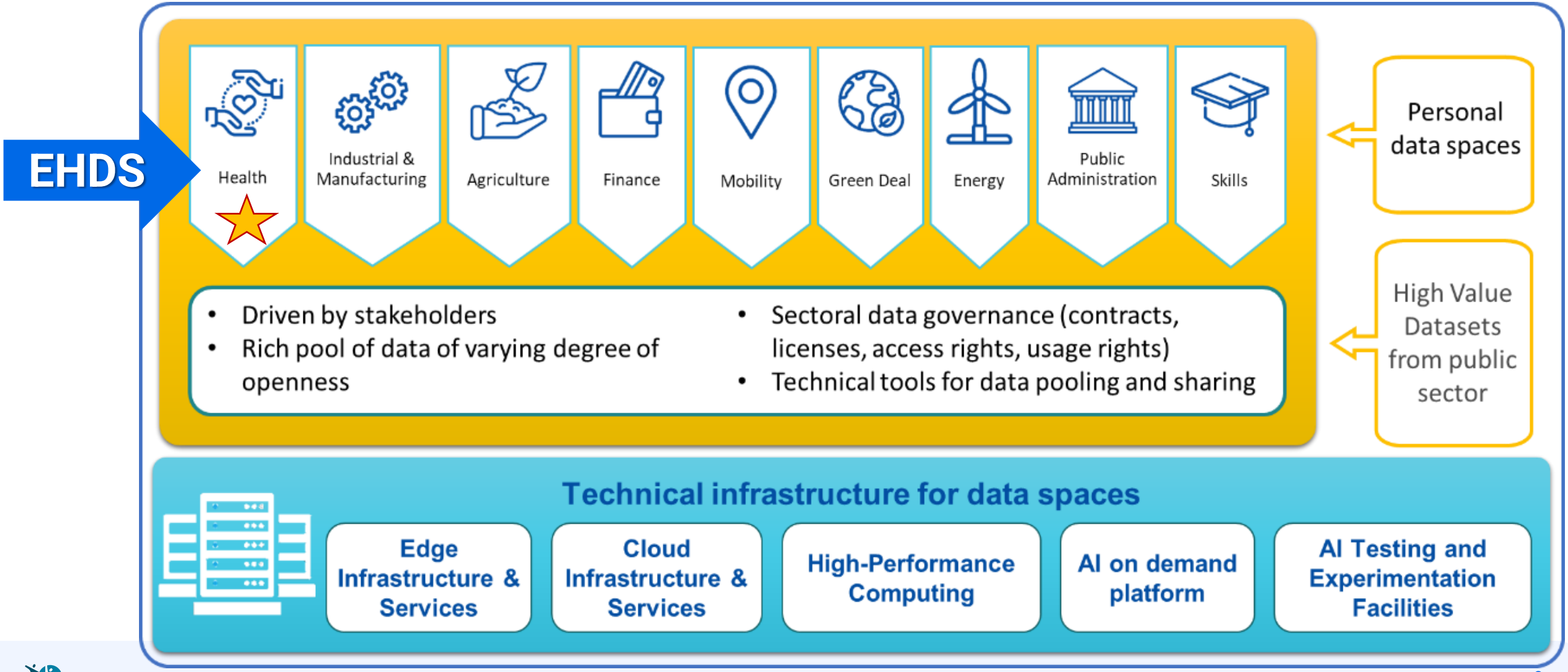
Helsedirektoratet

EHDS og FHIR

EHDS arbeidet og FHIR i EHDS spesifikasjoner

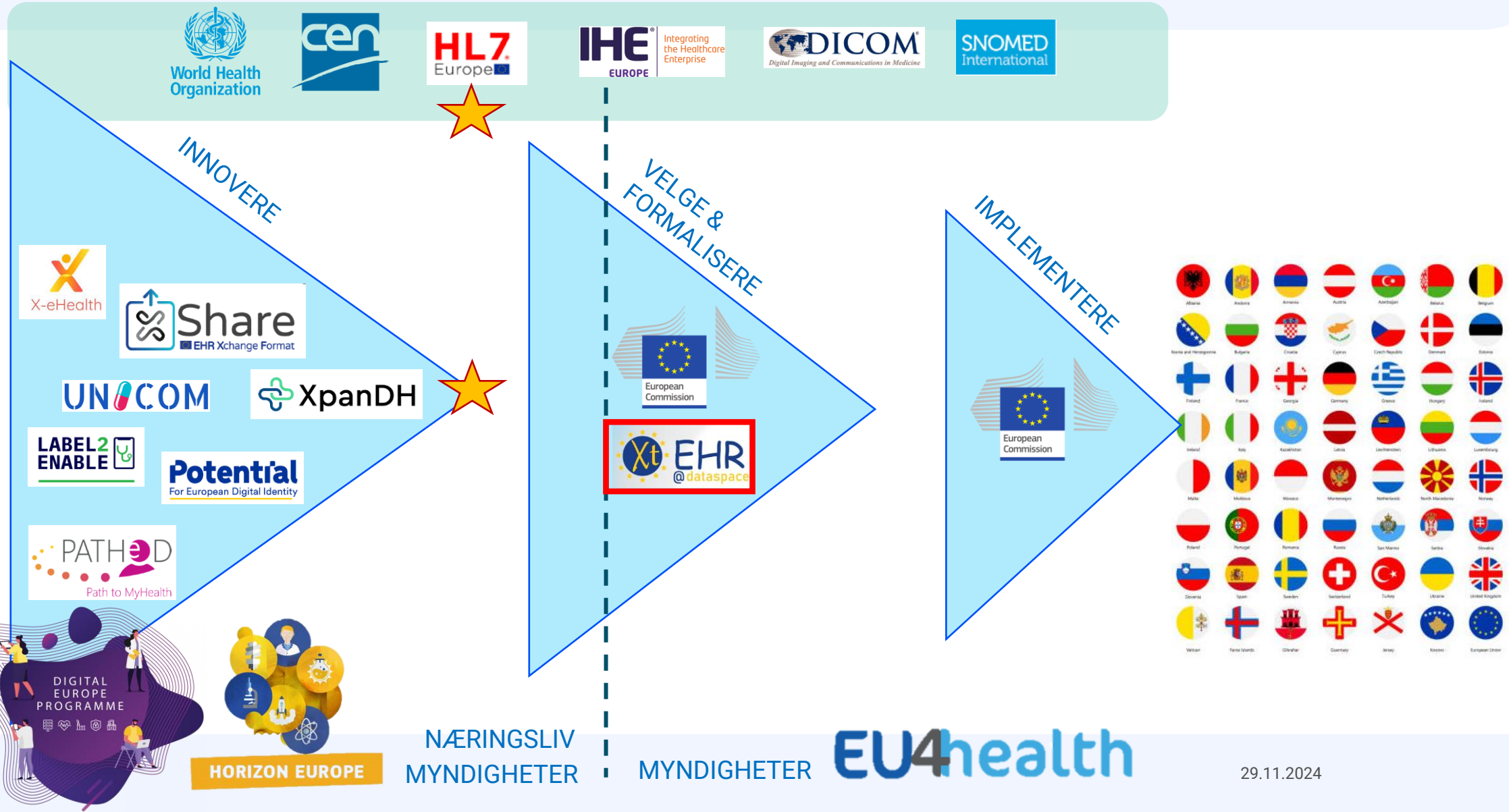
HL7 – FHIR Fagforum #27 : Europeisk standardiseringsarbeid og standardisering i Helsedirektoratet

