

Nictiz

The competence centre  
for digital information  
management in  
healthcare.



# How does the Netherlands contribute to the building of the European Health Data Space (EHDS)?

Esther Peelen

International advisor/coordinator

International Team





# European digital strategy

‘Fit for the digital age’



# Provisionary agreement on the European Health Data Space (EHDS) Regulation

## European Parliament and Council reach deal on European Health Data Space

After months of hard work and delicate negotiations, the European Parliament and Council have a deal that will strongly support patient care and scientific research in the EU. The new law agreed on today will allow patients to access their health data wherever they are in the EU, while also providing scientific research for important reasons of public interest with a wealth of secure data that will greatly benefit the development of health policies.

— Frank Vandenbroucke, Belgian Deputy Prime-Minister and Minister of Social Affairs and Public Health



Moving forward with the European health data space: the need to restore trust in European health systems

Jaisalmer de Frutos Lucas<sup>a,b,\*</sup> and Hans Torvald Haugbo<sup>c</sup>

Author information Article notes Copyright and License information PMC Disclaimer

The European institutions reached an agreement on the regulation of European Health Data Space (EHDS) on March 15th, 2024, after three months of intense negotiations that prolonged beyond the original deadline. Harmonizing the needs and priorities of all stakeholders takes time; yet, we critically argue that heated negotiations and fragmentation of the solutions unquestionably shake the cornerstone of the project: Trust.

In May 2022, the European Commission (EC) presented the EHDS as a framework that would revolutionize European health systems. This space was meant to upgrade the primary use of health data, providing citizens with immediate access to their electronic health records and enabling data sharing with health professionals cross-border. Moreover, the EHDS was set to create a robust legal

## European Health Data Space: Council and Parliament strike deal





# What does the European Health Data Space envision?



## Citizens

Empower individuals to take control of their health data & facilitate exchange of data for delivery of healthcare across EU



## Market

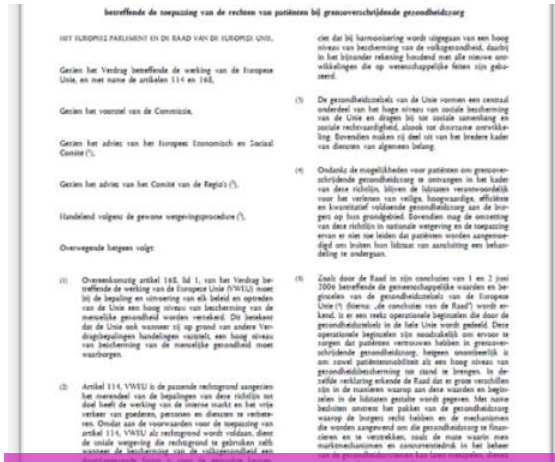
Foster a single market for EHR systems



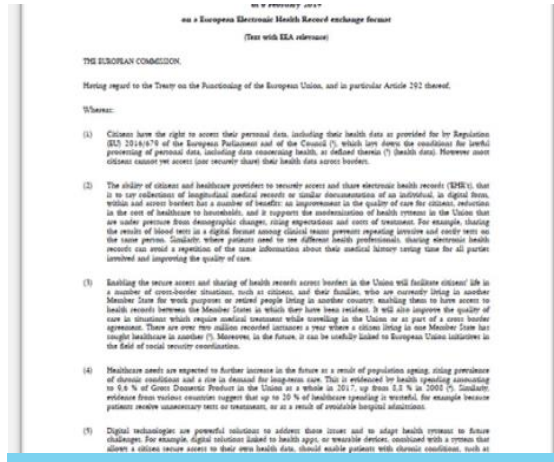
## Data availability

For research, innovation, policy, regulation

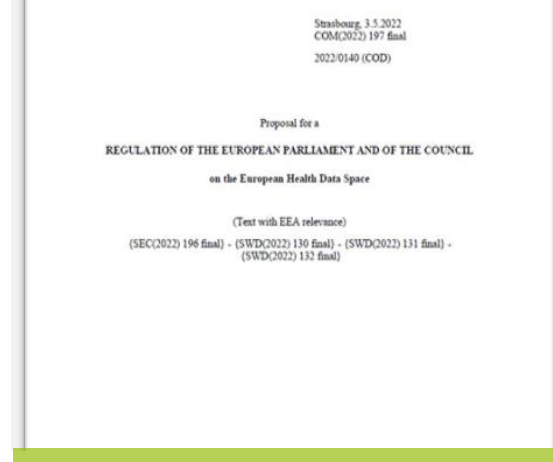
# EHDS has been on a long journey



2011  
Citizens' right on their health data within EU



2019  
EeHRxF Recommendation



2022  
EHDS Regulation Proposal



# What is the European electronic health record exchange format EEHRxF, ‘the format’?

EHDS proposal Article 6:

*European electronic health record exchange format*

1. 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 5, setting out the European electronic health record exchange format. The format shall include the following elements:

(a) **datasets** containing electronic health data and defining structures for the representation of clinical content and other parts of the content

(b) **coding systems** and **values** to be used

(c) **technical specifications** for the representation, standards and professional use of the data

2. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2). Member States shall ensure that the priority categories of personal electronic health data referred to in Article 5 are **provided by a natural person directly or through a health care provider** by automatic means in the format referred to in paragraph 1, such data shall be **read and accepted** by the data recipient.

3. Member States shall ensure that the priority categories of personal electronic health data referred to in Article 5 are **issued** in the format referred to in paragraph 1 and such data shall be read and accepted by the data recipient.

The EEHRxF is a set of technical specifications, targeted at ensuring the interoperability of electronic health record systems used on the Union market.

