

EHDS og FHIR

Utkast til agenda for Linn og Arne



EHDS og FHIR (Arne – max 20 min)

- «Hvem hva hvor» - intro
- Litt historikk (3 min max)
 - eHN -> EHDS / EDS
 - Fra gulerot til pisk – ny forordning
 - forventinger og foreløpig veikart
 - Innhold i forordningen og kobling samt gjenbruk av/ til andre EU «ting» (GDPR)
- Arbeid pågår i EU relevant for HL7-FHIR
 - EEHRxF – XPAND – Xt-EHR
 - Hvem er med
 - Hva gjøres - se på sider
- Overgang til Linn

Health is the first common EU data space => EDS

EHDS



- Driven by stakeholders
- Rich pool of data of varying degree of openness

- Sectoral data governance (contracts, licenses, access rights, usage rights)
- Technical tools for data pooling and sharing

Personal data spaces

High Value Datasets from public sector

Technical infrastructure for data spaces



Edge Infrastructure & Services

Cloud Infrastructure & Services

High-Performance Computing

AI on demand platform

AI Testing and Experimentation Facilities

Hva er EHDS og hvem er det for?

Innbyggere:
tilgang og kontroll
over egne
helsesdata



Bedre diagnostikk og behandling,
øke pasientsikkerhet og kontinuitet,
få en mer sømløs helsetjeneste

