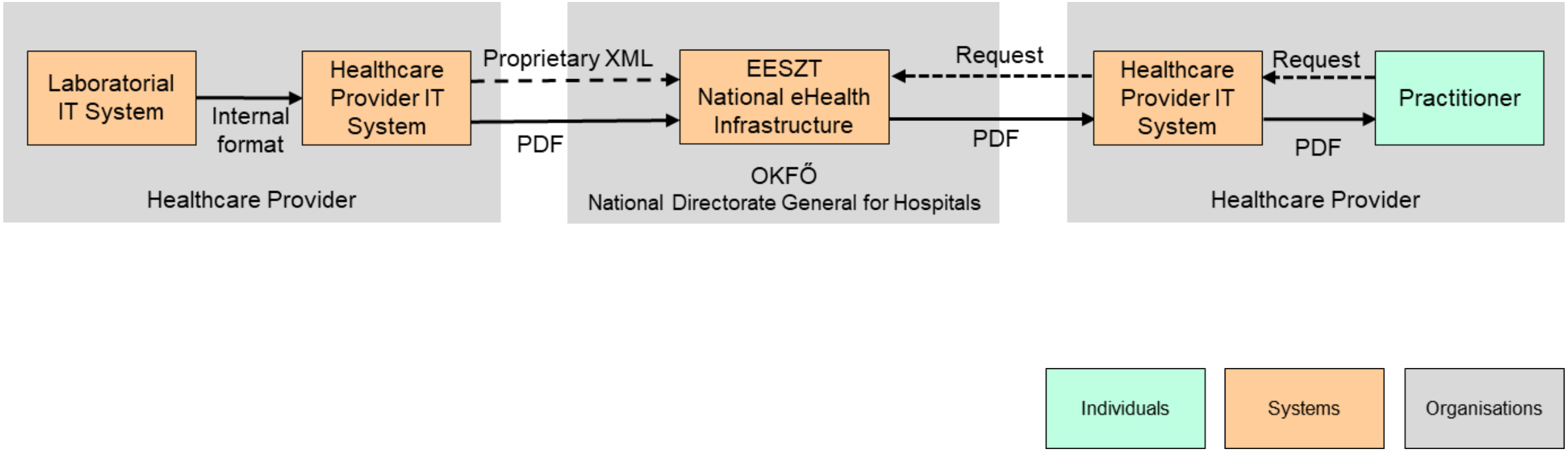
Trigger	Every time a lab examination is performed in a hospital/outpatient clinic that can create structured lab results.
Flow	1. Physician: uses hospital information system to retrieve already existing structured documents of the patient. 2. Hospital information system: retrieves already existing structured documents of the patient from EESZT. 3. Laboratory and/or hospital information system: sends structured laboratory results to EESZT. 4. EESZT: validates and stores the structured laboratory results, provides access to stored structured documents. 5. Patient: may use the patient portal of EESZT to retrieve structured documents a
Post conditions	Continuity of care documen EESZT.
Requirements	**User requirements** Same as for EESZT which is and can be already used portal. **Technical requirements** Structured document specif other value set to be used) f **Operational requirements** Only the already existing EESZT is needed. **Ethics requirements** Medical data has to be sent healthcare encounters anc healthcare provision provide

X-Bubble Major Challenges	Developments in EESZT and HIS necessary for structured document handling.
Architecture	

Funded by the European Union

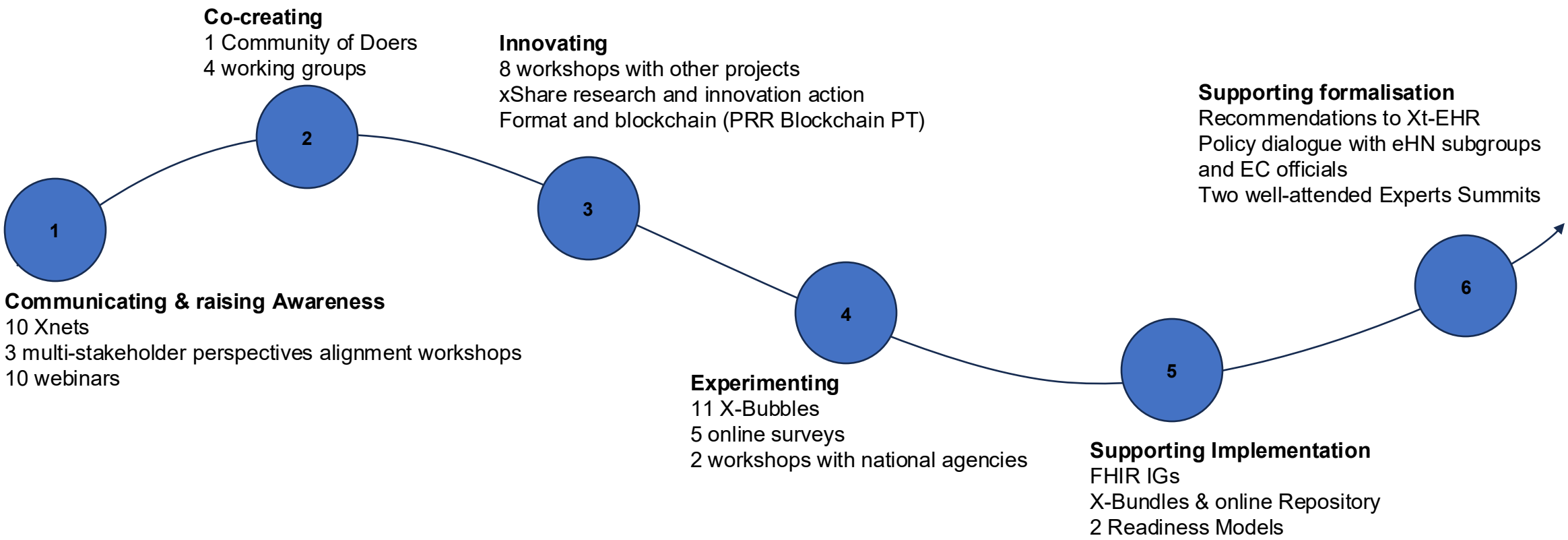
Example of Experimentation in Laboatory Report

Bubble 1 – Laboratory Report – Organisation to Organisation – OKFO - Hungary - AS-IS



Funded by the European Union

XpanDH Journey Preparing the Digital Health Ecosystem for the Format



XpanDH
Expanding Digital Health through a pan-European EHRxF-based Ecosystem

bru _ Digital Health International

In 24 months…



Consortium

35 partners from **13 MS**

27 Leadership Committee/ Steering Committee meetings

Experimentation

11 X-Bubbles from **6 countries**, of which 7 "in-silico" Bubbles

3 available online survey tools

EEHRxF Awareness raising

12+ hours of public webinars

400+ hours of workshops

80+ projects engaged

Present in **30+ events**, of which 13 were (co)organised by XpanDH and 14 were in-person.