# For Primary and Secondary use

## Primary

- Patient Summary
- ePrescription/eDispensation
- Laboratory Results
- Medical Imaging and Reports
- Hospital Discharge Reports

Via: MyHealth@EU



## Secondary

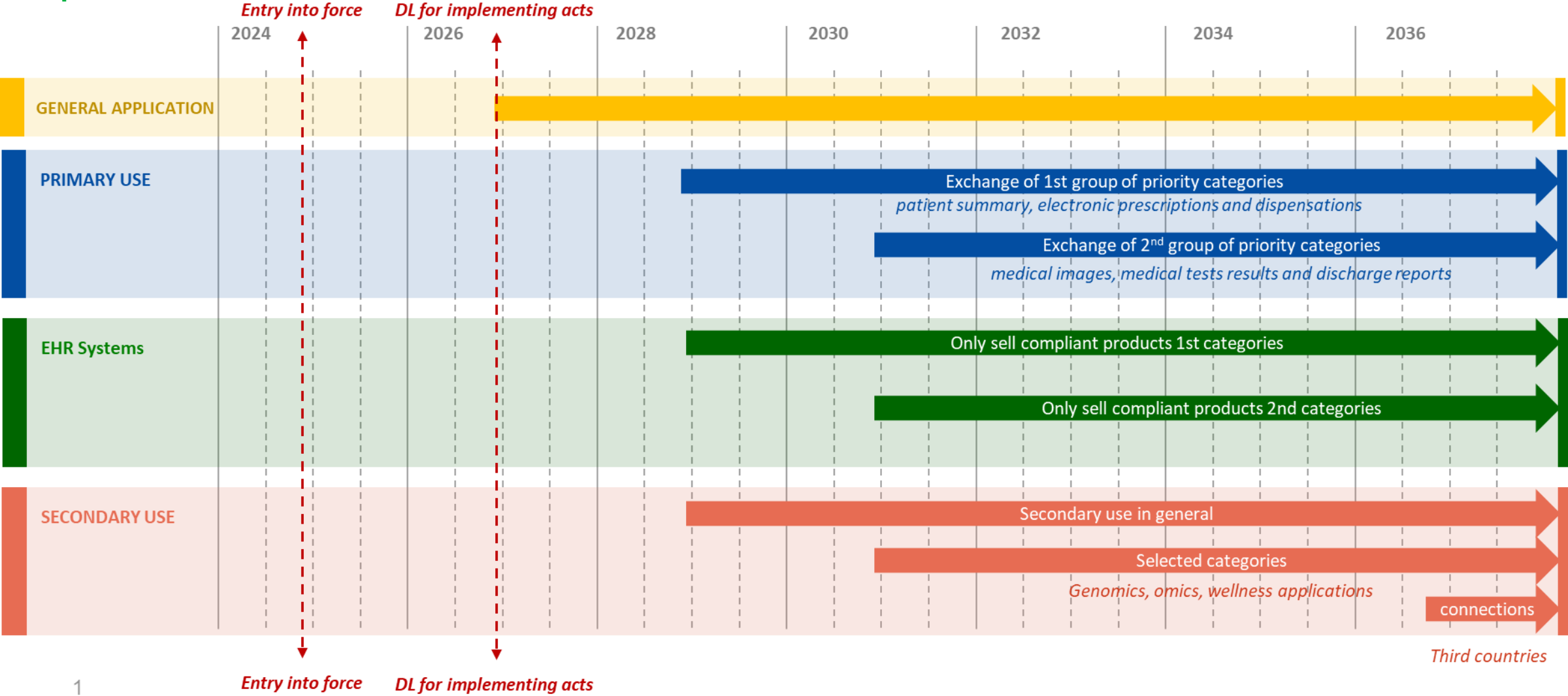
- Research
- Innovation
- Public Health
- Statistics

