Xt-EHR – towards EHDS implementation Acts in primary care

KANTA toimittajayhteistyökokous
18.9.2024

Kehittämispäällikkö
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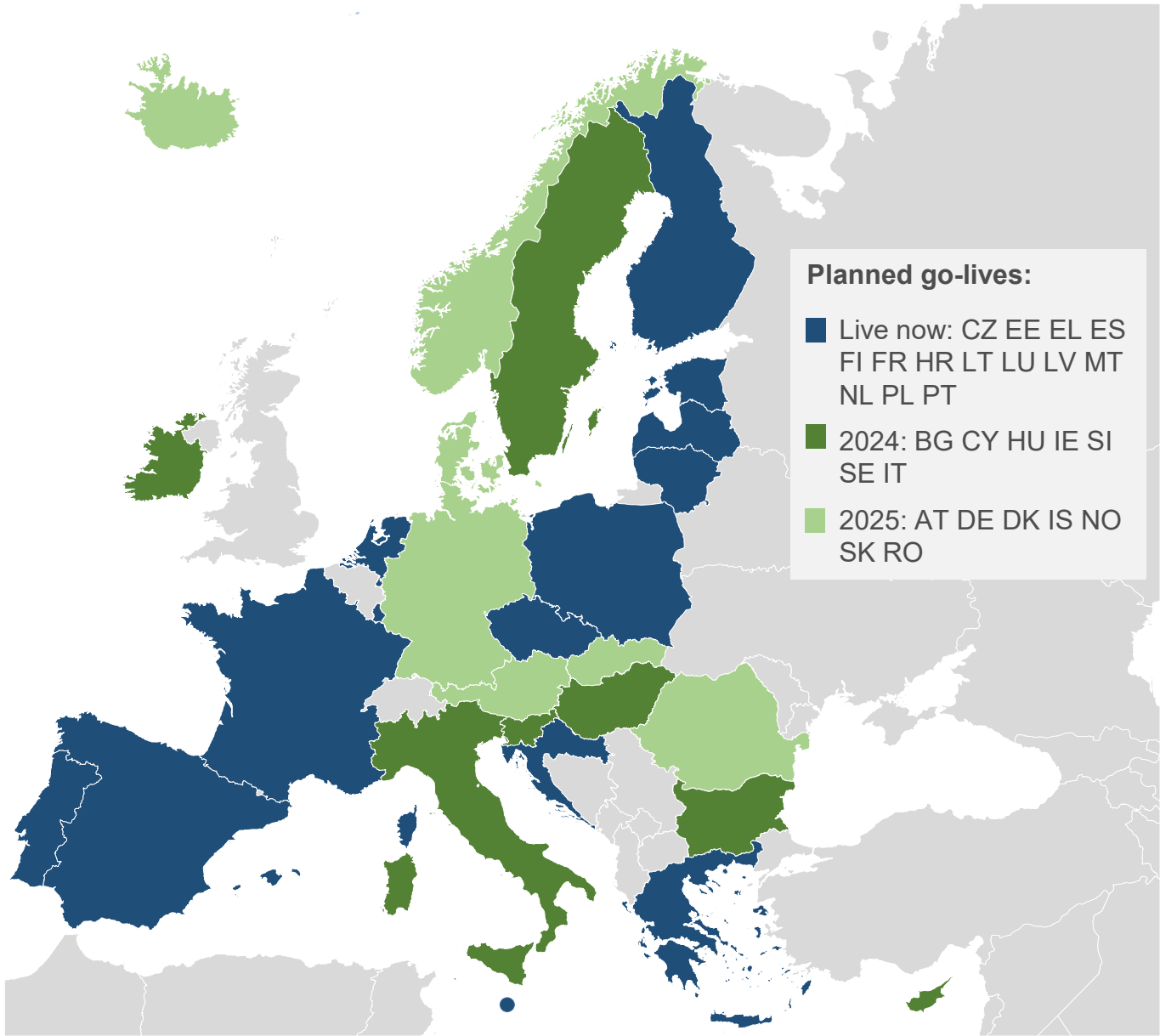
Agenda

- Background: MyHealth@EU
- EHDS and Xt-EHR in the galaxy of eHN primary use communities
- Joint Action Xt-EHR
- Targeted stakeholder consultation

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

MyHealth@EU

- MyHealth@EU is the existing infrastructure for **cross-border health services** that connects healthcare providers in 14 Member States
- Development started already in 2008
- Services includes exchange of PS, eP/eD, imaging studies and reports, test results and hospital discharge reports
- Evolution of MyHealth@EU for the EHDS
- Voluntary → mandatory



40 services live in June 2024...