1,840+ Youtube views

2,000+ followers on social media

Ecosystem building

10 X-Nets:

150 active individuals

1000+ informed individuals

3 Multi-stakeholder meetings

Community of Doers:

4 Working groups and focuses

60+ active individuals

200+ informed individuals

…

+22% participants

2024: 330+

2023: 250+

EEHRxF Expert Summits



Note: some numbers are approximations

bru _ Digital Health International *(Coordinating)*

XiA_ Xpanding Innovative Alliance



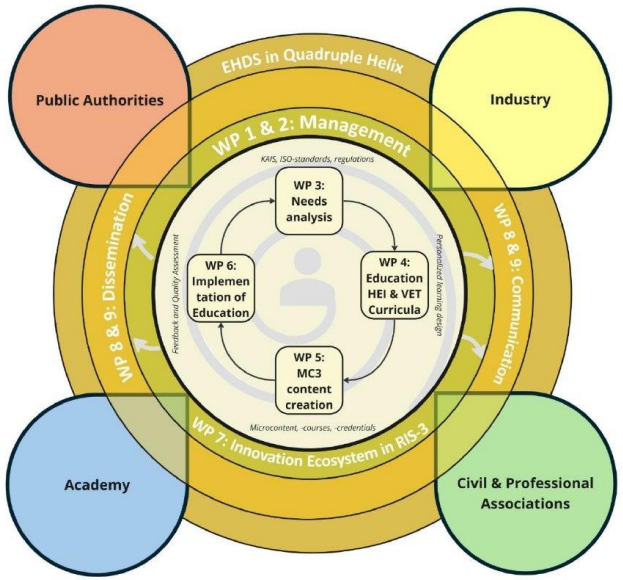
Through a 4-years duration comprehensive **educational initiative**, XiA aims to address the **skills gap** in advanced **digital health interoperability** standards among healthcare providers, digital health solution providers and individuals.

XiA
Xpanding innovative Alliance



Iscte lidera iniciativa europeia para formar mais de 10.000 profissionais do setor da saúde e das TI até 2028





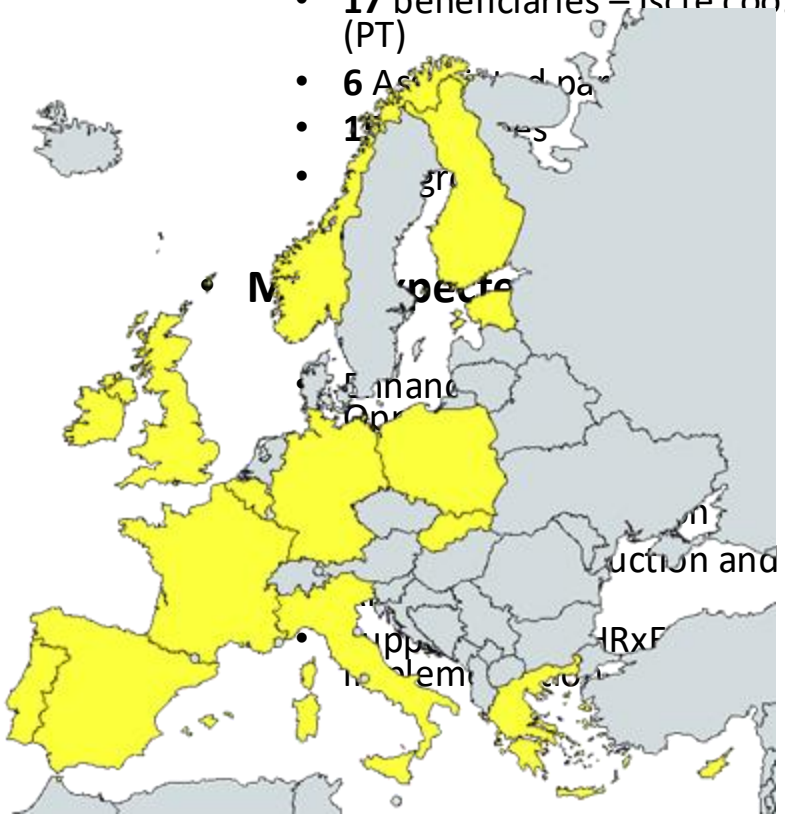
Co-funded by the European Union

m EHDS to high-quality courses about Key Advanced Interoperability Standards

- **General Objectives**
  - Enhancing **Digital Health Interoperability Skills**
  - Developing **Future-Oriented Education on the EEHRxF**
  - Building a Pan-European **Educational Digital Health Ecosystem**

- **Specific Objectives**
  - Digital Health Needs Analysis
  - Skill and Curriculum Development
  - Content Creation and Delivery
  - Community Building and Sustainability
  - Certification and Quality Assurance
  - Outreach and Impact

- **Partners:**
  - **17** beneficiaries – Iscte coo. (PT)
  - **6** As
  - **1**
  -
  - **M**
  -
  -
  -



XiA Framework

Xpanding innovative Alliance

Who are XiA courses for?

#	Stakeholders
A	Informatics/ EHR producers/ Developers
B	IT Managers/ EHR Implementer/ Procurers/ Buyers
C	Healthcare Professionals/ Care & Process Managers
D	Patients and Informal Caregivers

Student learning journey

Standard

LB A1 + LB B1

LB A2 + LB B2

Personalised ad hoc

LB A1

LB B2

LB C2

LB D1

Microlearning approach

Microcontent

Microcourses

Accreditation

Microcredentials

XiA Library

Open educational materials

Learning Block A1

Learning Block A2

Learning Block B1

Learning Block C1

Learning Block C2

Learning Block D1

Learning Block D2

Learning Block B2

Learning Block ID

Name…

Code…

Authors…

Learning Objectives…

Content description…

Support (e.g. video)…

Duration (e.g. 5 min)…

Credits (ECTS)…

Smallest educational piece

Family of Blocks B e.g., LOINC

Learning Block B1

Learning Block B2

Learning Block B3

Family of Blocks B e.g., FHIR

Learning Block B1

Learning Block B2

Learning Block B3



https://ehr-exchange-format.eu/what-is-ehrxf/

https://ehr-exchange-format.eu/working-on-ehrxf/eshia/

Why, How and What is the Global EHR?