Helsepersonell:
enkel tilgang til
pasientens
helsesdata



Helsesdata fra
apper og
medisinsk utstyr



Elektroniske
pasientjournaler



Helseregistre



Beslutningstakere:
informerte
beslutninger og
effektiv styring



Industri:
Innovasjon, nye
teknologier,
behandlinger
og løsninger

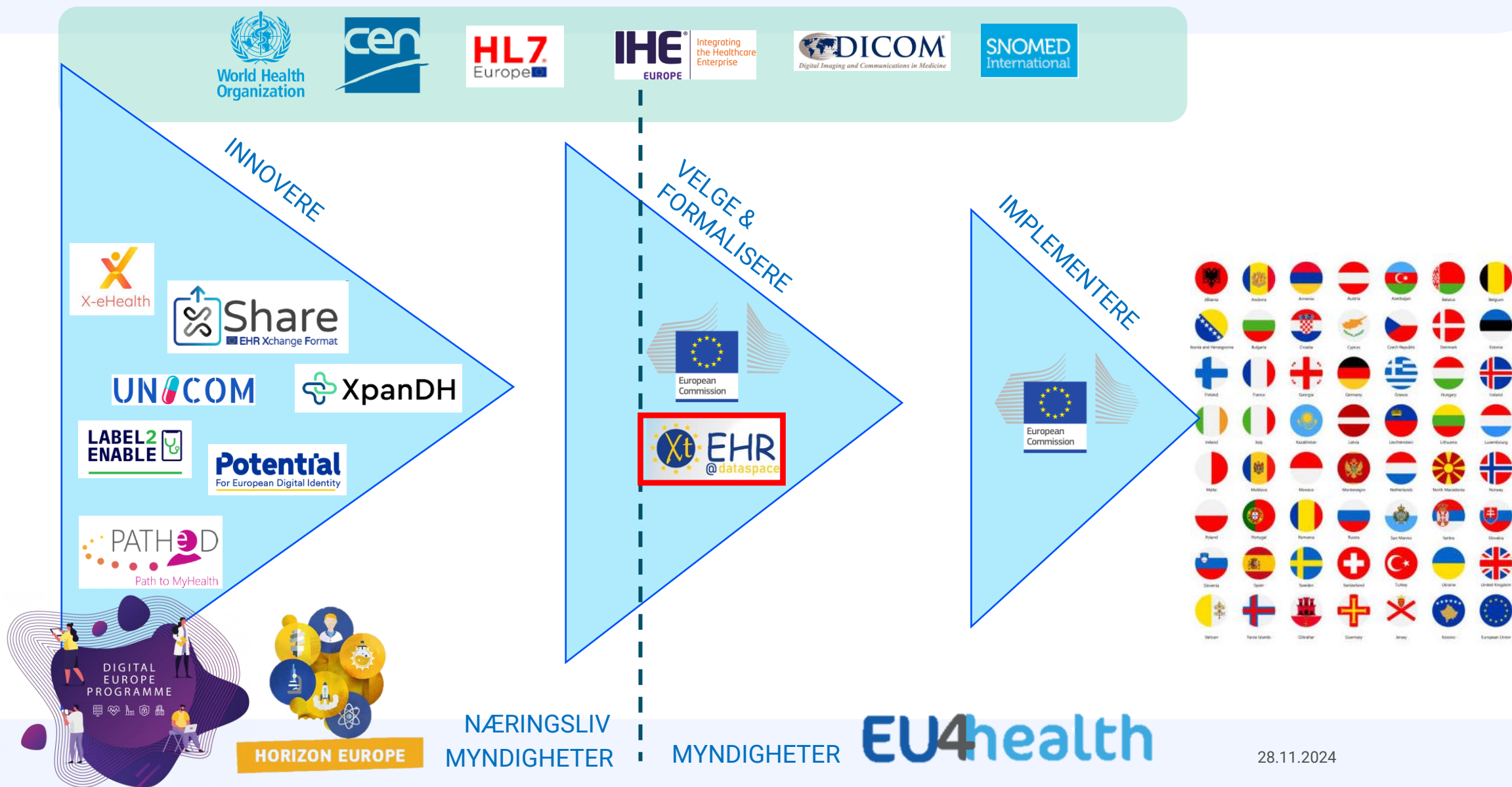


Forskning:
Tilgang til
helsesdata



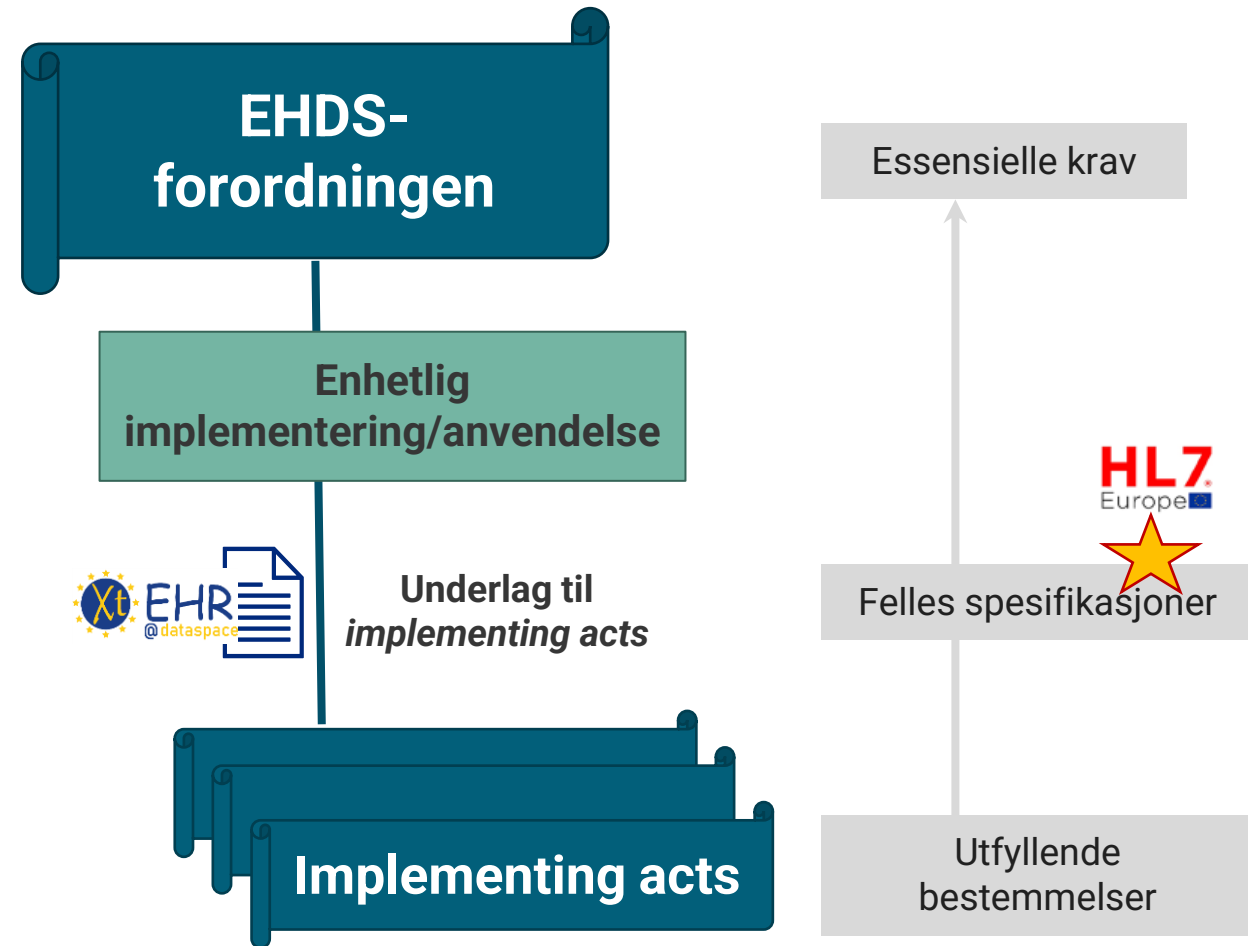
Bedre
helsepolitikk,
bedre
forutsetninger
for forskning og
innovasjon