Via: HealthData@EU





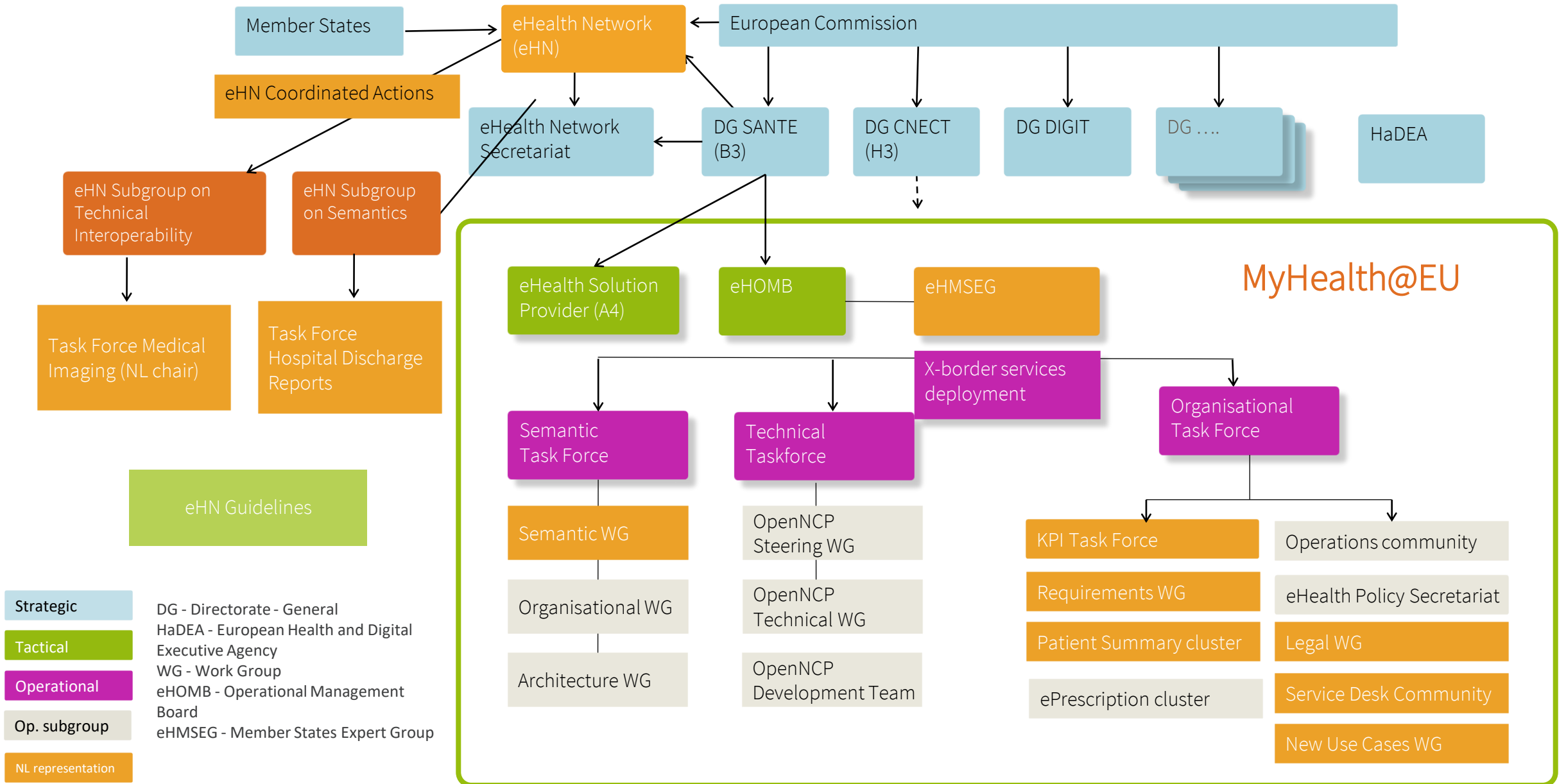
# EHDS – Overall timeline





# European Cooperation

# EU eHealth Network Governance







## eHN Guidelines

High level document with descriptions of:

- Use case (cross-border) and purpose
- General considerations (legal, policy, international standards)
- Dataset
- References

[eHealth Network - European Commission \(europa.eu\)](https://ec.europa.eu/ehealth/ehealth-network/)

Are part of the EEHRxF

# MyHealth@EU



Infrastructure for primary use of Health Data  
Via National Contact Points for eHealth  
In a secure way

## Available services:

- European Patient Summary
- ePrescription/eDispensation

## New services:

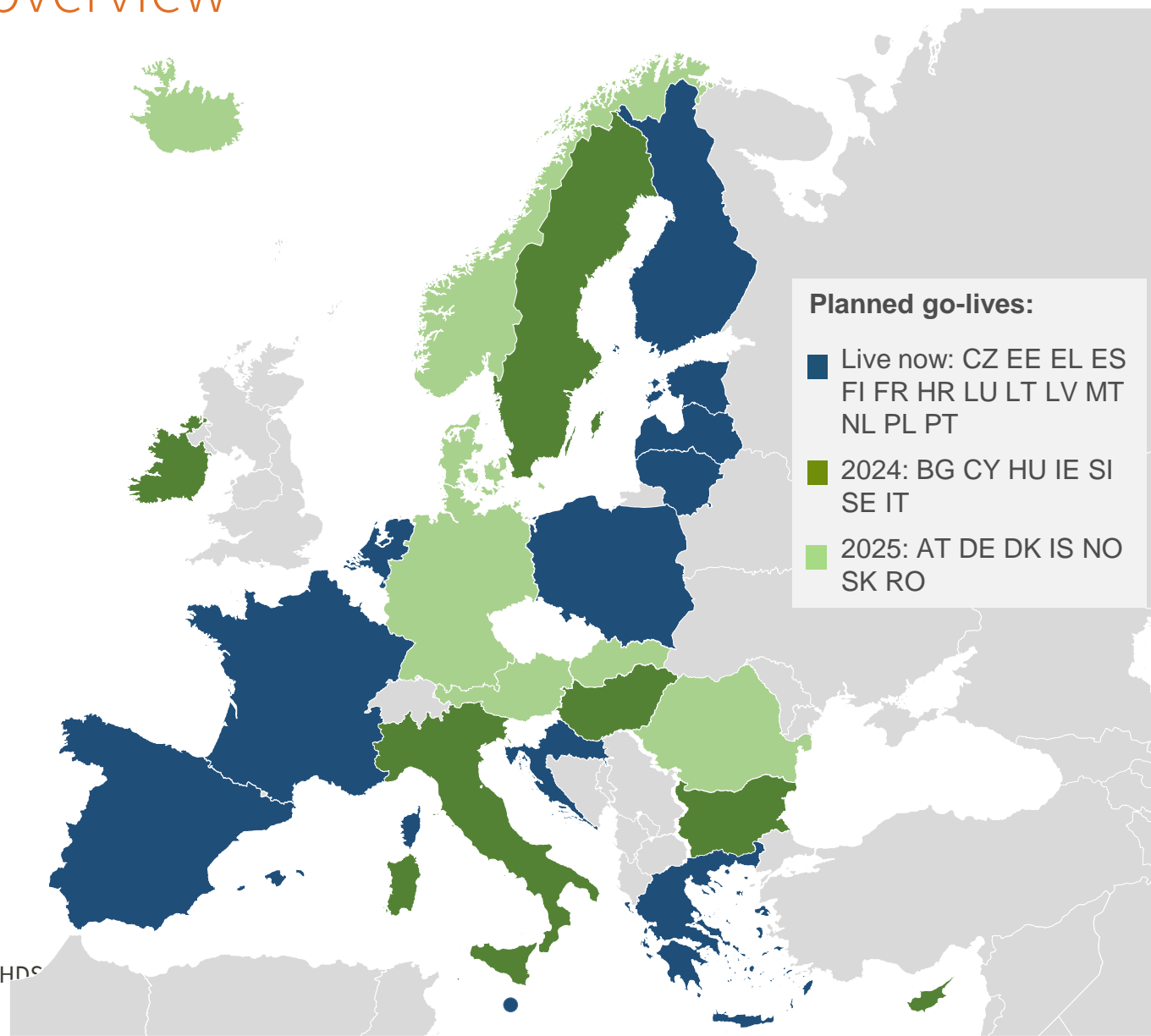
- Laboratory Results
- Medical Imaging & Reports
- Hospital Discharge Reports (HDR)

[Electronic cross-border health services \(europa.eu\)](http://europa.eu)

# MyHealth@EU: implementation overview

13 Member States are live

Expected grow for EU and EEA countries by 2025







How does the Netherlands participate in the building of the EHDS?

