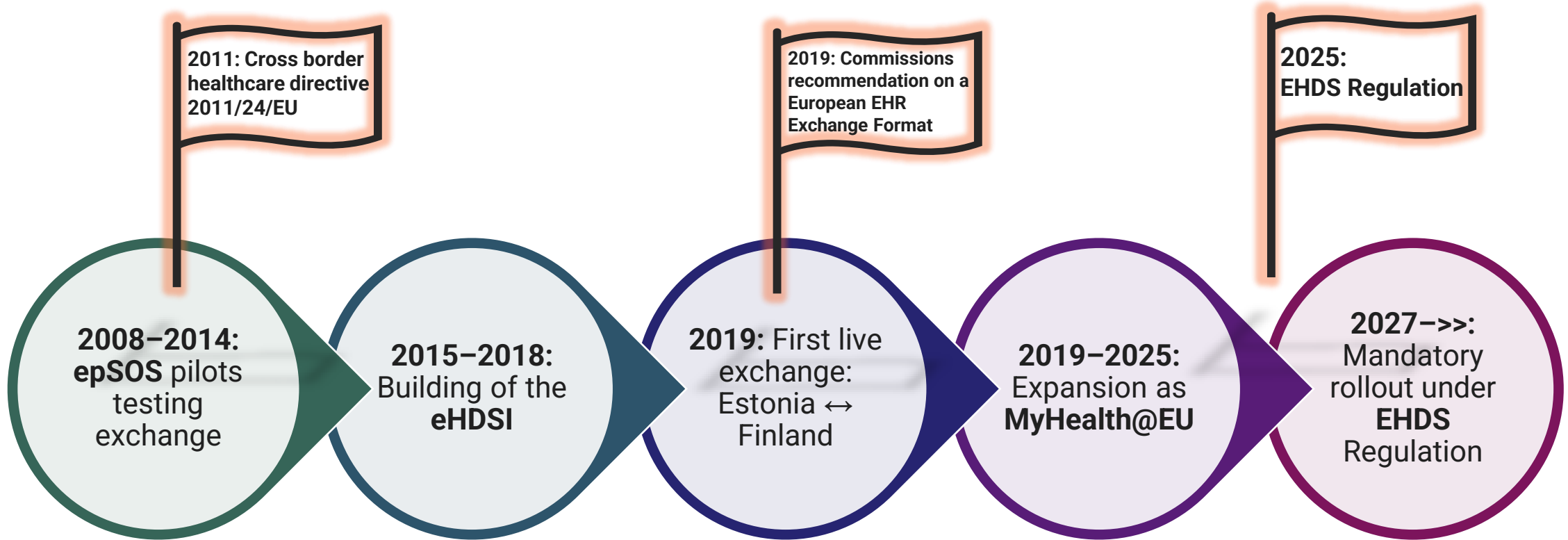**Helsedirektoratet**

EHDS and Xt-EHR work in Norway

FHIR fagforum #32, 22nd October 2025

Kerstin Engelhardt and Morten Bakken - Norwegian Directorate of Health, Department of standardisation
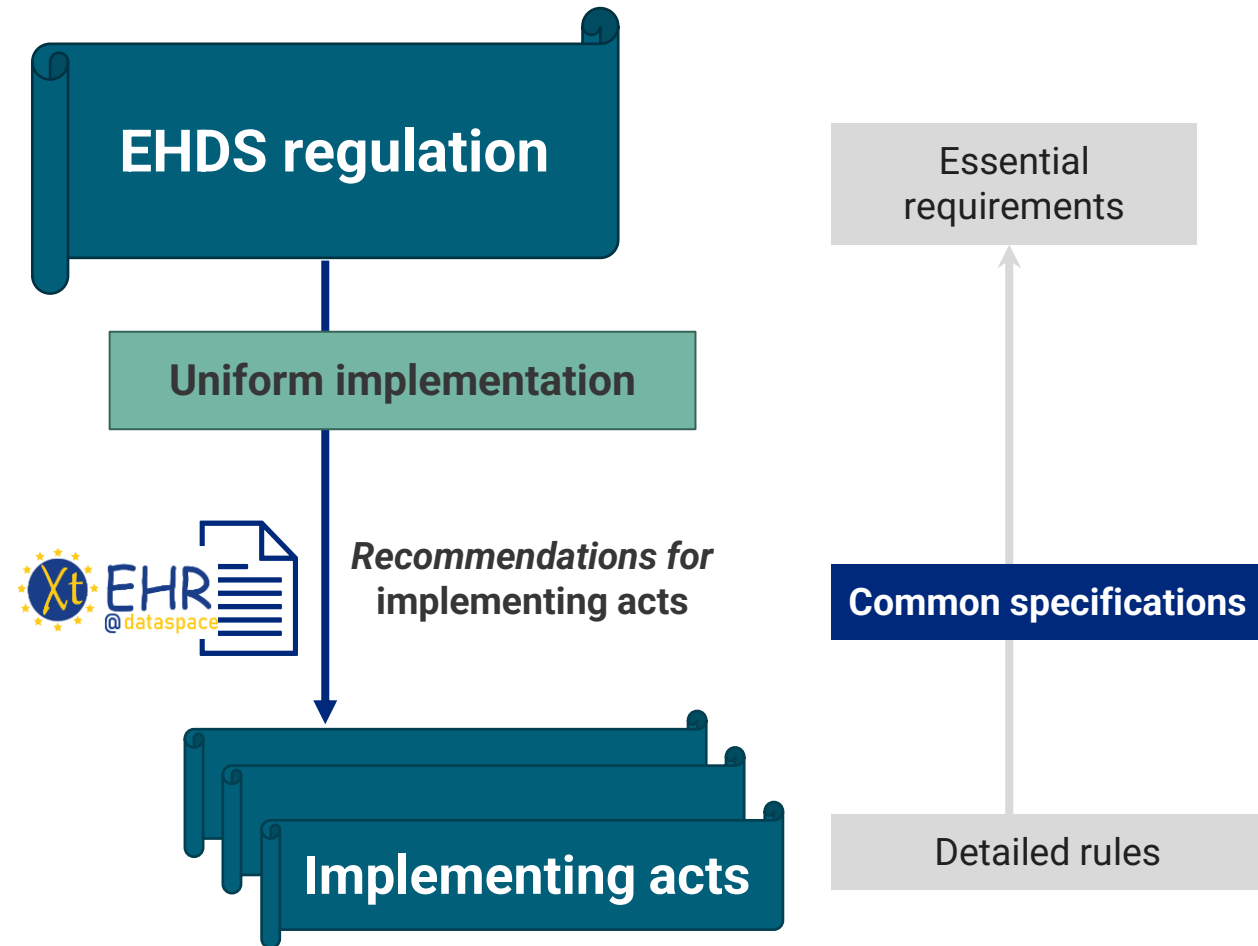
Evolution of European eHealth & EHR interoperability

2011: Cross border healthcare directive 2011/24/EU

2019: Commissions recommendation on a European EHR Exchange Format

**2025:
EHDS Regulation**

2008–2014: **epSOS** pilots testing exchange

2015–2018: Building of the **eHDSI**

2019: First live exchange: Estonia ↔ Finland

2019–2025: Expansion as **MyHealth@EU**

2027–>>: Mandatory rollout under **EHDS** Regulation

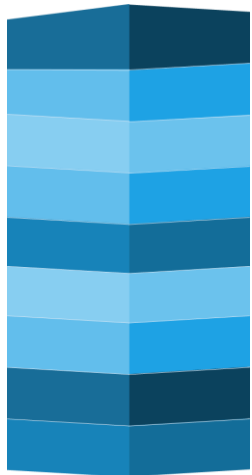# EHDS regulation, implementing acts and Xt-EHR

- EU regulations are binding legal acts that must be applied in full across all EU Member States.

- Although Norway is **not a member of the EU**, it is bound by the EEA Agreement to implement relevant EU regulations into Norwegian law.

- **Implementing acts** are supplementary legal instruments adopted by the **European Commission** that specify how a regulation should be applied in practice => common specifications.

- The Xt-EHR joint action was established to provide recommendations for technical specifications for key implementing acts for primary use in EHDS:
  - European Electronic Health Record Exchange Format, EEHRxF (art. 15)
  - Common specifications for EHR systems (art. 36)

EHDS regulation

Uniform implementation

Recommendations for implementing acts

Implementing acts

Essential requirements

Common specifications

Detailed rules

- EU4Health Joint Action Xt-EHR

  «Preparatory actions for a European Health Data Space; primary use of data (for healthcare) and reuse of data»

- Consortium of >50 partners

- Coordinator: Cyprus (National eHealth Authority)

- Norway is participating with Directorate of Health as competent authority

- Duration: 1.11.2023 – 30.04.2026 (30 months)

Norway's participation in Xt-EHR

Xt·EHR @dataspace

Co-funded by the European Union

Helsedirektoratet
Norwegian Directorate of Health

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

Norway's participation in the Xt-EHR Joint Action

- Norwegian Directorate of Health is Norway's national eHealth authority

- Subordinate agency under the Ministry of Health and Care Services

- Mandate related to Xt-EHR for 2024/2025:

  - **Participate** in Joint Action 09: Xt-EHR

  - **Involvement** of relevant stakeholders in Norwegian health sector, via national joint commitee for eHealth Standardisation

  - Carry out **Targeted Stakeholder Consultations** in Norway on project deliverables linked toEHDS Implementing Acts

Communication about EHDS+Xt-EHR

2024 2025

Joint committee for eHealth standardisation

- Updates on ongoing international standardization activities
- Broad range of stakeholders from the Norwegian healthcare sector: regional health authorities, municipalities, medical associations of HPs, EHR software and system vendors, standardization organizations
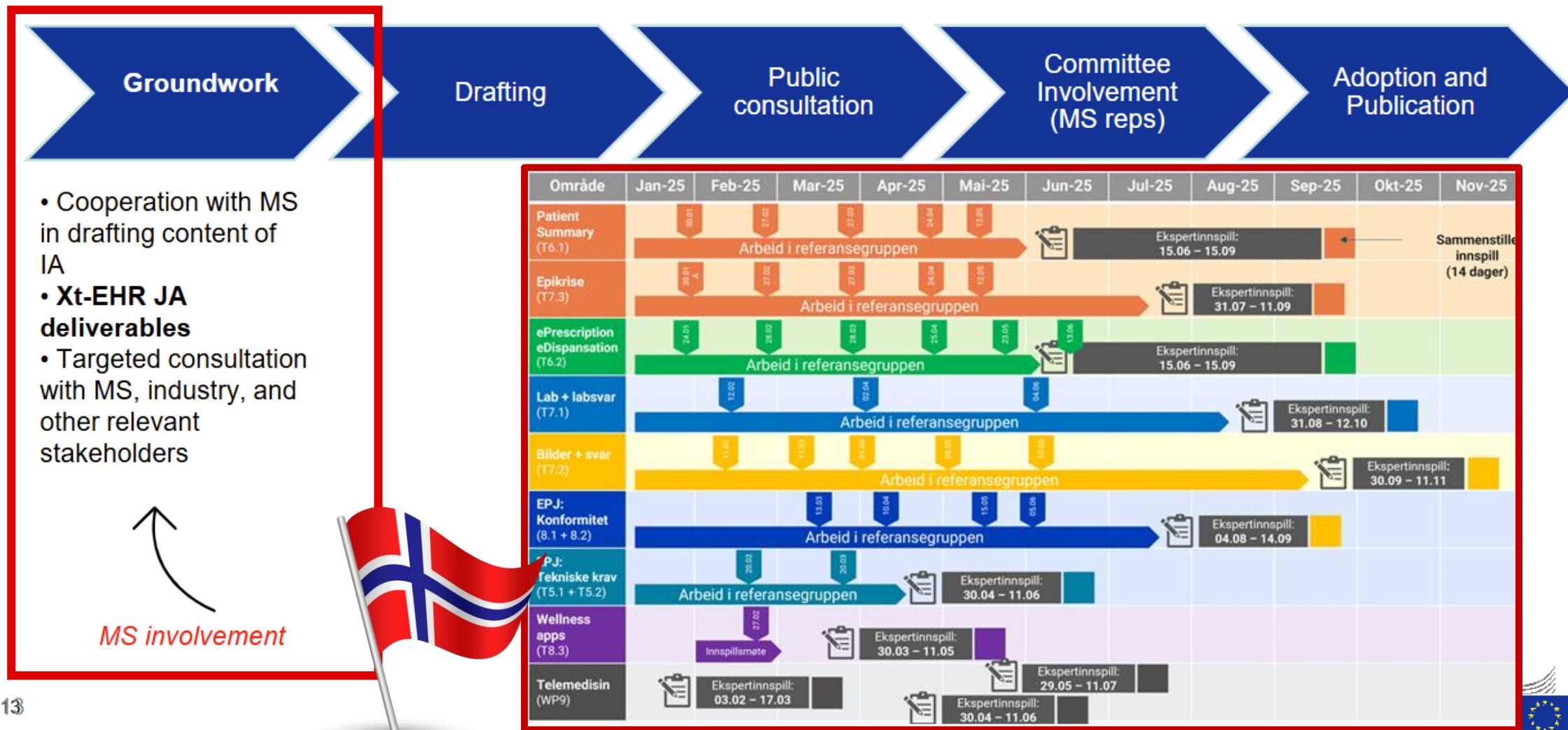
Collaboration model for international standards
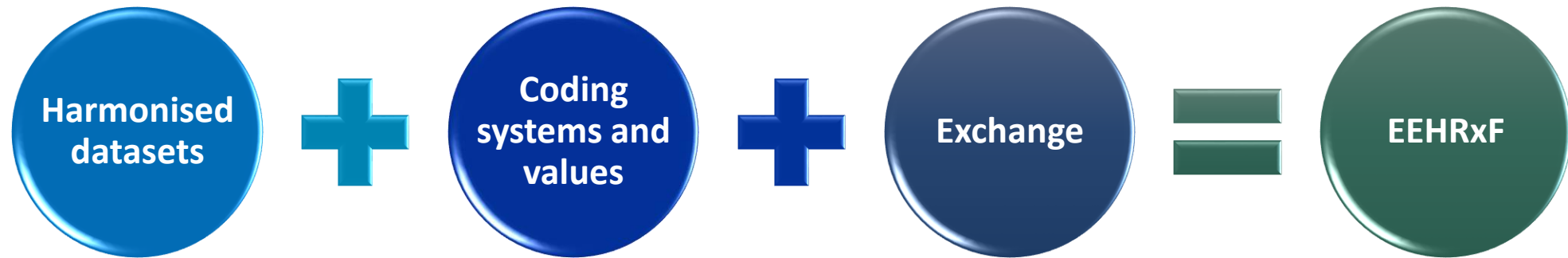
- Cooperation between various stakeholder groups in Norway
- Defined roles and responsibilities to accelerate standardization, strengthen digitalization, and improve resource management