EU - Utvikling av nye spesifikasjoner og tjenester



EHDS-forordningen, implementing acts og Xt-EHR

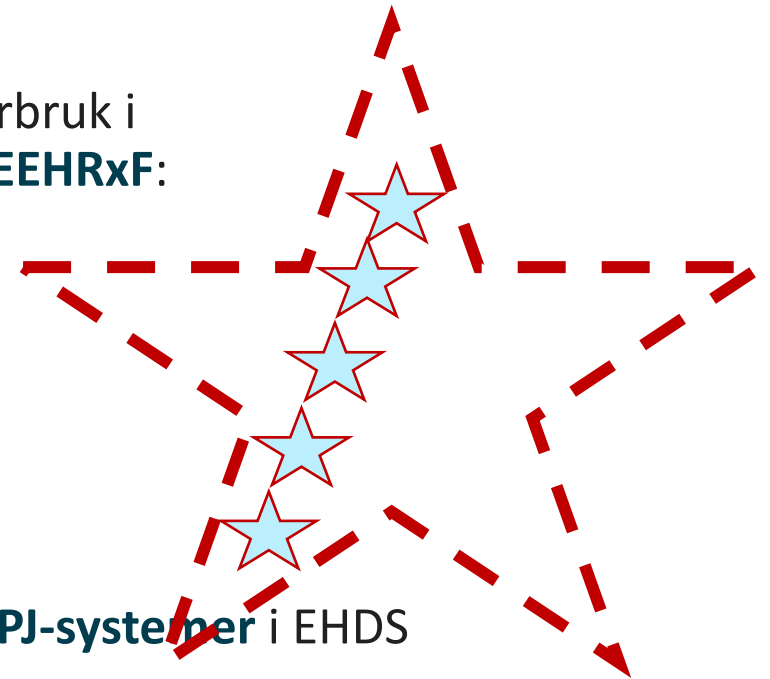
- EU-forordninger er bindende rettsakter, skal følges i alle detaljer i hele EU.
- Norge er forpliktet å gjennomføre forordninger i norsk rett.
- Kommisjonen har fullmakt til å vedta visse endringer, gjennomførings- eller utfyllende bestemmelser.
- **Gjennomføringsrettsakter ("implementing acts")** er utfyllende bestemmelser på hvordan en rettsakt skal gjennomføres.
- Kommisjonen vedtar implementing acts på områder hvor **enhetlig implementering** av lovverket er nødvendig.



Xt-EHR Joint Action – hovedoppdrag

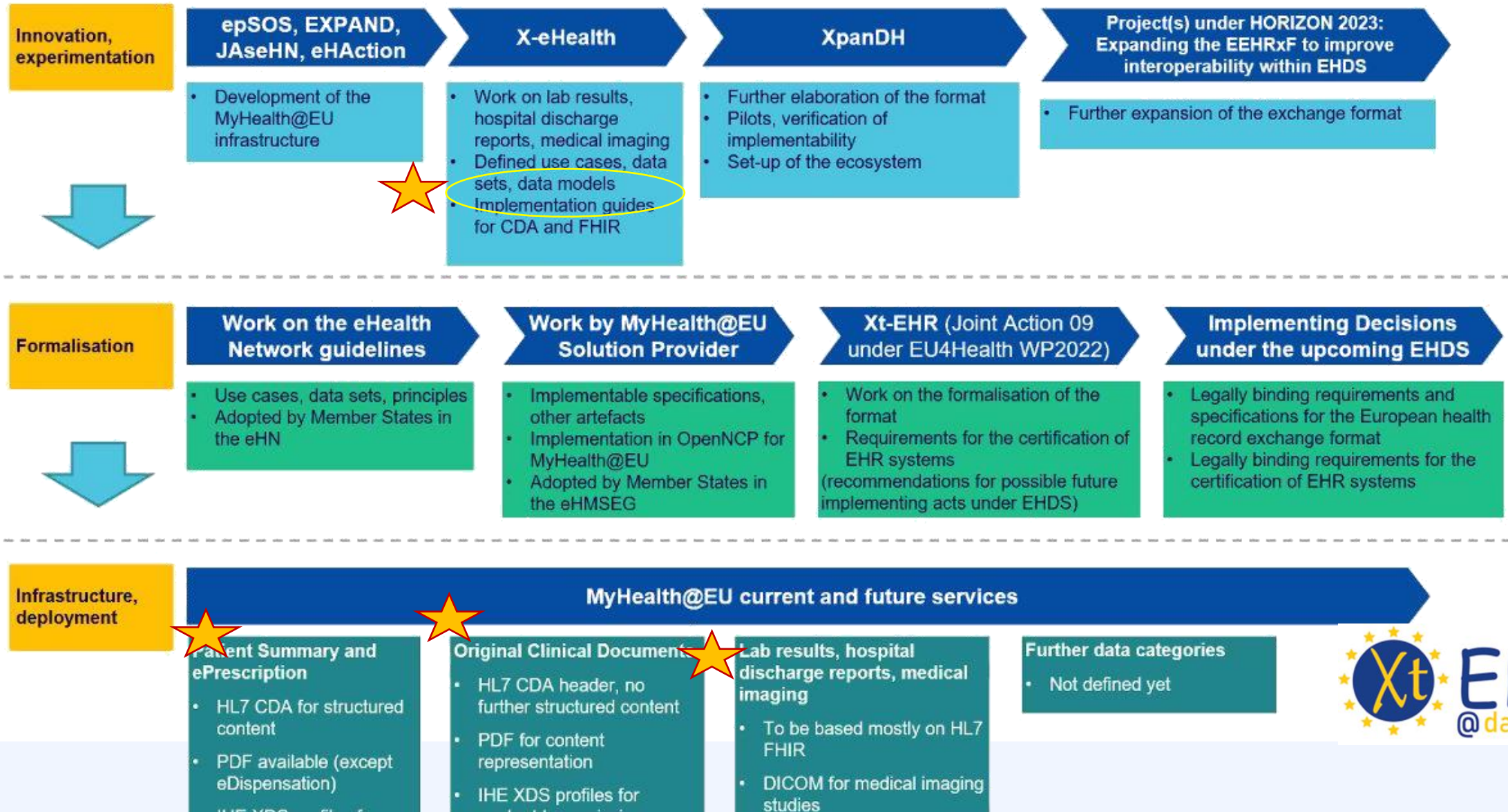
Utarbeide felles europeiske spesifikasjoner