- A global electronic health record (G-EHR) is **a set of interconnected digital systems and services that support the sharing of personal health data across the globe** to support primary use of health data regardless of geographical, jurisdictional and language barriers creating an electronic health record support environment as similar as possible to that experienced by the individual and his/her caregivers in is home country. It is based on standards and is a *de facto* promotion of data harmonization leading up to a potential "Global Health Data Space" of nominal/anonymized health data for it potential secondary and tertiary use.
- A global electronic health record (G-EHR) is not something utopic. It requires focus, concrete steps, value creation and determination to explore the following elements.
  1) Creating a worldwide voluntary patient and health professionals' registries
  2) Setting up a **global regime/governance forum for the advancement of agreements and common creations**
  3) Using a **common exchange format** (possibly inspired in the European EHR exchange format?)
- Source: H. Martins 2020: https://healthmanagement.org/c/healthmanagement/issuearticle/digital-health-diplomacy-in-chained-globalised-health-context



Global Digital Health Diplomacy: The Global-EHR and First Steps for a Global Treaty on Digital Health

https://jas.bayern/index.php/jair/article/view/169

1) Knowledge & Experience Sharing
2) Piloting together
3) Creating a "trust basis" and "sharing" legal/organizational mechanisms

Digital Health Diplomacy refers to the concentrated international efforts towards supranational interoperability in eHealth/Digital Health. These may include international agreements for mutual health data transmission, recognition of information systems or common approaches to the use of international standards.

Why and how on Global EHR? IPS and lab Sharing

- A global electronic health record (G-EHR) is achievable with focus, concrete steps, value creation and determination to explore certain elements.
- To reach a truly global digital healthcare system, however, we need to work much more profoundly and more decisively on real worldwide cross-border eHealth services, like a global ePrescription system or sharing of minimum sets of data (e.g. the ISO International Patient Summary) and progressively bigger components, such as a vaccination passport, summary or e-cards. For example, medical devices (e.g. insulin infusion pumps, or non-invasive home ventilators) are increasingly globally produced and standardised, yet, the information that they require and generate seems to get 'chained' to local, regional or national health systems, in turn, chaining citizens down to their institutions, often their homes. People fear to travel to a remote location where access to their device or health data is not possible. They know healthcare may not be equally safe, which makes them feel unsafe to travel and 'chained'.
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Worldwide eHealth cross-border services

The following worldwide eHealth cross-border services serve as initial steps:

1) Global ePrescription system

2) **Global sharing of minimum sets of data** (for example, the ISO International Patient Summary) and, progressively, bigger components, such as vaccination passports/summary/e-cards

3) exploring Globally with the EU European EHRxFormat

4) Internationally approved **minimum information sets** for advanced data-rich medical devices

5) Internationally approved and maintained digital information leaflets for prescribed drugs.

6) International sharing of larges datasets for research/public health based on Commonly agreed minimum sets of data

Global Treaty on Digital Health

"Digital Health for all and around the world"

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

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Global Treaty on Digital Health

"Digital Health for all and around the world"

Agenda

1:00 - 1:10 **Welcome and Introduction** *Yasunari Shiokawa (IHE-Japan)*
1:10 - 2:10 **EHDS Overview** *Prof. Henrique Martins (ISCTE)*
2:10 - 2:20 *Break*
2:20 - 3:20 **EEHRxF Overview** *Prof. Henrique Martins (ISCTE)*
3:20 - 3:30 *Break*
3:30 - 4:30 **EEHRxF Specification Overview** *Giorgio Cangioli (HL7 EU) & Diogo Martins (i2X)*
4:30 - 4:45 **Overview of Japan EHR Information Exchange Service** *Yasunari Shiokawa (IHE-Japan)*
4:45 - 4:50 *Closing Yasunari Shiokawa (IHE-Japan)*

in a nutshell

WP1: Project Coordination
UpHill (PT) | New Angle (PT)

WP2: Innovative tools for EHRs and data use
UTH (GR) | FTGM (IT)

WP3: EEHRxF Testing, Implementation & Specifications
IHE Catalyst (BE) | DOHIE (IE)

WP4: Demonstrators for first group of priority categories
UNL (PT) | Gnomon SA (GR)

Including identification of X-format requirements and recognition of additional eXcange demonstrators

Patient Summary

ePresciptions & eDispensations

WP5: Demonstrators for second group of priority categories
FTGM (IT) | Gnomon SA (GR)

Exam Results

Imaging Studies and Reports

Discharge Reports

WP6: Evidence gathering on the format's added value
NeHA (CY)

WP7: Dissemination, Outreach and Explotation
Mindview (GR) | UpHill (PT)

WP8: Ethics Work package – Ethics Requirements
UpHill (PT)

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Iscte BRU_Digital Health International

Visit us!
https://brudhi.iscte-iul.pt/

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.