Health is the first common EU data space => EDS



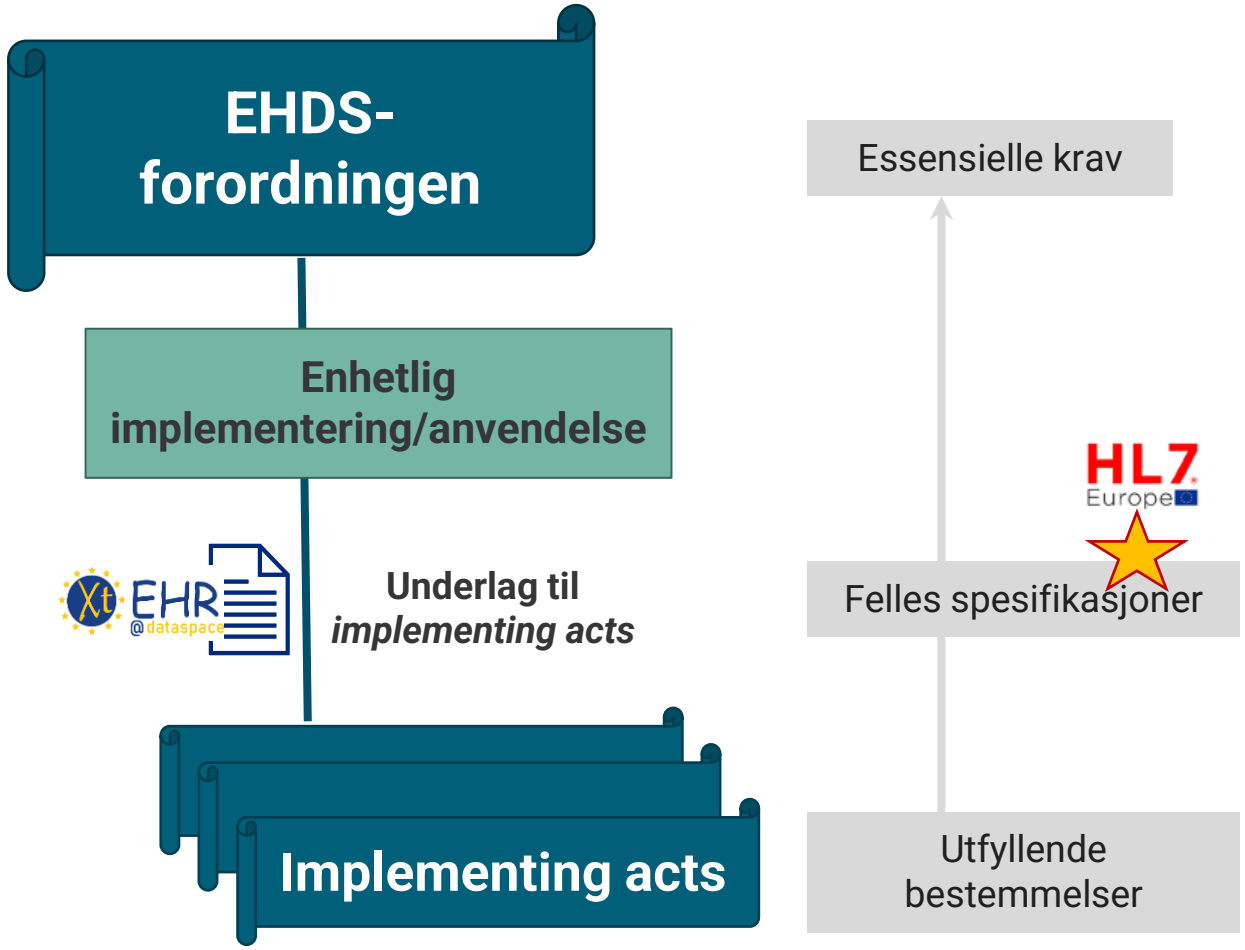
[1] How to make common European data spaces a reality | data.europa.eu

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.