# Programme implementation European Healthcare Services: Piezo

Since 2022 NCPeH live in the Netherlands

Hosted by CIBG, [web portal](#)

Retrieve the European Patient Summary of EU citizens from Czech Republic, Estonia, Portugal, Spain, Malta and Luxembourg.

Listen to the experience of Saxenburg Medical Center ([video](#))

For more information or want to connect? Please contact CIBG



# Piezo II – Sharing Patient Summary of Dutch citizen



Ministerie van Volksgezondheid,  
Welzijn en Sport



CIBG  
Ministerie van Volksgezondheid,  
Welzijn en Sport



Medegefinancierd door de financieringsfaciliteit  
voor Europese verbindingen





# Wegiz and EHDS make a strong pair

# Wegiz

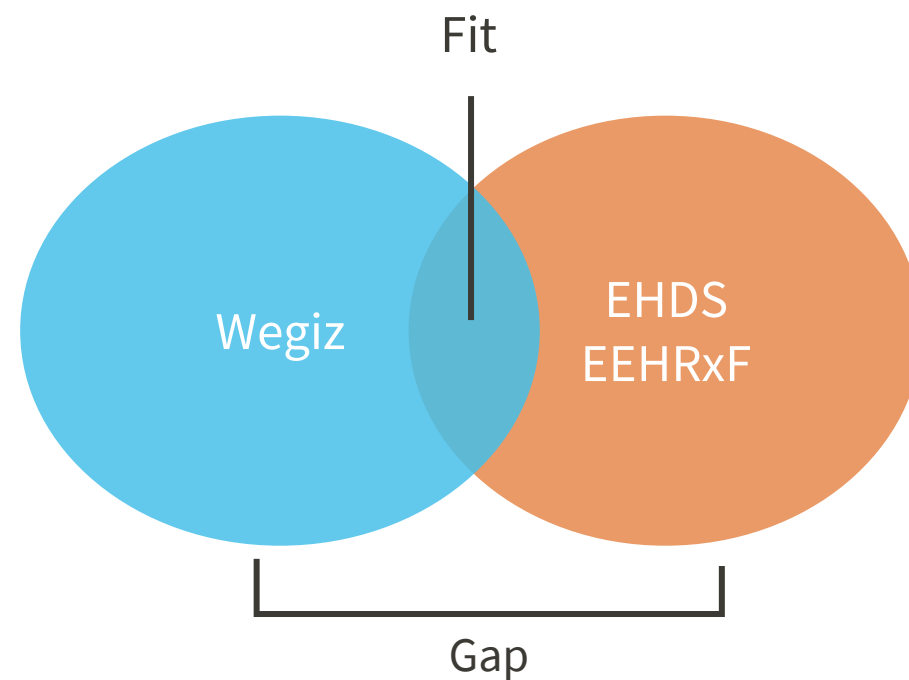
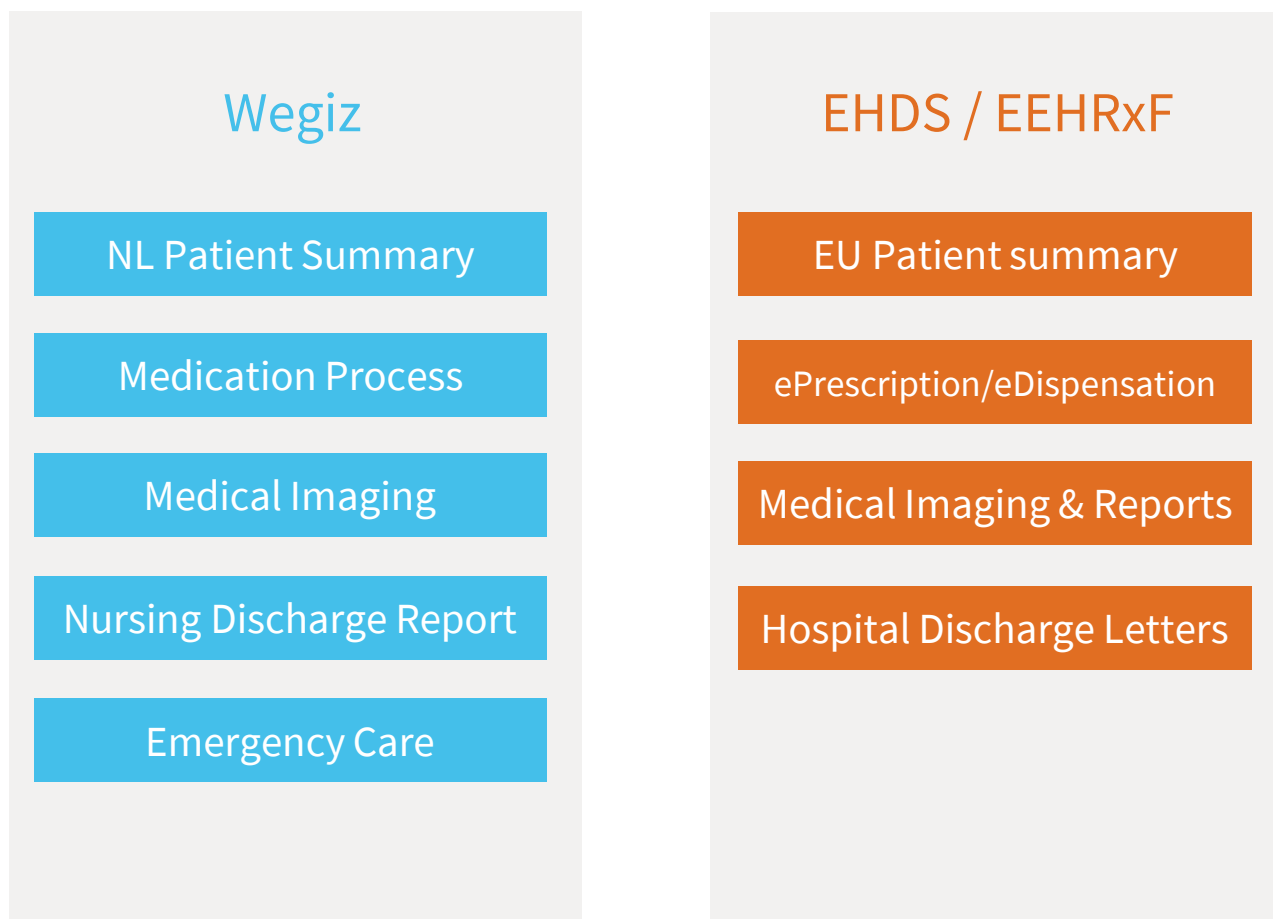
## Dutch Legislation on digital information exchange in Healthcare