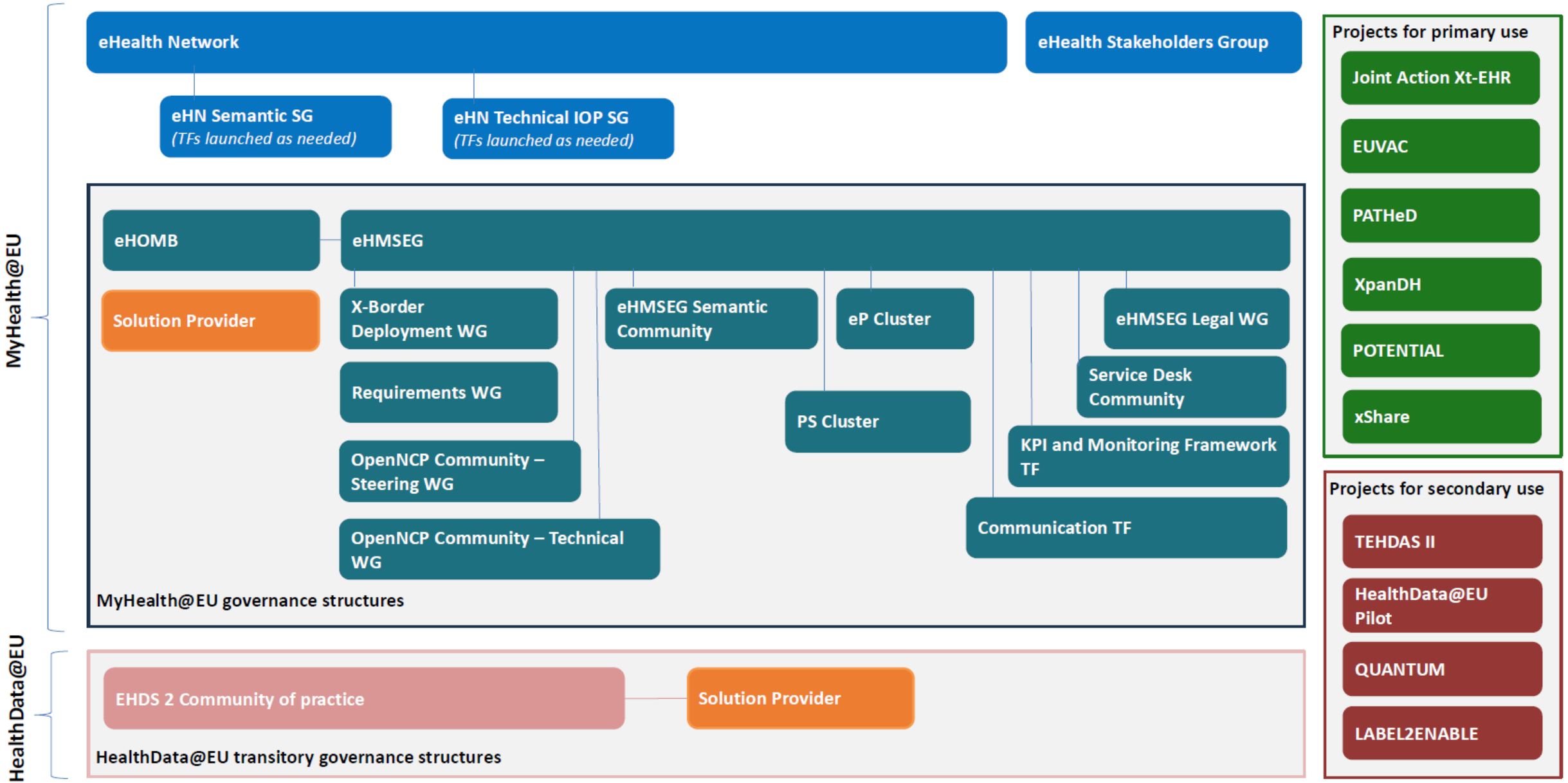
	eP (A)	eP (B)	PS (A)	PS (B)
CZ	2023	2023	2019	2019
EE	2020	2019	2022	2022
EL	2023	2023	2023	2023
ES	2022	2022	2021	2021
FI	2019	2020		
FR				2021
HR	2020	2019	2020	2019
LT	2024	2024		
LU			2022	2019
LV	2024	2024	2024	2024
MT			2019	2020
NL				2022
PL	2022	2022		
PT	2020	2020	2020	2020