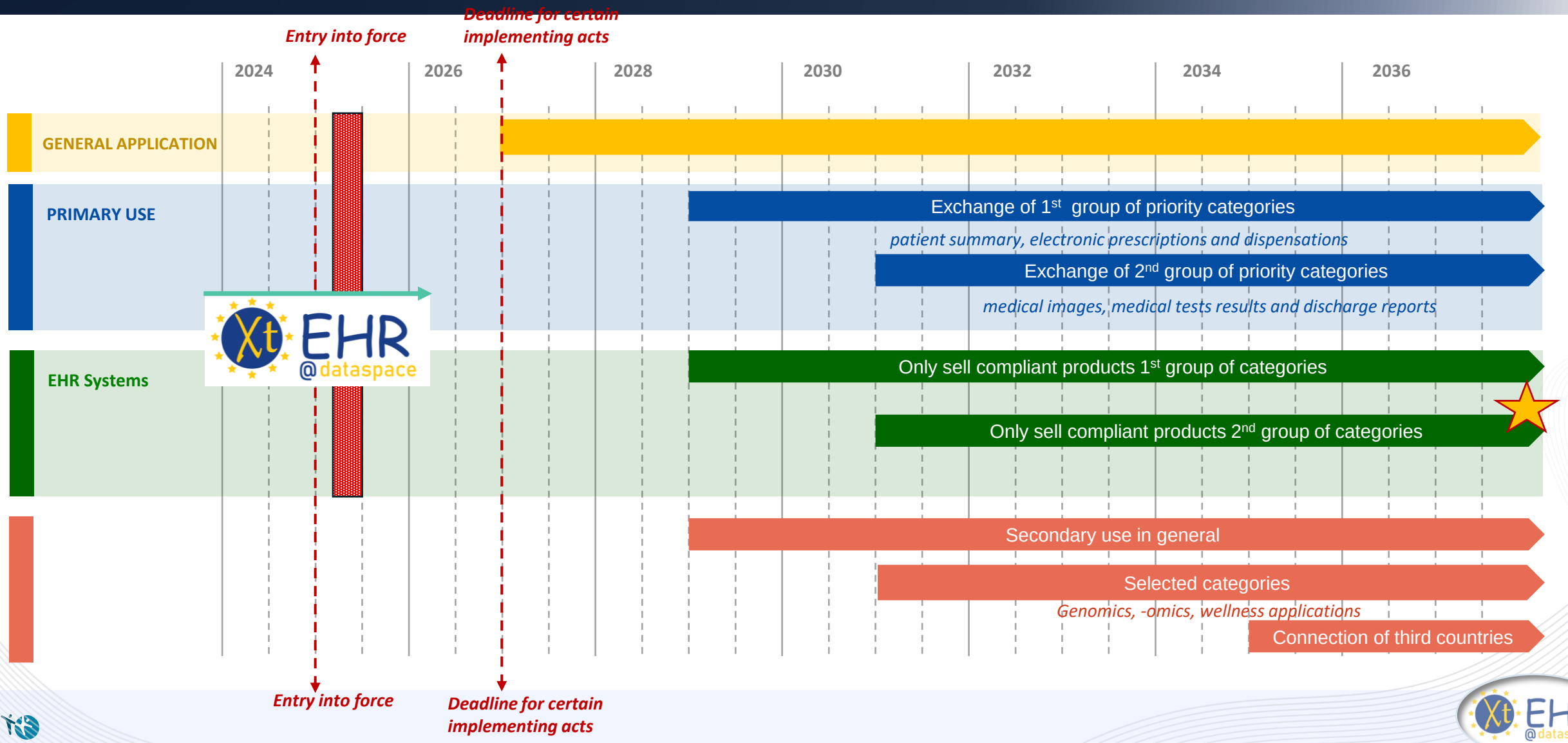


Xt-EHR Joint Action – hovedoppdrag