bru _ Digital
Health International

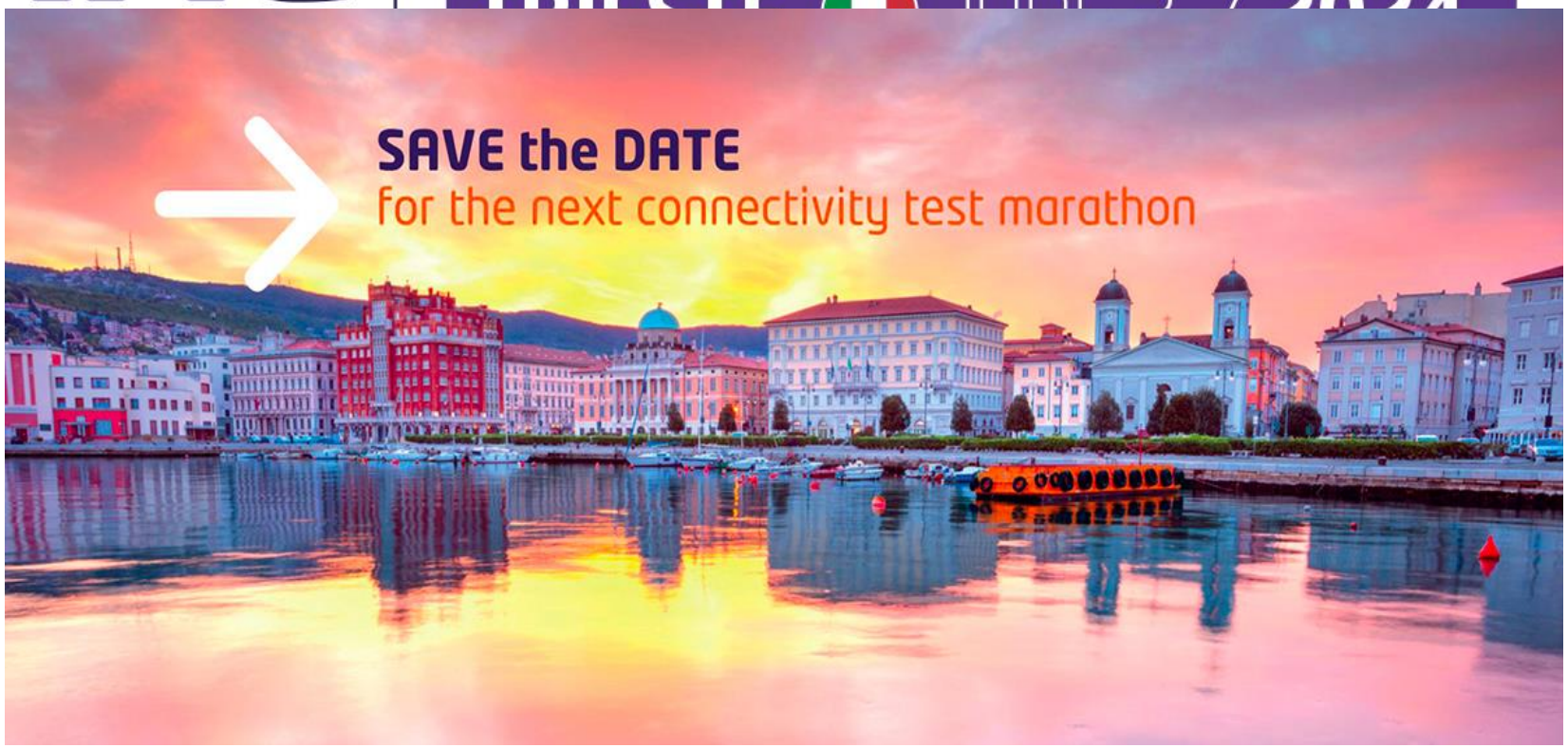


Coordinating XIA Xpanding innovative Alliance

Partner of Share EHR Xchange Format CANDLE

Join us in IHE EUROPE _ BRUSSELS 25-28March2026

- i2X
- Idea to have a "GlobalEHR"
- Join us!



Thank YOU

Futher contacts please reach me at:

Henrique.manuel.martins@iscte-iul.pt for XiA

Henrique.martins@uphillhealth.com for i2X

Or

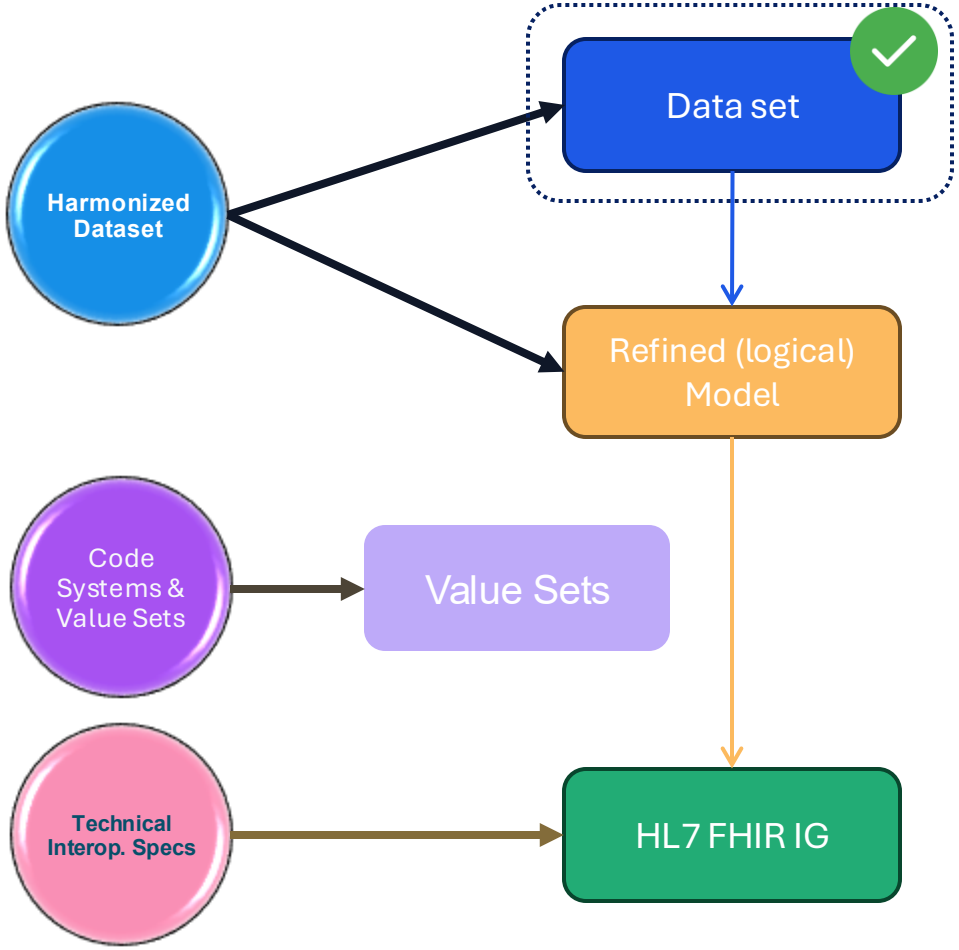
Henrique@henriquemartins.eu for anything and everything else ☺