...still to be sep up 308 services for EHDS

	eP (A)	eP (B)	PS (A)	PS (B)	HDR (A)	HDR (B)	LR (A)	LR (B)	MI (A)	MI (B)	OrCD (A)	OrCD (B)
AT	2025	2025		2025		2026	2025	2025				
BE												
BG	2024	2024	2024	2024								
CY	2024	2024	2024	2024							Unknown	Unknown
CZ	2023	2023	2019	2019	2025	2025	2025	2025			2025	2025
DE	2025		2025									
DK	2025		2025									
EE	2020	2019	2022	2022								
EL	2023	2023	2023	2023	2026	2026	2025	2025	2026	2026	2025	2025
ES	2022	2022	2021	2021								
FI	2019	2020	2024	2024								
FR	2026	2025		2021								
HR	2020	2019	2020	2019	2026	2026	2025	2025			2025	2025
HU	2024	2024	2024		2026	2026	2025	2025	2026	2026	2025	2025
IE	2024	2024	2024	2024	2026	2027	2026	2026			2025	2025
IS	2025	2025	2025	2025	2026	2026	2025	2025	2026	2026	2026	2026
IT	2024	2024	2024	2025	2027	2027	2026	2026	2027	2027		
LT	2024	2024	2024	2024								
LU	2026	2026	2022	2019							2025	2025
LV	2024	2024	2024	2024			2025	2025				
MT		2026	2019	2020								
NL			2026	2022								
NO		2025		2025								
PL	2022	2022	2026	2026								
PT	2020	2020	2020	2020								
RO	2025	2025	2026	2026								
SE	2024	2024		2026								
SI	2024	2024	2024	2024	2026	2026					2026	2026
SK	2026	2026	2026	2026								