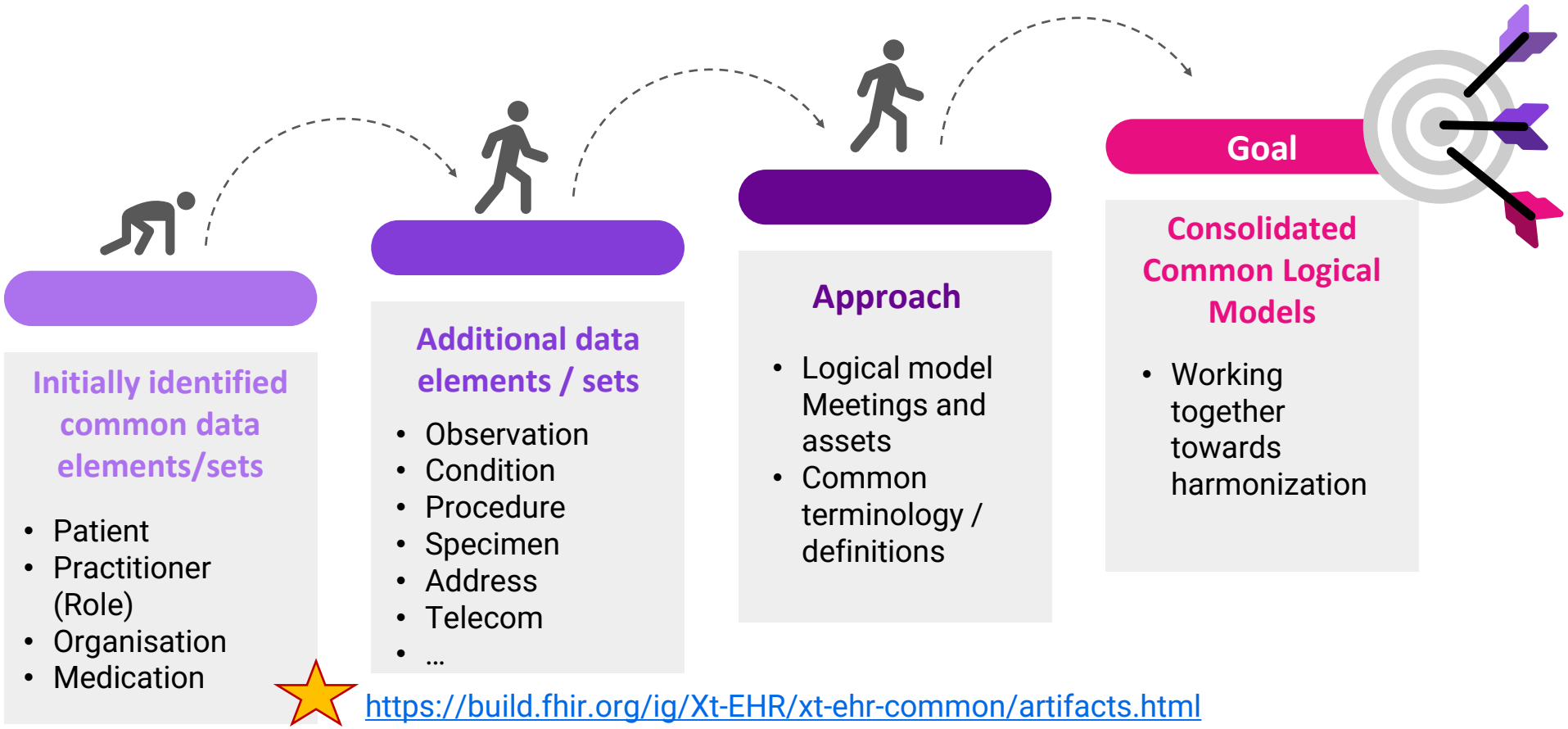
Utarbeide felles europeiske spesifikasjoner