### Current status



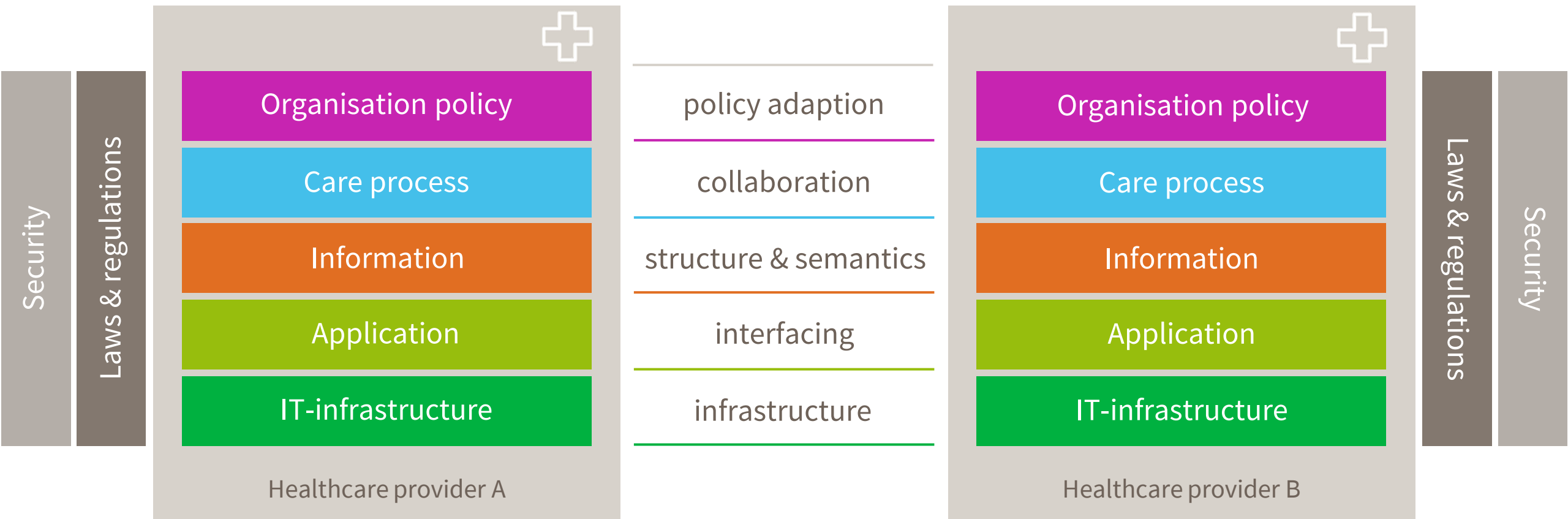
- Proposed Legislation passed Chamber (September 22) and Parliament in April 23
- 1 July 2023 into force
- Step-based approach on implementation, spreaded over multiple years (2023-2028)
- Prioritised domains:
  - Patient Summary data
  - Nursing Discharge Report
  - Medical Imaging
  - Medication (prescription and dispensation, medication overview, lab results for medication, adverse event monitoring)
  - Emergency Care

# Fit-gap analysis Netherlands/Europe





# Five layer model





## Example: Medical Imaging and Reports

Cooperation in eHealth Network subgroup on Interoperability and EU-project Xt-EHR to align National specifications and European specifications