- **Felles europeisk format** for utveksling av helsedata for primærbruk i EHDS = European Electronic Health Record Exchange Format, **EEHRxF**:
 - ePrescription/eDispensation
 - Patient Summary
 - Lab
 - Bilder
 - Epikrise
- Kriterier og rammeverk for obligatorisk **(selv)sertifisering av EPJ-systemer** i EHDS
- Kriterier og rammeverk for **merking av wellnessapplikasjoner** i EHDS
- **Telemedisin** som ny tjeneste i MyHealth@EU

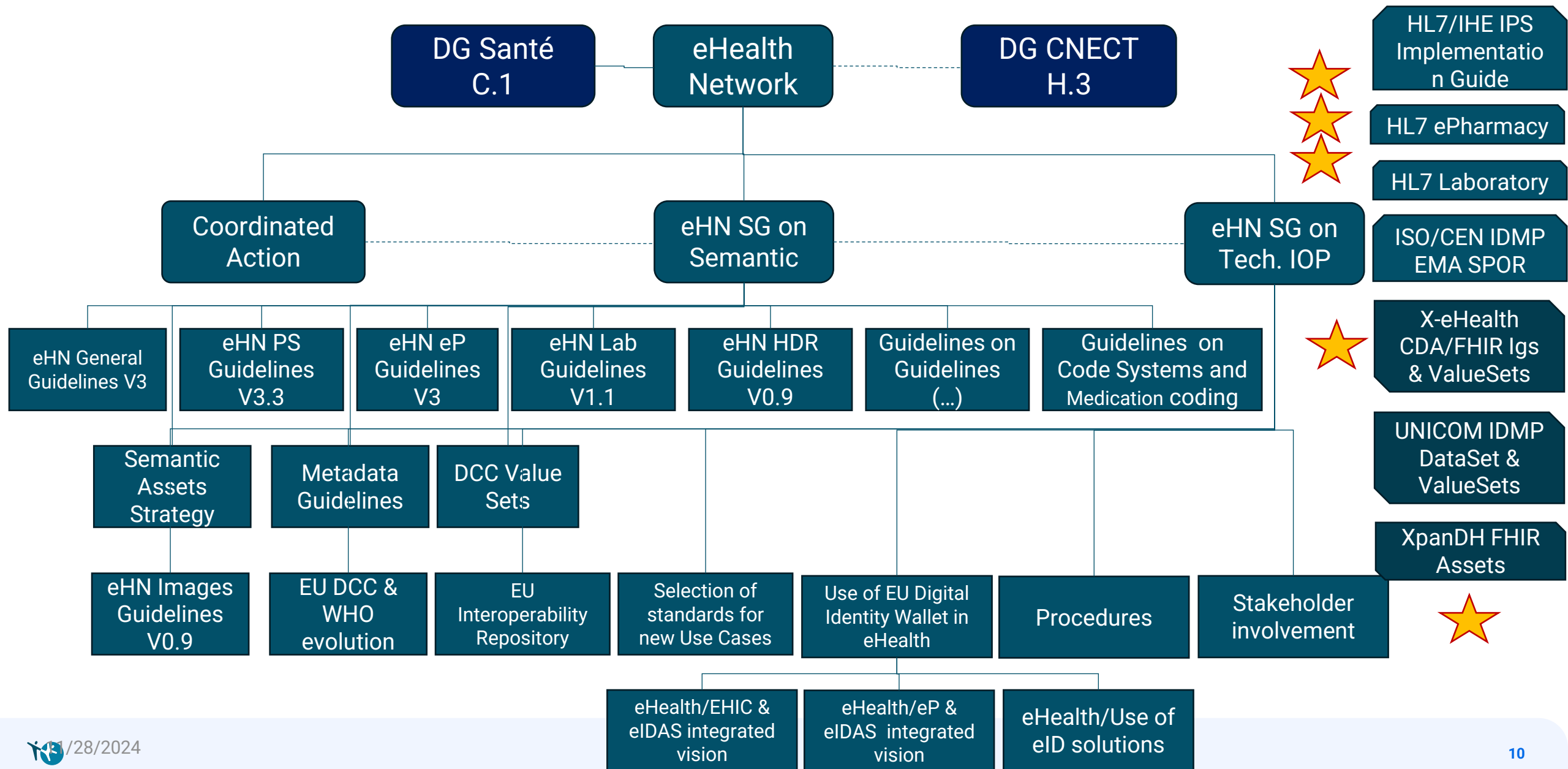


The overall scope of Xt-EHR

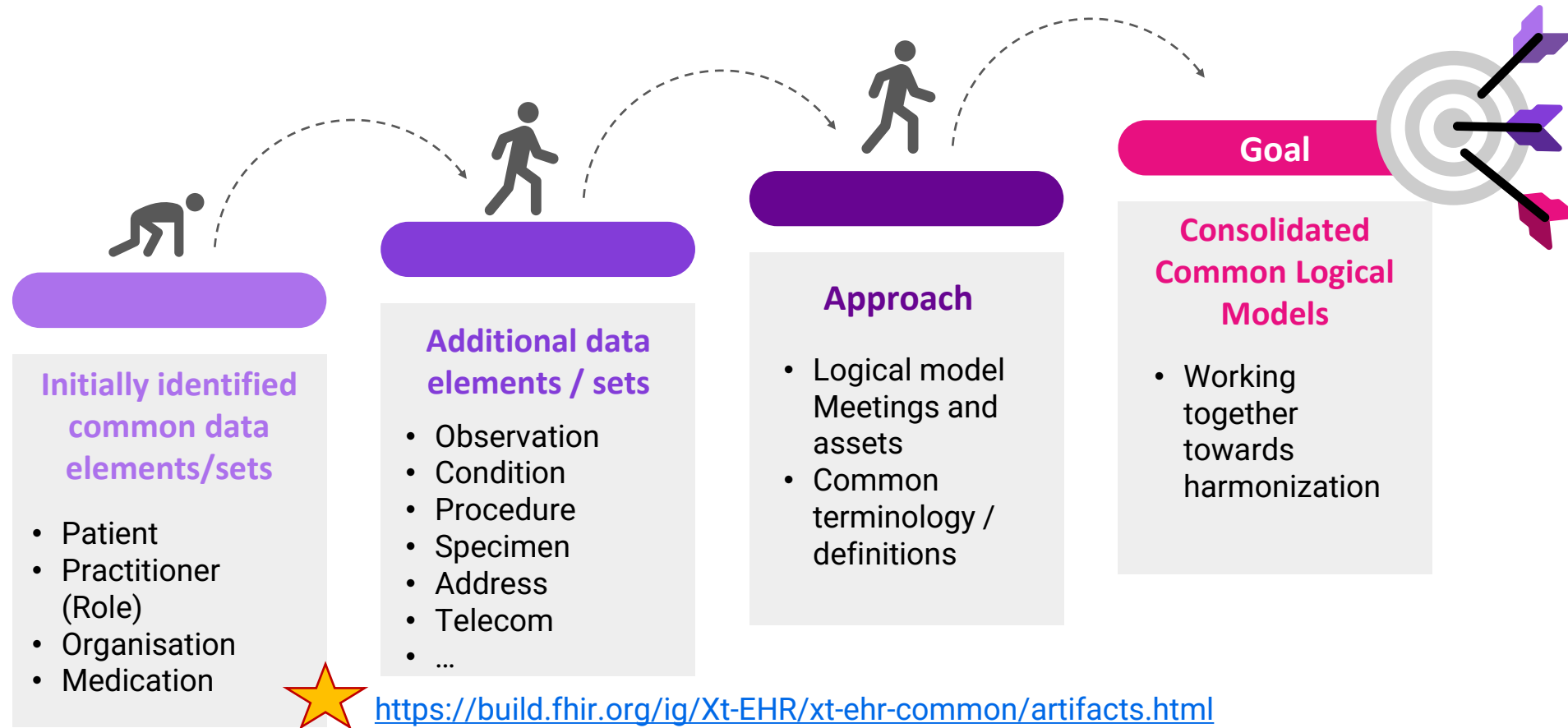
Actions related to the European electronic health record exchange format (EEHRxF)



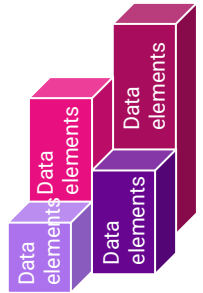
The EHDS – 1 Galaxy: eHealth strategy



Towards common logical models



Common data elements/sets



Common Data Elements/sets

used in multiple places
across the EEHRxF



Medical test results: ...

Medication-related information:

- Prescriptions and dispensations are the main concern of the e-prescription/-dispensation artefacts
- Medications are used in many non-prescription situations (drug allergy, administration, abuse, ...)



ePrescription / eDispensation (eP/eD)

Discharge reports (DR)

Medical imaging studies and related imaging reports (MISR)

Medical test results, including laboratory and other diagnostic results and related reports

Patient Summary (PS)

**Are the requirements on
medication data different
across the EEHRxF?**

WP4: Sustainability and cross-border interoperability – Progress

Sustainability plan is aimed at maintaining financial, operational, and technical viability for the EHDS, enabling cross-border health data exchange across EU MS while complying with the EHDS Regulation and GDPR. Key points addressed:

- ★ **Technical sustainability:** Ensures scalable, secure, and interoperable systems using standards like FHIR, HL7, and SNOMED. It includes continuous integration, encryption, and compliance with GDPR.
- **Operational Sustainability:** Focuses on governance structures, regular updates, cross-border collaboration, and training to maintain system efficiency.
- **Legal and Policy Sustainability:** Aligns national policies with the EHDS Regulation and GDPR, establishing governance for monitoring and compliance.
- **Financial Sustainability:** Proposes funding models and public-private partnerships for long-term financial support.
- **Implementation:** A phased approach with regular reviews ensures scalability and alignment with MS' needs.