- **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

EHDS – Tidslinje og mulighet for innspill

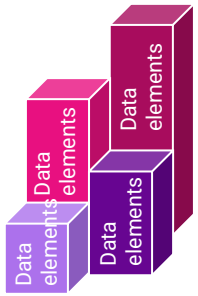


Towards common logical models



https://build.fhir.org/ig/Xt-EHR/xt-ehr-common/artifacts.html

Common data elements/sets



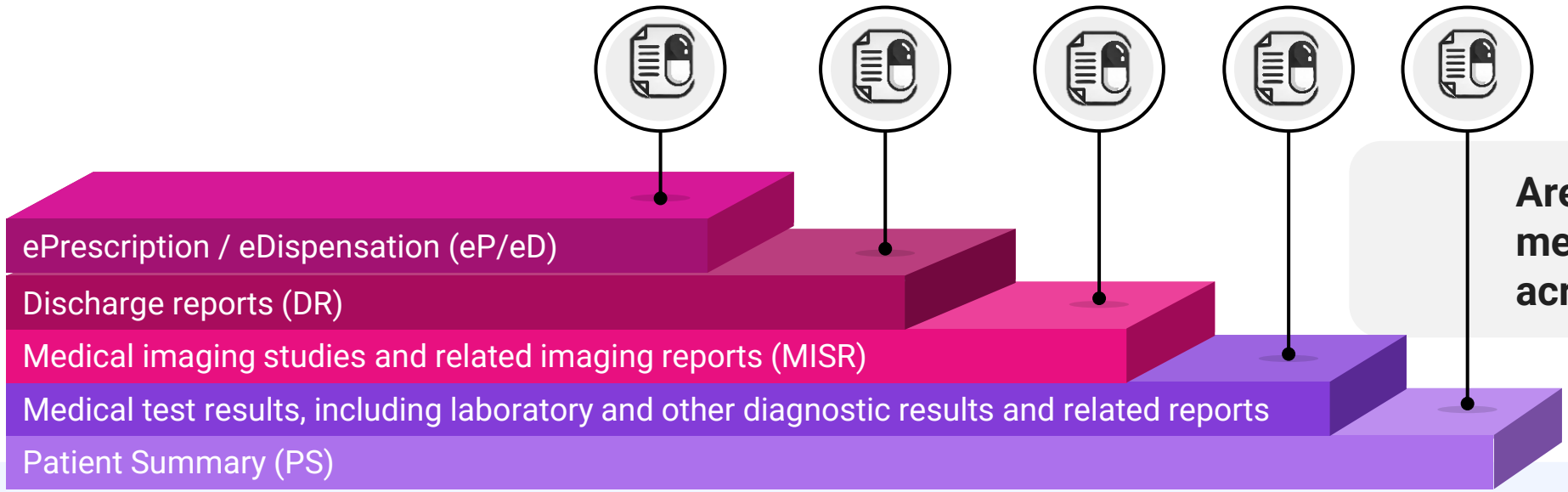
Common Data Elements/sets

used in multiple places across the EEHRxF

Medical test results: ...