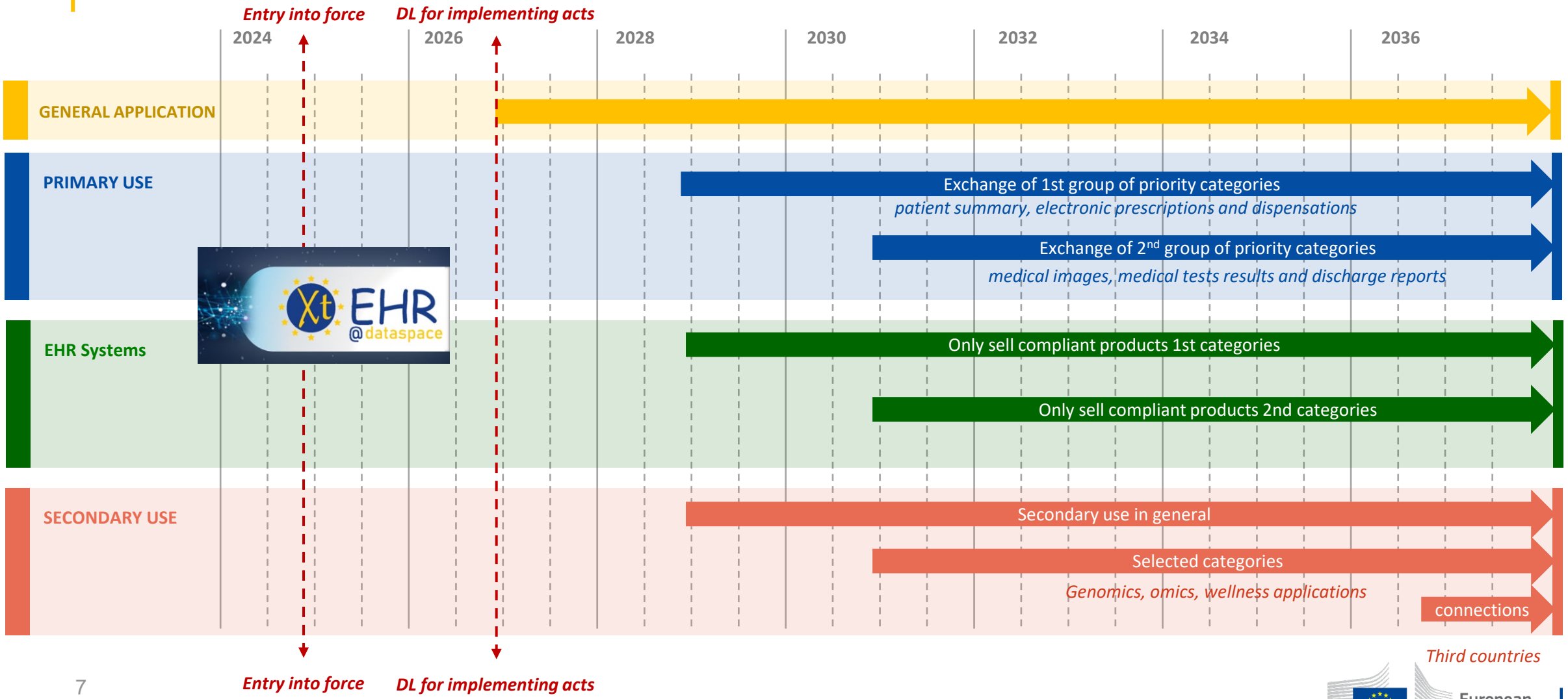
European Commission

Current governance of the eHealth Network



EHDS – Overall timeline

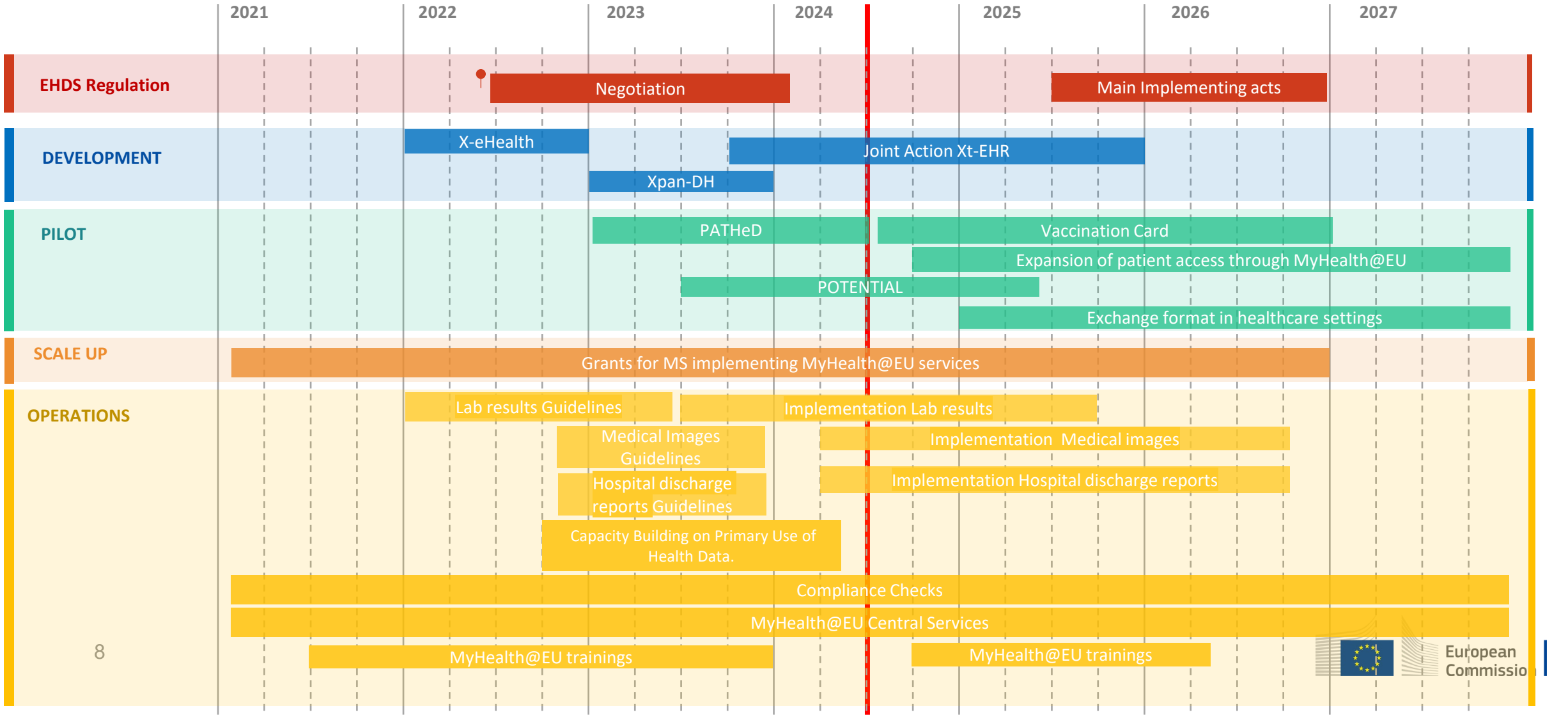
Timelines are indicative.