Task 6.1 Patient Summary: EEHRxF, Requirements, and Specifications for EHR Systems

- **Progress status:**

- Draft of deliverable D6.1 in preparation, will be finalised by the 31th of October, will contain the analysis of the state-of-the-art of implementation of PS across the Union and proposals to move forward
- Collaboration with PS Cluster (f2f in Lombardy Region Delegation, Brussels, 3rd of October)
- ★ Synergies with CEN on International Patient Summary convergence (virtual meeting 17th of September) and HL7 Europé on HL7 FHIR IG on European Patient Summary (kickoff meeting 4th of October)
- Work on maturity model is on hold (initial proposal is available yet deleted from D6.1), need to align with other WPs (especially WP7 and WP8), not a subject for PS only, approach must be common to all clinical documents

- **Timeline:**

- D6.1 first draft by end of October; stable draft by May 2025 to kickstart the Stakeholders consultation process

- **Needs and main risks:**

- Shared with T6.2 (see next slide)

WP6: Electronic prescriptions and patient summary towards EHDS – Progress

- **Milestone Update**

- **MS17: Patient Summary: EEHRxF –**

- First draft of D6.1
 - Due in Oct 2024


- **MS18: Patient Summary: functional and technical requirements for EHR systems**

- Due in Apr 2025 [M18]

- **MS19: Electronic prescription and electronic dispensation: EEHRxF**

- First draft of D6.2
 - Due in Aug 2024 [M10] – pending approval for extending to Oct 2024 [M12]

- **Ongoing and Future work**

- Integration efforts with MyHealth@EU, the Patient Summary Cluster, the ePrescription Cluster, Semantics Task Force, HL7 
 - Assessment of FHIR implementation guides of Patient Summary
 - Align with WP8 on maturity models


WP7: New services for EHR systems towards EHDS

Task Descriptions


T7.1 Laboratory Results and Reports: EEHRxF, Requirements, and Specifications for EHR Systems

Develop specifications for secure, machine-readable transmission of laboratory and diagnostic data. It will include harmonized datasets, coding systems, technical standards, and quality requirements to support interoperability and data exchange as per the EHDS regulation.

T7.2 Medical Images and Reports: EEHRxF, Requirements, and Specifications for EHR Systems

Establish technical requirements for exchanging medical images and reports based on standards like HL7, FHIR, and DICOM, to support cross-border interoperability in alignment with the EHDS Regulation. 

T7.3 Discharge Reports: EEHRxF, Requirements, and Specifications for EHR Systems

Specify requirements for the interoperable exchange of discharge reports using standards such as HL7 CDA, FHIR, and SNOMED, and provide implementation guides to facilitate cross-border exchange within the EHDS framework. 

Key Objectives

1. EEHRxF for Medical Images, Laboratory Results, and Discharge Letters:

Develop requirements for implementing the EEHRxF to securely exchange medical images, laboratory results, and discharge letters, supporting the European Health Data Space (EHDS).