Both sides in development

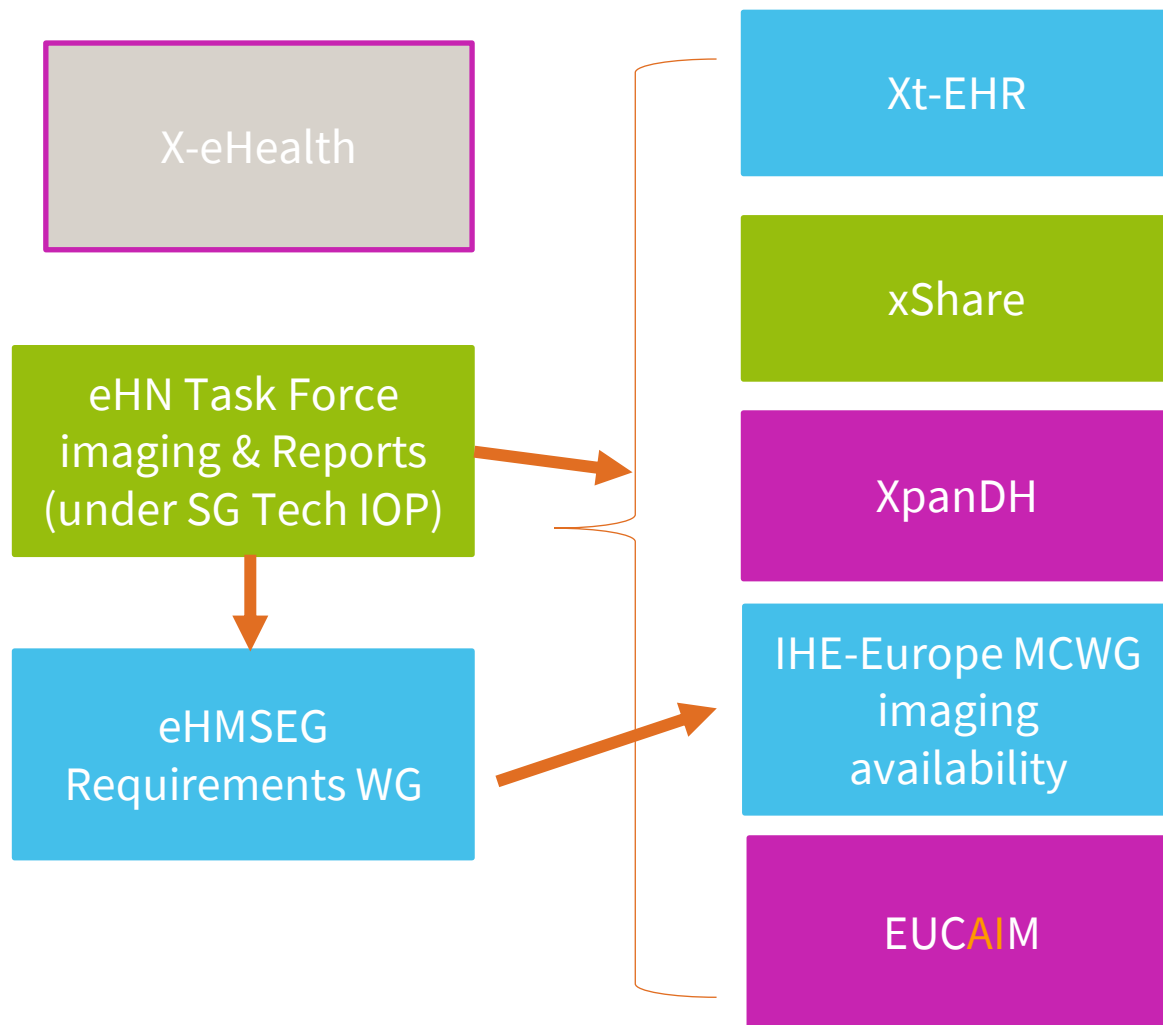
### **Examples:**

Common metadata set

Unique linkage between Imaging study and report

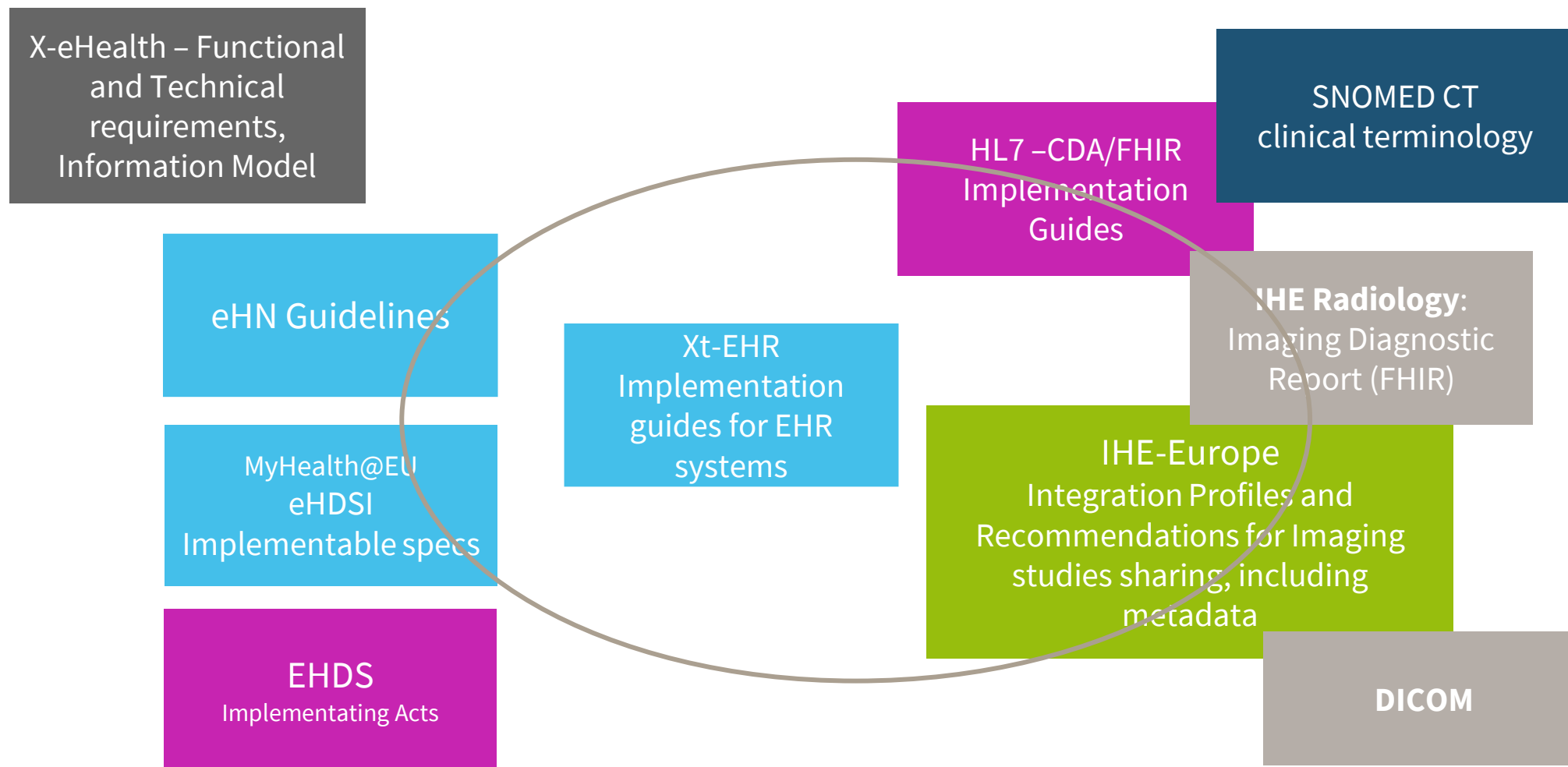
Supports Dutch request on building a timeline

# Seeking cooperation in EU initiatives for medical Imaging Studies and Reports under EHDS





# Reuse of available material





## EU-Projects that facilitate EHDS becoming a reality

# Xt-EHR

[Project | Xt-EHR](#)

Extended EHR at EU Dataspace for primary use



# xShare

[xShare](#)



## The xShare Yellow Button

The xShare Yellow Button will allow us to share our health data in the European Electronic Health Records Exchange Format (EHRxF) as noted in the upcoming European Health Data Space (EHDS) regulation.