European Commission

Timelines are indicative.

Implementation of the EHDS (primary uses)



European Commissio

Xt-EHR - Introduction of the Joint Action

Extended EHR@EU Data Space for Primary Use (Xt-EHR)

- **Joint Action** under the EU4Health Programme
- **Duration:** 30 months (01.11.2023 – 30.04.2026)
- **Consortium Setup:** 25 Partners, 25 Associated Entities and 8 Associated Partners in 26 European countries
- **Coordinator:** National eHealth Authority, Cyprus (NeHA)
- Finnish participants: THL and KELA

Co-funded by the European Union

- Xt-EHR supports the European Commission's policy priority for '**A Europe fit for the digital age**' and aims to provide the necessary documentation to promote the adoption of **common specifications in EHR systems across Europe** based on the European EHR exchange format (EEHRxF).
- Xt-EHR aims **to establish requirements, guidelines, specifications, and implementation guides** to enhance the interoperability and exchange of healthcare data between EU Member States, in anticipation of the upcoming EHDS regulation.
- Xt-EHR provides the essential technical specifications that will be a major contribution into the most important **Implementing Acts**

Xt EHR @dataspace

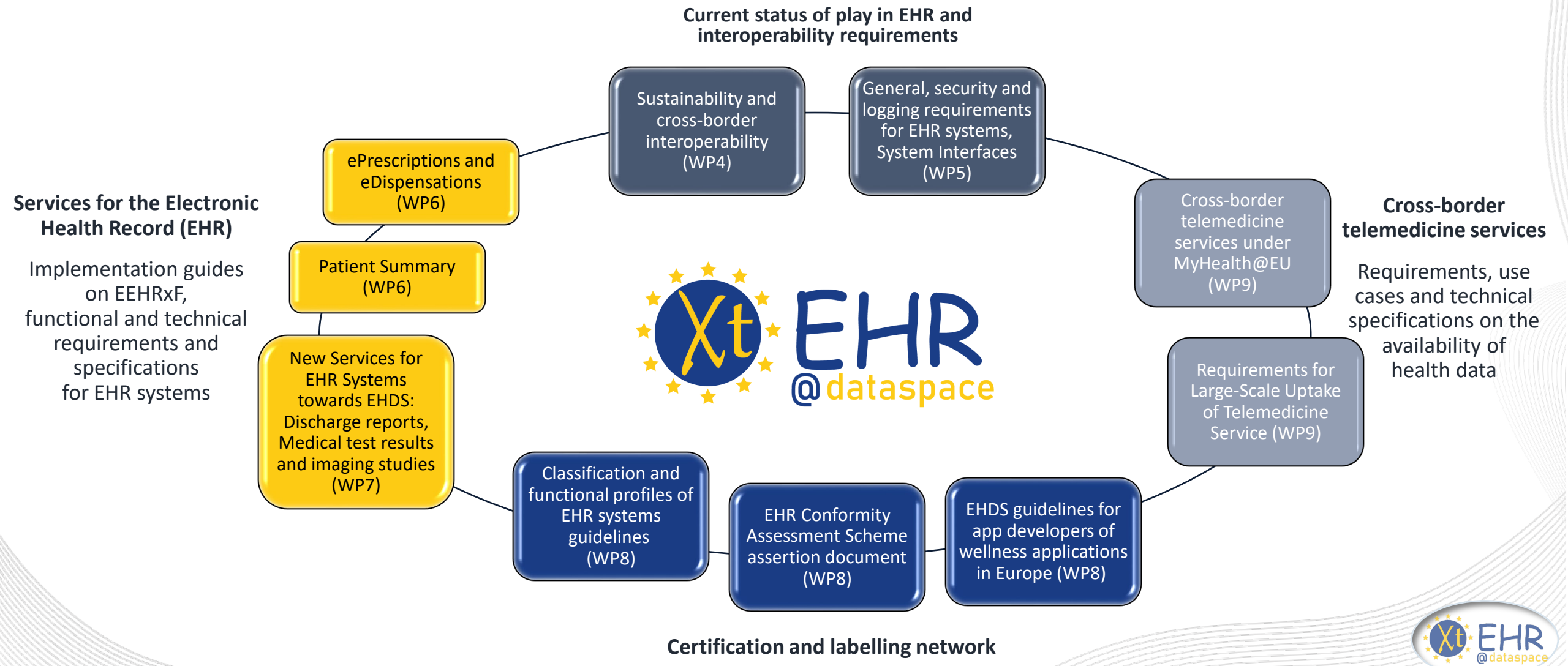
Implementing acts under EHDS

Article	Contents	Type
Article 6(1)	**Exchange format**	**Implementing act**
Article 12 (1)	Establish MyHealth@EU	Establish platform
Article 12(4)	**Necessary measures for technical development of MyHealth@EU**	**Implementing act**
Article 12(7)	The national contact points for digital health shall act as joint controllers of the personal electronic health data communicated through 'MyHealth@EU' for the processing operations in which they are involved. The Commission shall act as processor	Act as processor
Article 12(8)	**By means of implementing acts, the Commission shall lay down the rules regarding the requirements of cybersecurity, technical interoperability, semantic interoperability, operations and service management in relation to the processing by the processor (COM) and its responsibilities towards the controllers**	**Implementing act**
Article 23 (1)	**common specifications in respect of the essential requirements set out in Annex II**	**Implementing act**
Article 23(6)	Where common specifications covering interoperability and security requirements of medical devices, in vitro diagnostic medical devices or high-risk AI systems falling under other acts such as Regulations (EU) 2017/745 and (EU) 2017/746 or Regulation […] [AI Act COM/2021/206 final], impact EHR systems, the Commission shall ensure that the adoption of those common specifications shall have been preceded by a consultation with the EHDS Board and the EDPB	Ensure consultation with EHDS board and EDPB