2. Implementation Guides for EHR Systems:

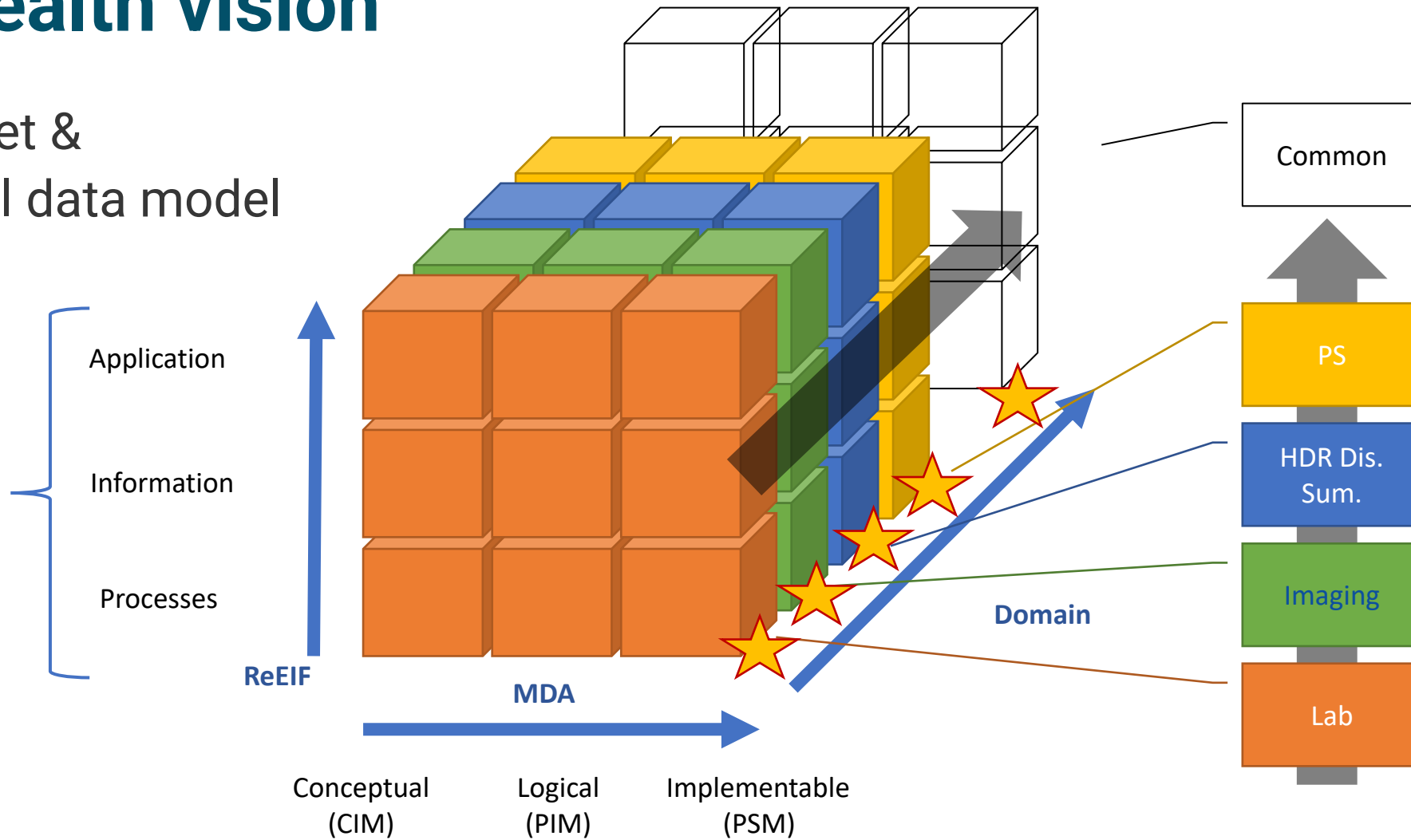
Create implementation guides that define common specifications for processing medical images, laboratory results, and discharge letters across different EHR systems.

3. Analysis of Common Specifications:

Analyze and harmonize common specifications across various services (medical images, lab results, discharge letters) to ensure interoperability.