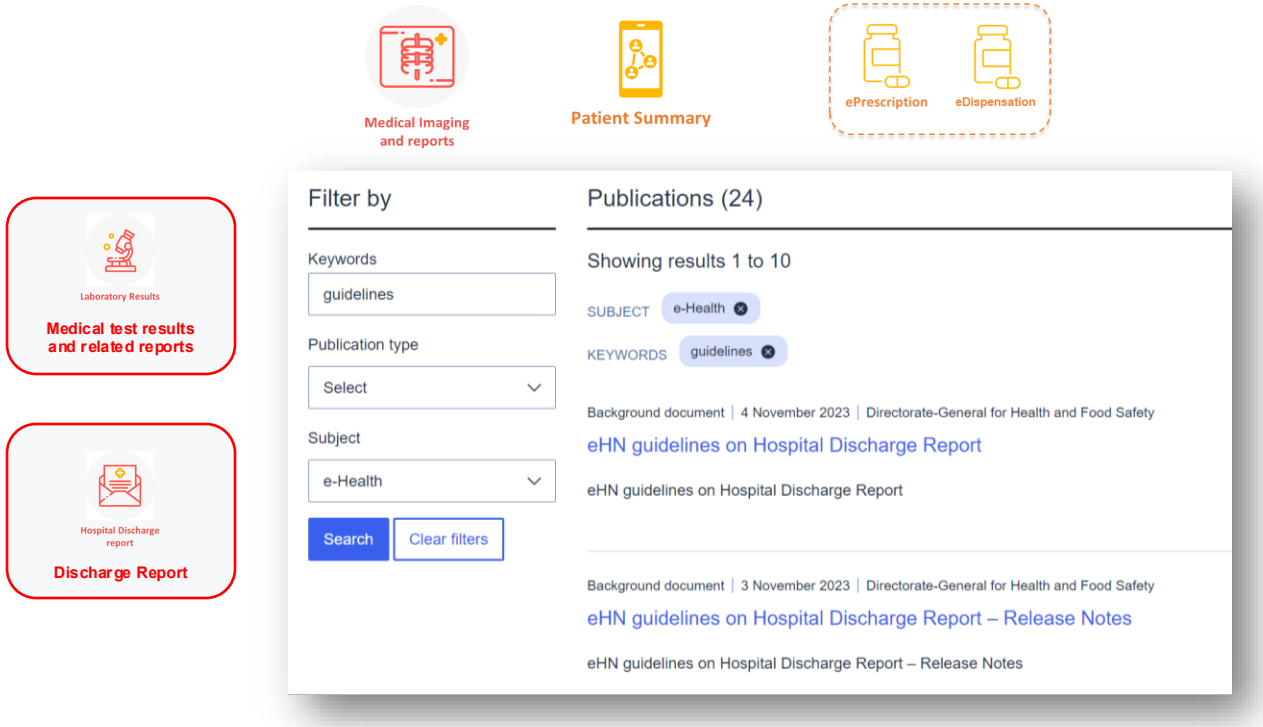
Extra Slides

EEHRxF (art. 15): content

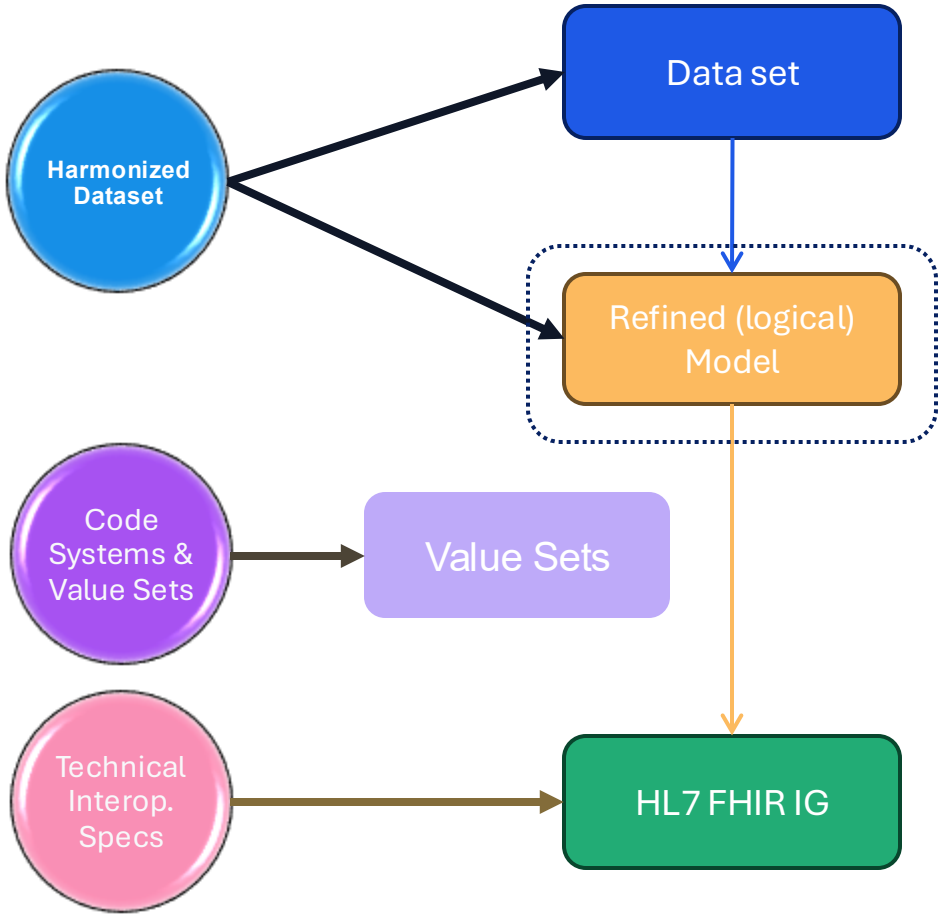


eHN Guidelines – data sets

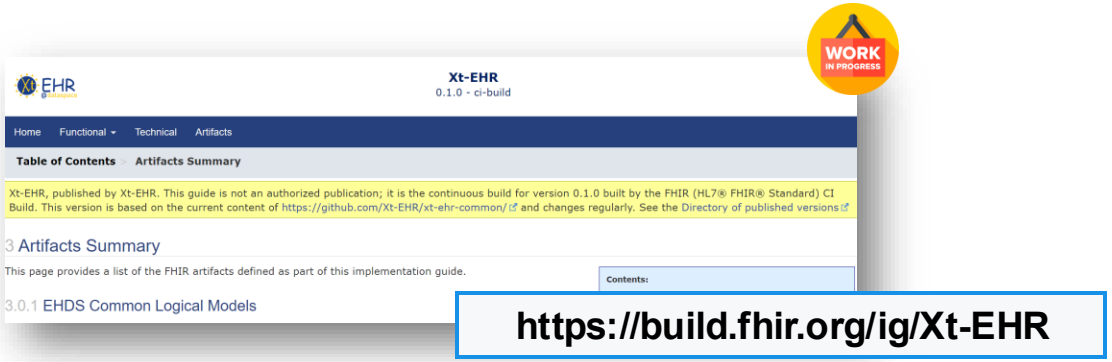
https://health.ec.europa.eu/publications_en