Article 26 (4B)	**standard uniformed template** for the EU declaration of conformity and make it available in a digital format in all the official Union languages.	Template for EU declaration of conformity
Article 26a (1)	**The Commission shall develop a European digital testing environment for the assessment of harmonised components of EHR systems. The Commission shall make the software supporting the European digital testing environment available as open source.**	Develop software
Article 26a (4)	**The Commission shall, by means of implementing acts, lay down the common specifications for the European digital testing environment.**	**Implementing act**
Article 28 (5)	The market surveillance authorities of the Member States shall cooperate with each other and with the Commission. The Commission shall provide for the **organisation of exchanges of information** necessary to that effect	Organize information exchange
Article 32 (1)	**EU Database with information on EHR systems for which an EU declaration of conformity has been issued**	Implementing act
Article 64 (8)	**The Commission shall, by means of implementing acts, adopt the necessary measures for the establishment and operations of the EHDS Board.**	**Implementing act**

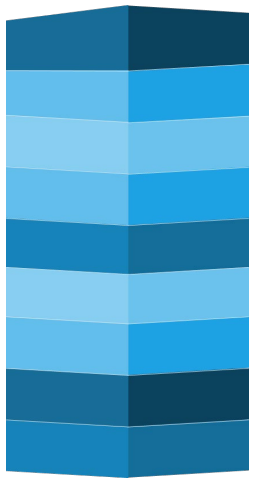
Implementing acts under EHDS

Article	Contents	Type
Article 3(12)	Implementing acts for rights	Implementing act
Article 6 (1a)	Regular updates of the Exchange format	Implementing act
Article 7(3)	Data quality requirements	Implementing act
Article 8g(2a)	Technical specifications for Proxy services	Implementing act
Article 30a(1)	Safeguards procedure. Implementing act if a decision is made towards a member state	Implementing act
Article 31 (3)	**format and content of the wellness label**	Implementing act
Article 9(1)	Cross border identification	Implementing act
Article 9(4)	The commission shall implement the authentication mechanism at union level	Implementation
Article 10(1)	Make information on the identity of digital health authorities available	Publication of information
Article 13 (1)	Technical aspects of supplementary services	Implementing act
Article 13 (2)	Exchange of health data with "other infrastructures"	Implementing act
Article 13 (3)	maintain the list of national contact points of a third country or of systems established at an international level connected to MyHealth@EU	Publication of information