# XpanDH

[XpanDH](#)



[About the Project](#) ▾ [Communication](#) ▾ [Consortium](#) ▾ [Contact us](#)

[Home](#) » [News](#)

## News

Shape the Future of Healthcare: Join XpanDH's Community of Doers and Co-creators!

The scope of this open community is to find use cases and business needs that would be reused in practice domains of the European EHR



European EHR Exchange Format Summit: Building a Unified European Health Data Ecosystem

The European Electronic Health Record Exchange Format (EEHRxF) Summit, held in December 2023, brought together key stakeholders to discuss the development, challenges, and future of



# PatheD

Patient Access to eHealth Data

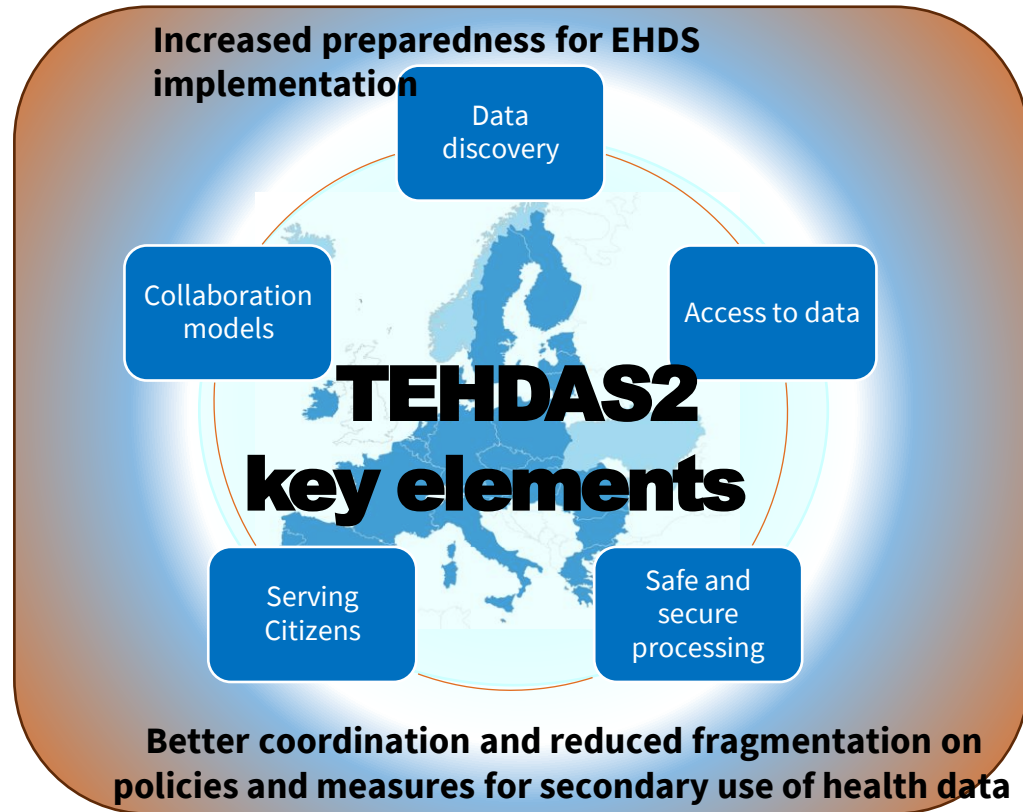


# TEHDAS2

Towards the European Health Data Space

[TEHDAS project](#)