EEHRxF (art. 15): content



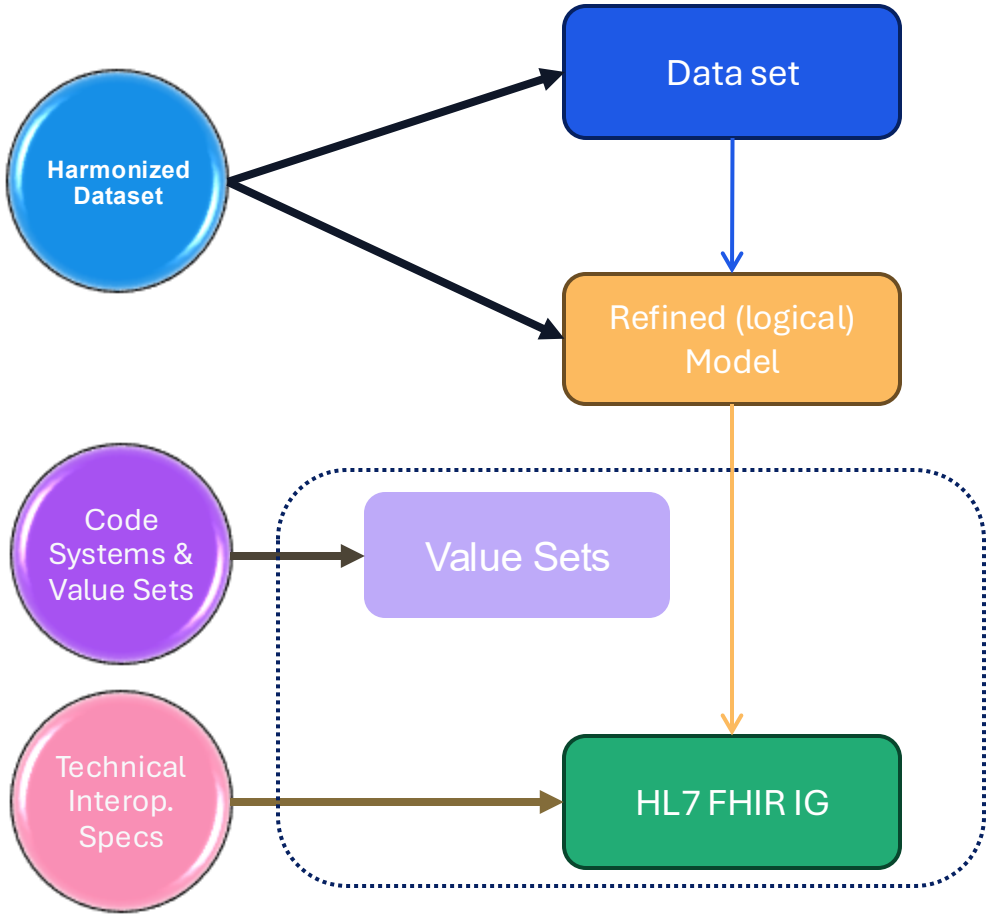
Xt-EHR Logical Models

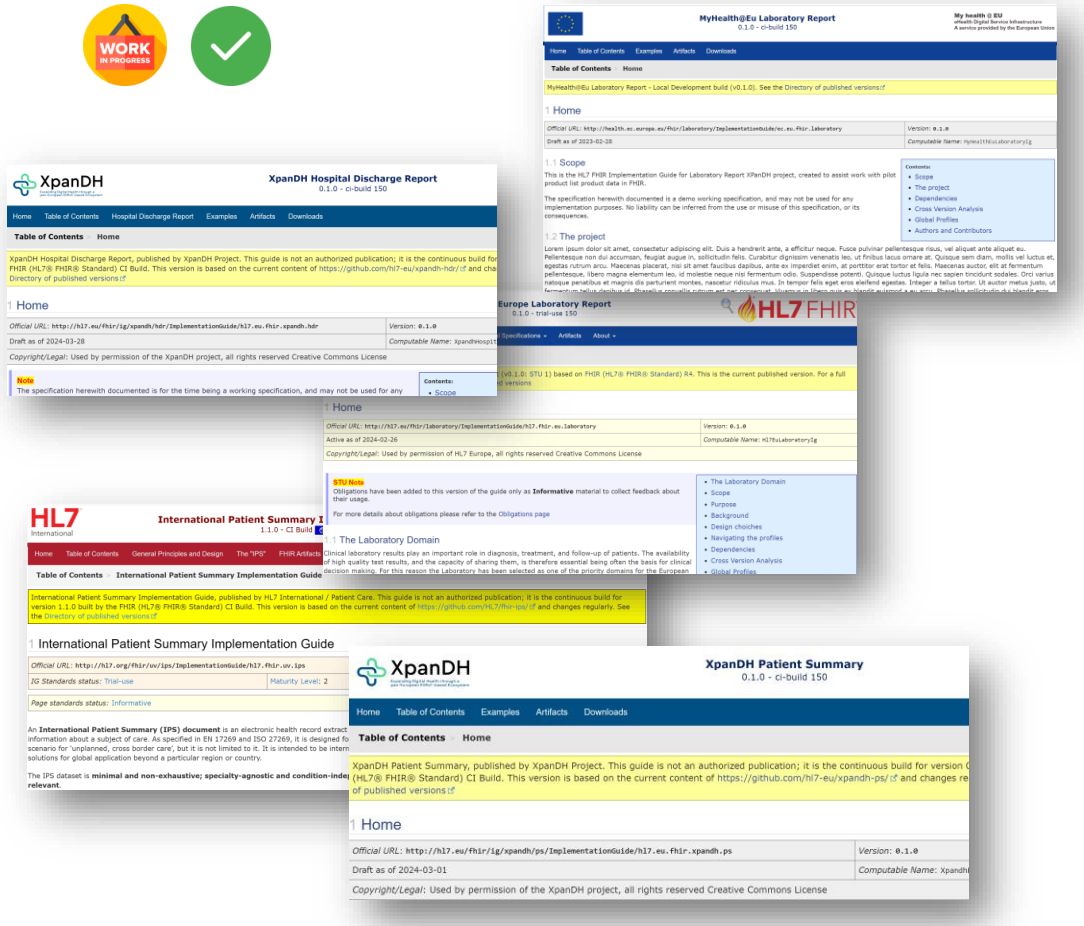


MyHealth@EU Requirements Catalogue

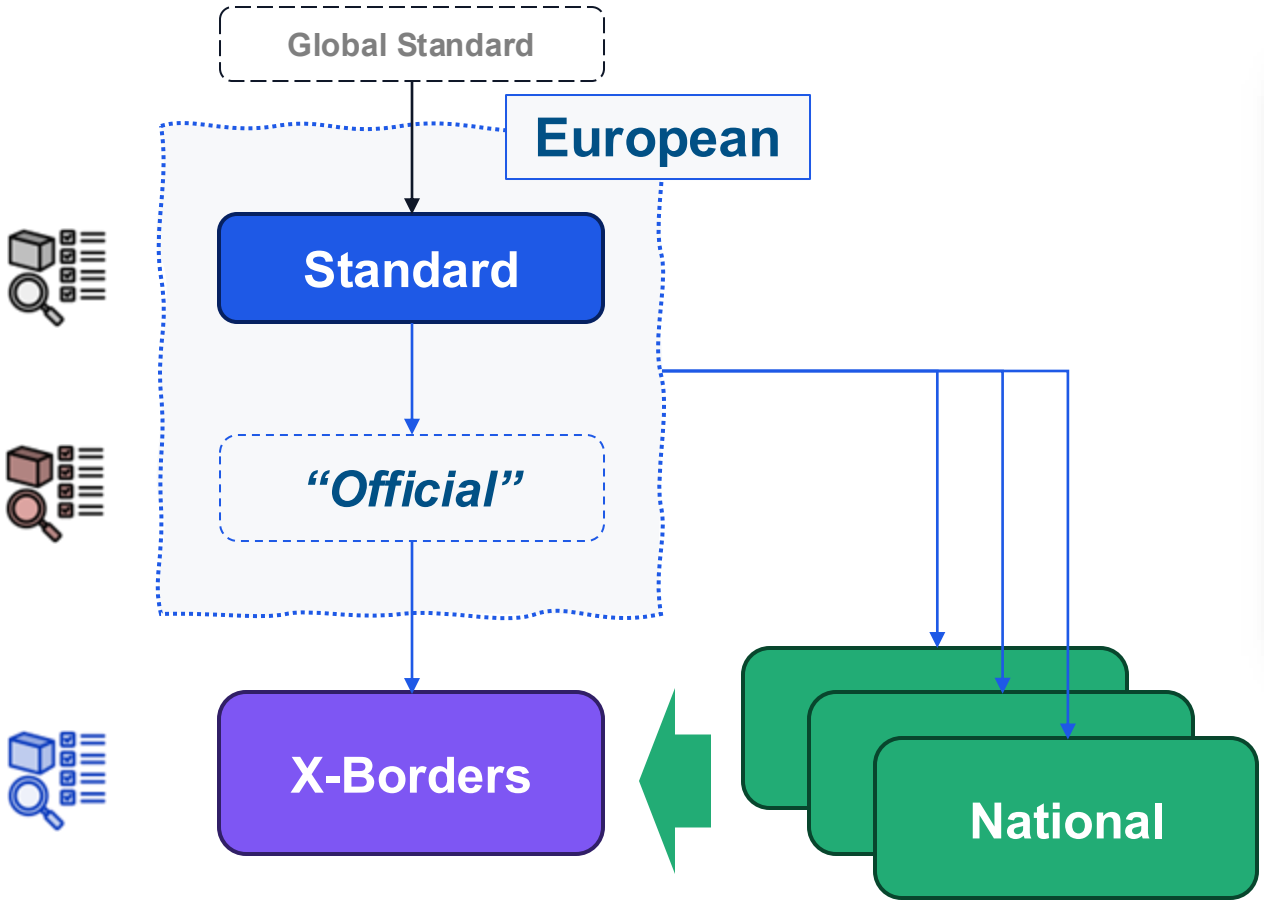


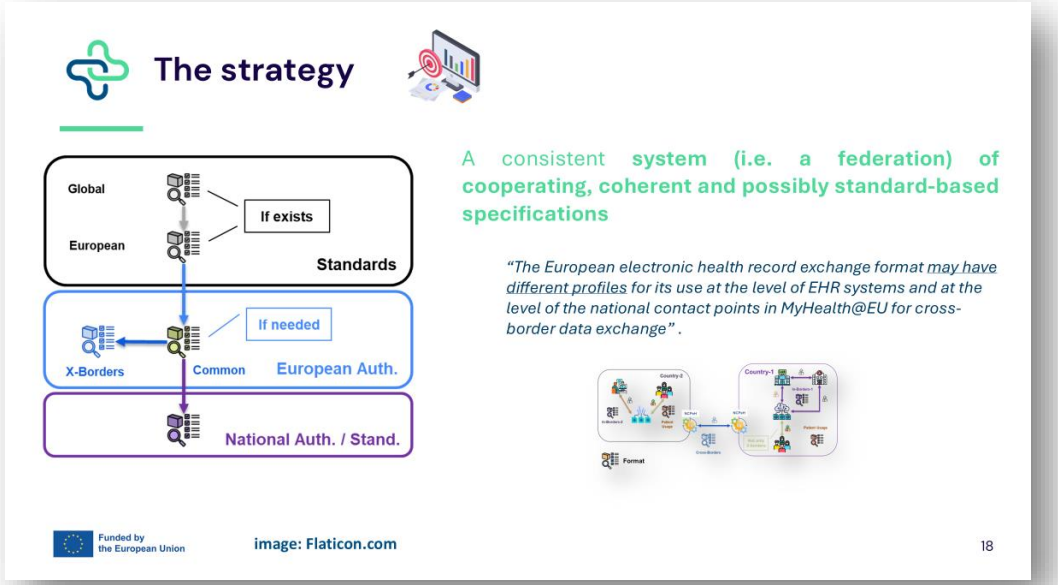
EEHRxF (art. 15): content





The EU HL7 FHIR IGs design strategy



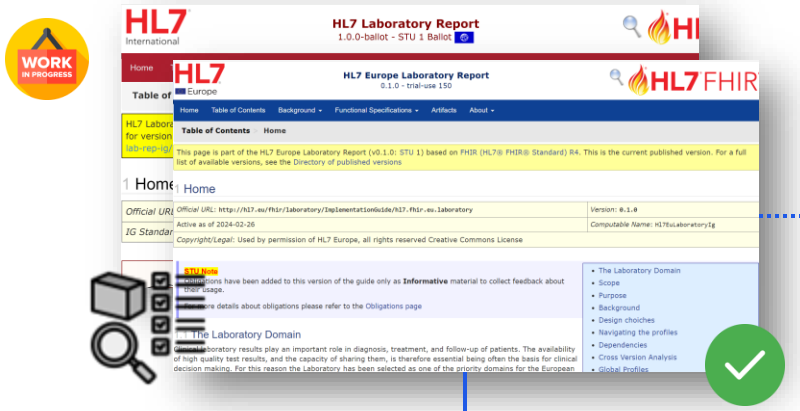


HL7 FHIR IGs overview

	Patient Summary	Laboratory Results	Hospital Discharge report	ePrescription	Medical Imaging and reports	BASE
Global Standard	✓	WORK IN PROGRESS		WORK IN PROGRESS	WORK IN PROGRESS	
European Standard	WORK IN PROGRESS	✓	WORK IN PROGRESS	WORK IN PROGRESS	WORK IN PROGRESS	WORK IN PROGRESS
European (EU) *Official*	IF...	IF...	IF...	IF...	IF...	IF...
European (EU) X-border		✓	WORK IN PROGRESS		WORK IN PROGRESS	IF...