Open call for experts Dec 2024

Flow for the adoption of implementing acts

Groundwork → Drafting → Public consultation → Committee Involvement (MS reps) → Adoption and Publication

• Cooperation with MS in drafting content of IA
• **Xt-EHR JA deliverables**
• Targeted consultation with MS, industry, and other relevant stakeholders

MS involvement

Art. 15 – Technical specifications for EEHRxF

Harmonised datasets + **Coding systems and values** + **Exchange** = **EEHRxF**

- Mandatory European exchange format for transmission of structured and unstructred health data

- Commonly used, machine-readable

- For priority categories:
  - Patient summaries · Electronic prescriptions/dispensations · Medical imaging studies and reports · Laboratory results and reports · Discharge reports

- MS shall ensure issuing and acceptance of health data in EEHRxF (-> obligations on national infrastructure/portals and on healthcare providers/EHR systems)

- EC shall provide regular updates (revisions of coding systems, nomanclatures)

Xt-EHR choice of technical standards for EEHRxF

- Xt-EHR deliverables include recommendations for standards for technical interoperability specifications

- Specifications are developed in closed collaboration with SDOs, dedicated MoUs signed with:
  - HL7 Europe
  - IHE Europe

➢HL7 FHIR as baseline technical interoperability standard for Xt-EHR implementation guides, complemented by DICOM for medical imaging

EEHRxF use cases

the **download** of an electronic copy of at least the personal electronic health data in the priority categories (access right, Article 3(2))

the transmission to healthcare providers chosen by the patient of electronic health data downloaded based on the access right in Article 3(2) (**portability** right, Article 7(4))

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

the **harmonised interoperability component** of electronic health record (EHR) systems (common specifications, Article 36, and essential requirements for EHR systems, Annex II)

Development of the Format

Xt-EHR and the EEHRxF

- Publicly available logical models - : [Home - EHDS](#) [Logical Information Models v0.1.0](#)

- Xt-EHR – a guideline-level approach

After this deliverable is completed, Standards Development Organizations such as HL7 EU and IHE Europe will draft the **FHIR Specification level** that meets these functional requirements. These organizations run in a balloting process, which encourages open participation from the specification's community.

- Implementation profiles

Xt-EHR collaboration with SDOs

MEMORANDUM OF UNDERSTANDING

Between

National eHealth Authority (NeHA)
Representing the Project "Extended EHR@EU Data Space for Primary Use"
No 101128085 —Acronym "Xt-EHR"

and

HL7 Europe

MEMORANDUM OF UNDERSTANDING

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EURIDICE – HL7 and IHE

EURIDICE - European Interoperability Specifications for Digital Solutions in Healthcare

EURIDICE

Collaboration Goals

Joint co-branded Standards
   The best from both

Initially to address EHDS requirements
First Pilot:
   Imaging Study Report

(aligned with the IHE International RAD Imaging Diagnostic Report)

euridice.org
European Interopearbility
Specifications
for Digital Solutions in Healthcare

To be referred from

HUB EHRxF by ESHIA

| Offer these specifications to Xt-EHR and the EC for possible adoption by the EHDS Implementing Acts | Propose the derivation of global level specifictions, as applicable |