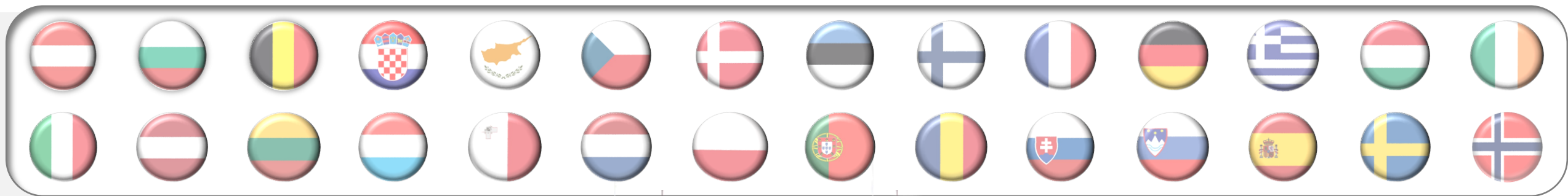
1-5-2024 t/m 1-1-2027





Extended EHR@EU Data Space for Primary Use





Participants: 28 countries, 55 organisations

# Extended EHR@EU Data Space for Primary Use

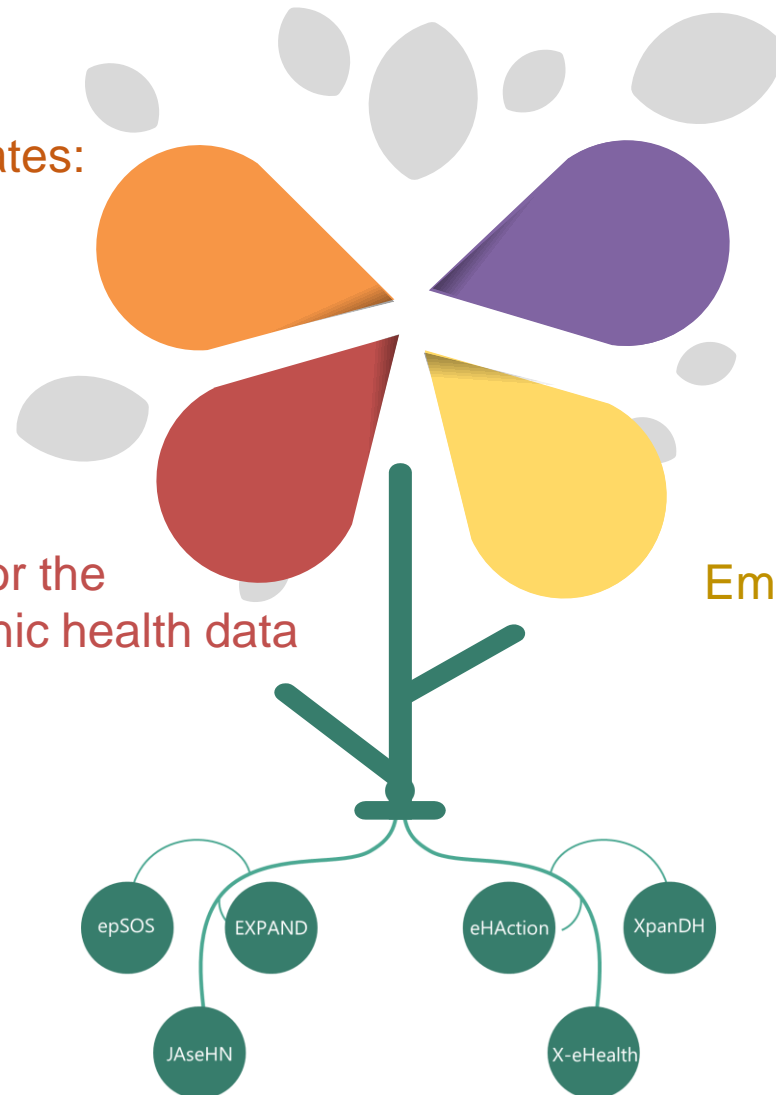


Cooperation among Member States:

- interoperability
- exchange of healthcare data



Preparation of the foundations for the improved primary use of electronic health data



New regulation for the European Health Data Space (EHDS)



Empower individuals to control their health data



# Purpose

## EHR solution in the European Digital Single Market

- Cross-border interoperability
- Technical Specification and Use Cases
- Implementation Guides
- Common agreed on use case



# Purpose

Definition of  
implementation  
guides  
for EHRs





# EHR-System definition

EHDS, article 2:

*‘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;*

# 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

# Stakeholder involvement

## European level

MedTech Europe (MTE)

Digital Europe (DE)

Standing Committee of European Doctors (CPME)

European Federation of Nurses Associations (EFN)

European Society of Radiology (ECR)

European Patients Forum (EPF)

European Committee for Standardization (CEN)

...and many more



Your input is very welcome!

If you want to get involved, please contact me at

[Esther.peelen@nictiz.nl](mailto:Esther.peelen@nictiz.nl)



# Ambition

Digital Health  
for all Member  
States



**European Health Union**



# Future events

# xShare – High Level Interoperability Workshop 21 May

DIGITALEUROPE  Share  
EHR Xchange Format

## High-level Digital Health Interoperability Workshop - EHDS Compliance

**Pathways to Digital Health Integration:**  
Unlocking the Potential of Digital Health: Strategies for Seamless Interoperability and Enhanced EHDS Readiness

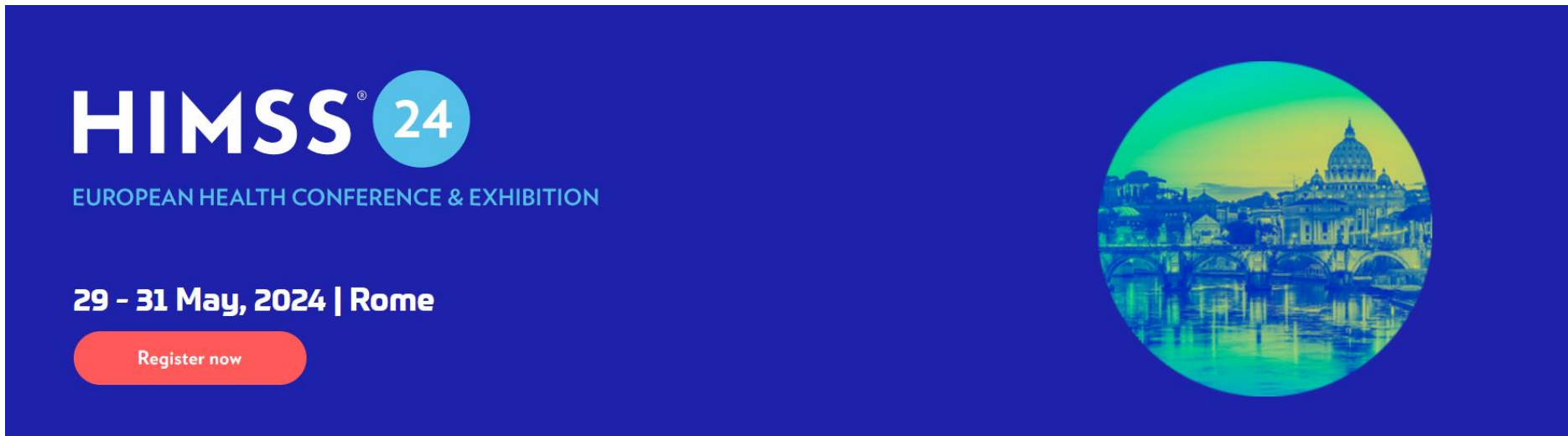
Tuesday, 21 May 2024 | 09:30-16:00 CET

Hybrid | Online + DIGITALEUROPE offices (Brussels)

 Co-funded by the European Union

[Registration](#)

# HIMSS Europe 29-31 May, Rome



**HIMSS<sup>®</sup> 24**  
EUROPEAN HEALTH CONFERENCE & EXHIBITION

**29 - 31 May, 2024 | Rome**

[Register now](#)

## Program

# IHE-Europe Experience Days 3 and 4 June, Trieste

- Medical Imaging – best practices from EU-countries and beyond
- Gemini (IHE/HL7)
- EHDS, AI Act, Interoperability Act

[Program & Registration](#)







# Questions?



## More information

[Internationaal – Nictiz](#)

XpanDH [Webinars](#)

[EEHRxF Recommendation](#) 2019

About NCPeH:

[Home](#) | [NCPeH-NL](#)

MoH Meet up, this afternoon





Keep in touch!

We'd love to hear your questions,  
needs and suggestions