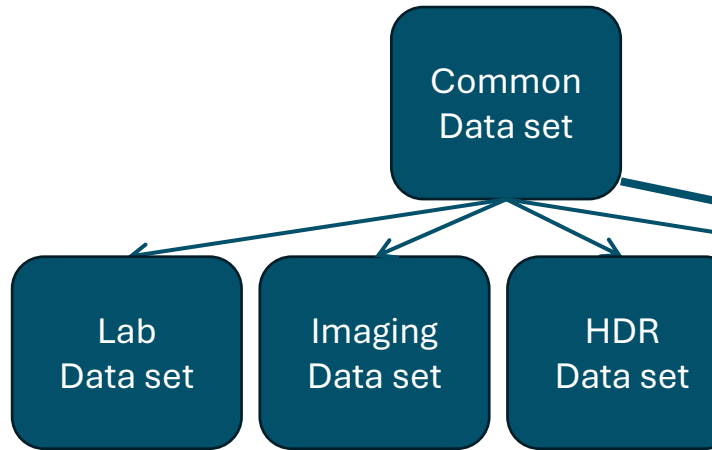
X-eHealth vision

- Data set & Logical data model

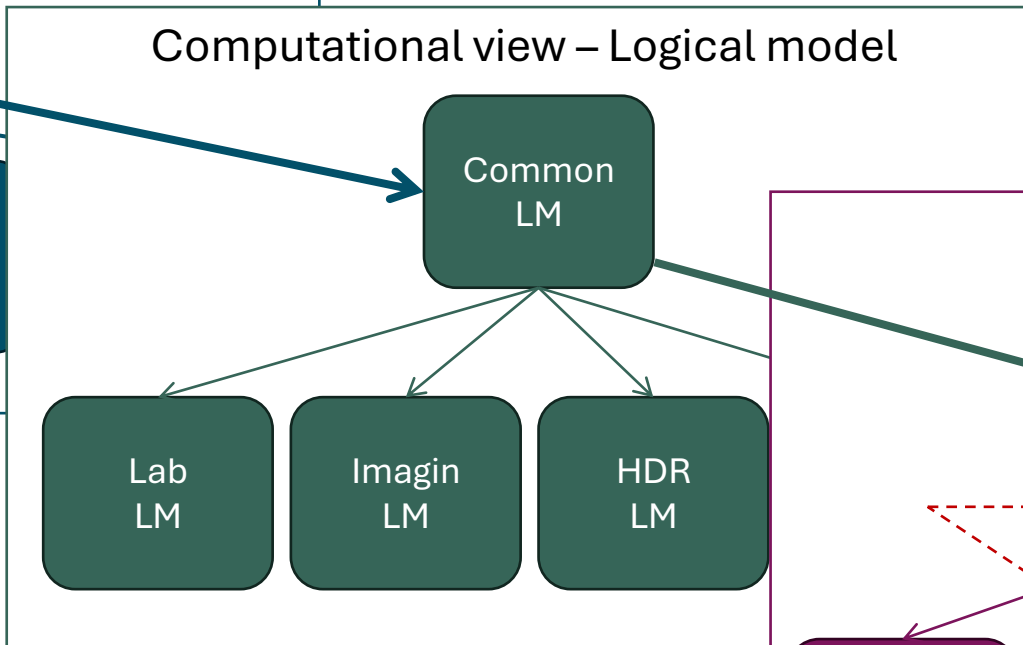


Artefacts at different levels of the MDA

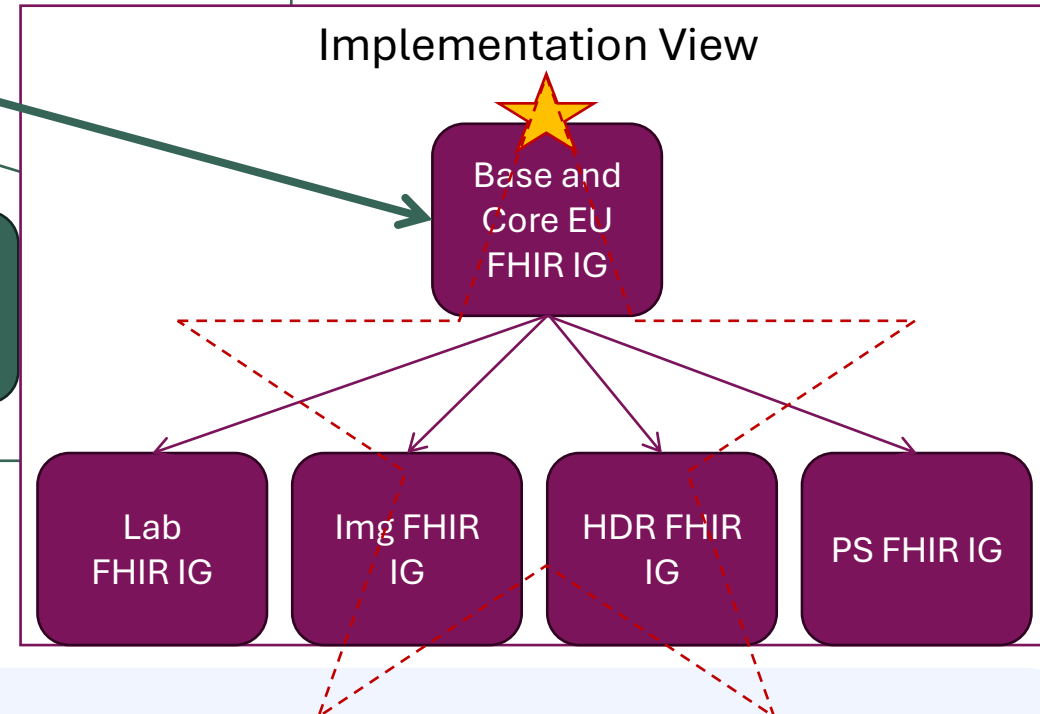
Conceptual view – Functional spec & data sets



Computational view – Logical model



Implementation View





Xt-EHR, published by Xt-EHR. This guide is not an authorized publication; it is the continuous build for version 0.1.0 built by the FHIR (HL7® FHIR® Standard) CI Build. This version is based on the current content of <https://github.com/Xt-EHR/xt-ehr-common/> and changes regularly. See the [Directory of published versions](#)

5 Artifacts Summary

This page provides a list of the FHIR artifacts defined as part of this implementation guide.

5.0.1 EHDS Common Logical Models

Information Models for implementing EEHRxF services under EHDS. Format based on ISO 13972 "Health informatics — Clinical information models — Characteristics, structures and requirements."

Address (model)	C.5 - EHDS refined base model for Address structure
Allergy Intolerance	C.21 - EHDS refined base model for Allergy Intolerance
Appointment (model)	C.20 - EHDS refined base model for Appointment
Attachment (model)	C.7 - EHDS refined base model for This type is for containing or referencing attachments - additional data content defined in other formats. The most common use of this type is to include images or reports in some report format such as PDF. However, it can be used for any data that has a MIME type.
Care plan (model)	C.19 - EHDS refined base model for Care plan
Condition (model)	C.15 - EHDS refined base model for A clinical condition, problem, diagnosis, or other event, situation, issue, or clinical concept that has risen to a level of concern.
Device (model)	C.12 - EHDS refined base model for Device information
Goal (model)	C.XX - EHDS refined base model for Goal
Group (model)	C. - EHDS refined base model for Group
Health professional (model)	C.2 - EHDS refined base model for Health professional (HP)
Health professional role (model)	C.4 - EHDS refined base model for Role and location details associated with a practitioner that are applicable to the healthcare event.

Contents:

- EHDS Common Logical Models
- EHDS ePrescription and eDispense Logical Models
- EHDS Laboratory Domain Logical Models
- EHDS Imaging Domain Logical Models
- eHN Guidelines Data Sets
- Structures: Logical Models
- Structures: Data Type Profiles