Laboratory Report

Share
EHR Xchange Format



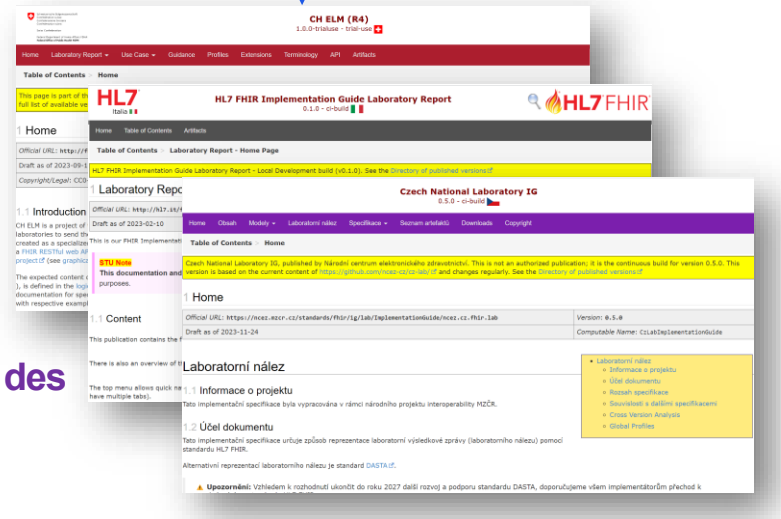
Standard
(EU/UV scope)



EU X-Borders



HL7 FHIR R4



National Guides

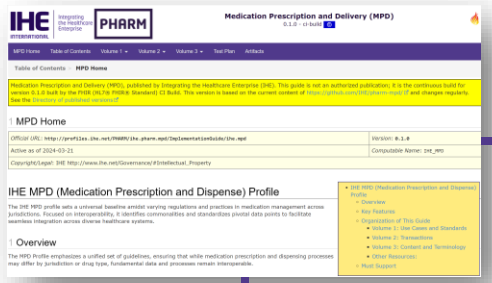
Laboratory Results

Medication Prescription & Dispense

IHE INTERNATIONAL Integrating the Healthcare Enterprise

HL7

GEMINI



ePrescription



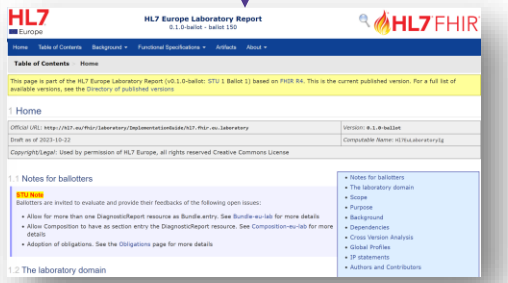
aligned

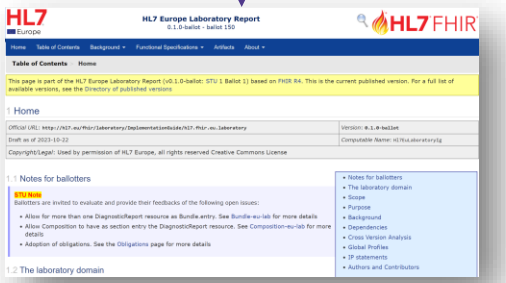
derived

WORK IN PROGRESS

HL7 Europe









HL7 FHIR R5

HL7 FHIR R4

Share EHR Xchange Format

UPHILL

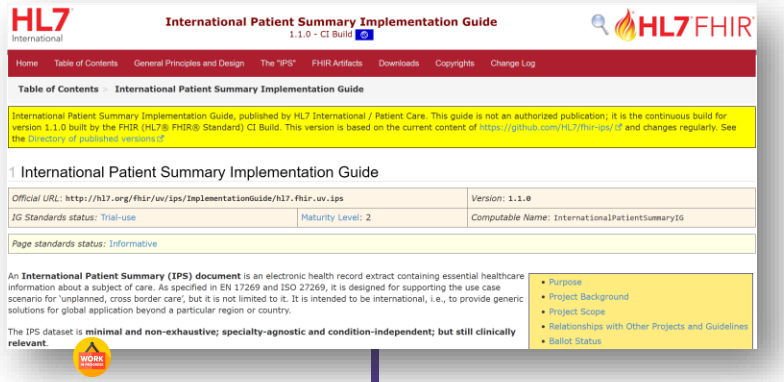
Patient Summary

Share
EHR Xchange Format

Patient Summary

IPS

HL7 FHIR R4











HL7 Europe

UPHILL

Hospital Discharge Report









Hospital Discharge report



HL7 Europe

HL7 FHIR R4

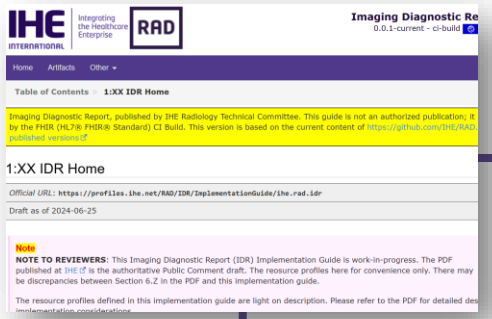
UPHILL

Imaging Report





Medical Imaging and reports



aligned

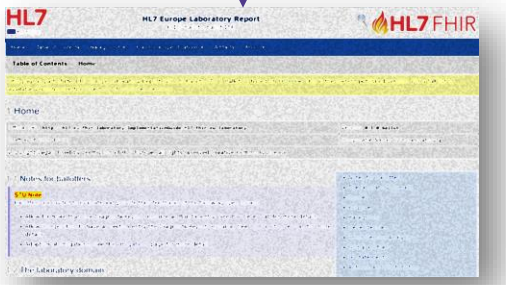


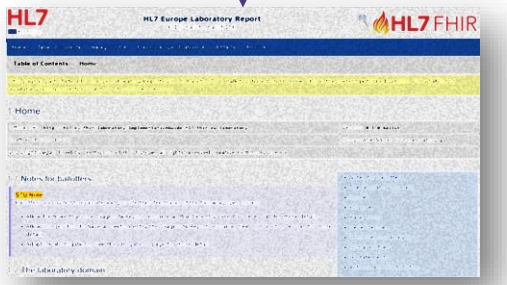
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HL7 Europe







HL7 FHIR R5

HL7 FHIR R4