Xt-EHR – domains of expected outcomes



Work Packages



- WP 01 Project management and coordination
- WP 02 Dissemination
- WP 03 Evaluation
- WP 04 Sustainability and cross-border interoperability
- WP 05 General requirements for EHRs and system interfaces
- WP 06 Electronic prescriptions and patient summary towards EHDS
- WP 07 New services for EHR systems towards EHDS
- WP 08 Certification and labelling framework
- WP 09 Telemedicine under MyHealth@EU in alignment with EHDS proposal

Xt-EHR

WORK PACKAGES

- WP1 - Project management and coordination
- WP2 - Dissemination
- WP3 - Evaluation
- WP4 - Sustainability and cross-border interoperability
- WP5 - General and security and logging requirements for EHR systems and System Interfaces
- WP6 - Electronic prescriptions and patient summary towards EHDS
- WP7 - New services for EHR systems towards EHDS
- WP8 - Certification and labelling framework
- WP9 - Telemedicine under MyHealth@EU in alignment with EHDS proposal

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No	TECHNICAL DELIVERABLES	Due date
D4.1	Current status of play in EHR and primary use of data	M6
D4.2	Sustainability plan and mapping of proxy services	M26
D5.1	Technical Requirements for EHRs, logging component and key system interfaces	M24
D5.2	Technical requirements for EEHRxF metadata	M24
D6.1	Patient Summary: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems	M27
D6.2	Electronic prescription and electronic dispensation: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems	M27
D7.1	Medical test results, including laboratory and other diagnostic results and related reports: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems	M29
D7.2	Medical imaging studies and related imaging reports: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems	M29
D7.3	Discharge reports: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems	M29
D8.1	Classification and functional profiles of EHR systems	M26
D8.2	EHR Conformity Assessment Scheme assertion document and checklists	M26
D8.3	Wellness application labelling guidelines	M22
D9.1	Requirements and use cases on the availability of health data in cross-border telemedicine services under MyHealth@EU	M12
D9.2	Technical specifications on the availability of health data in cross-border telemedicine services under MyHealth@EU	M26
D9.3	Requirements for Large-Scale Uptake of Telemedicine Service	M24

Targeted stakeholder engagement

- The deliverables of WP5 to WP9 are foreseen to prepare the content of implementing acts to the EHDS regulation.
- For this, it should be made sure that the WP5 to WP9 specifications meet the needs and expectations of the future users and concerned software developers and vendors.
- An early “informal” feedback of “closed” topic-related expert groups should be sought during the project and by the project partners.
- For the final deliverables / the implementing acts a formal consultation process will follow organized by the European Commission.

DRAFT - timetable for consultation round

DELIVERABLE	Due date	Start of Consultation period	End of Consultation period
D5.1 Technical Requirements for EHRs, logging component and key system interfaces	M24 (Oct 25)	2025-04-30	2025-06-11
D5.2 Technical requirements for EEHRxF metadata	M24 (Oct 25)	2025-04-30	2025-06-11
D6.1 Patient Summary: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems	M27 (Jan 26)	2025-07-31	2025-09-11
D6.2 Electronic prescription and electronic dispensation: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems	M27 (Jan 26)	2025-07-31	2025-09-11
D7.1 Medical test results, including laboratory and other diagnostic results and related reports: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems	M29 (Mar 26)	2025-07-31	2025-09-11
D7.2 Medical imaging studies and related imaging reports: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems	M29 (Mar 26)	2025-09-30	2025-11-11
D7.3 Discharge reports: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems	M29 (Mar 26)	2025-05-31	2025-07-12
D8.1 Classification and functional profiles of EHR systems guidelines	M26 (Dec 25)	2025-05-05	2025-06-15
D8.2 EHR Conformity Assessment Scheme assertion document and checklists	M26 (Dec 25)	2025-06-30	2025-08-11
D8.3 Wellness application labelling guidelines	M22 (Aug 25)	2025-02-28	2025-04-11
D9.1 Requirements and use cases on the availability of health data in cross- border telemedicine services under MyHealth@EU	M12 (Oct 24)	together with D9.2	together with D9.2
D9.2 Technical specifications on the availability of health data in cross-border telemedicine services under MyHealth@EU	M26 (Dec 25)	2025-06-30	2025-08-11
D9.3 Requirements for Large-Scale Uptake of Telemedicine Service	M24 (Oct 25)	2025-04-30	2025-06-11

Questions?

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