Medication-related information:

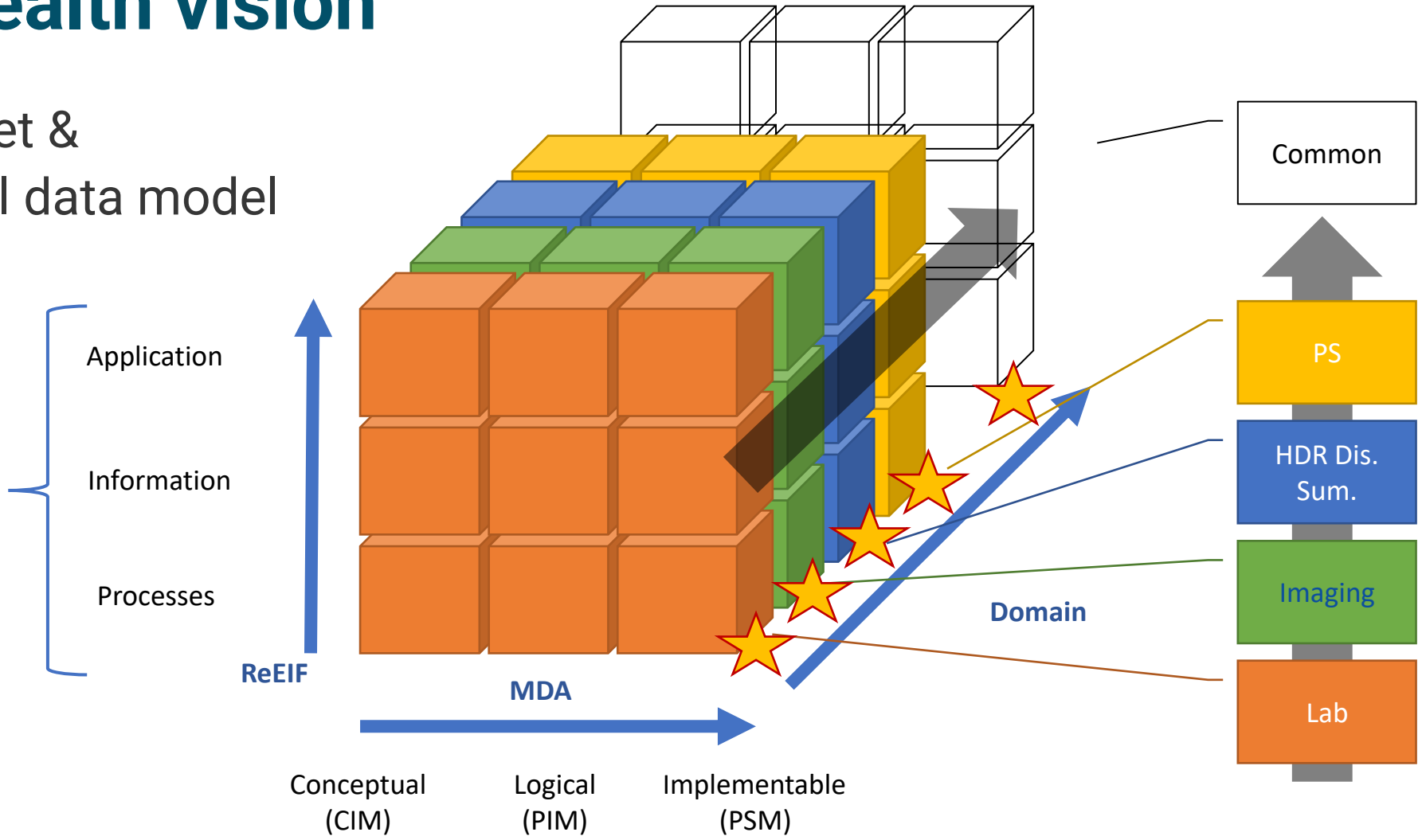
- Prescriptions and dispensations are the main concern of the e-prescription/-dispensation artefacts
- Medications are used in many non-prescription situations (drug allergy, administration, abuse, …)



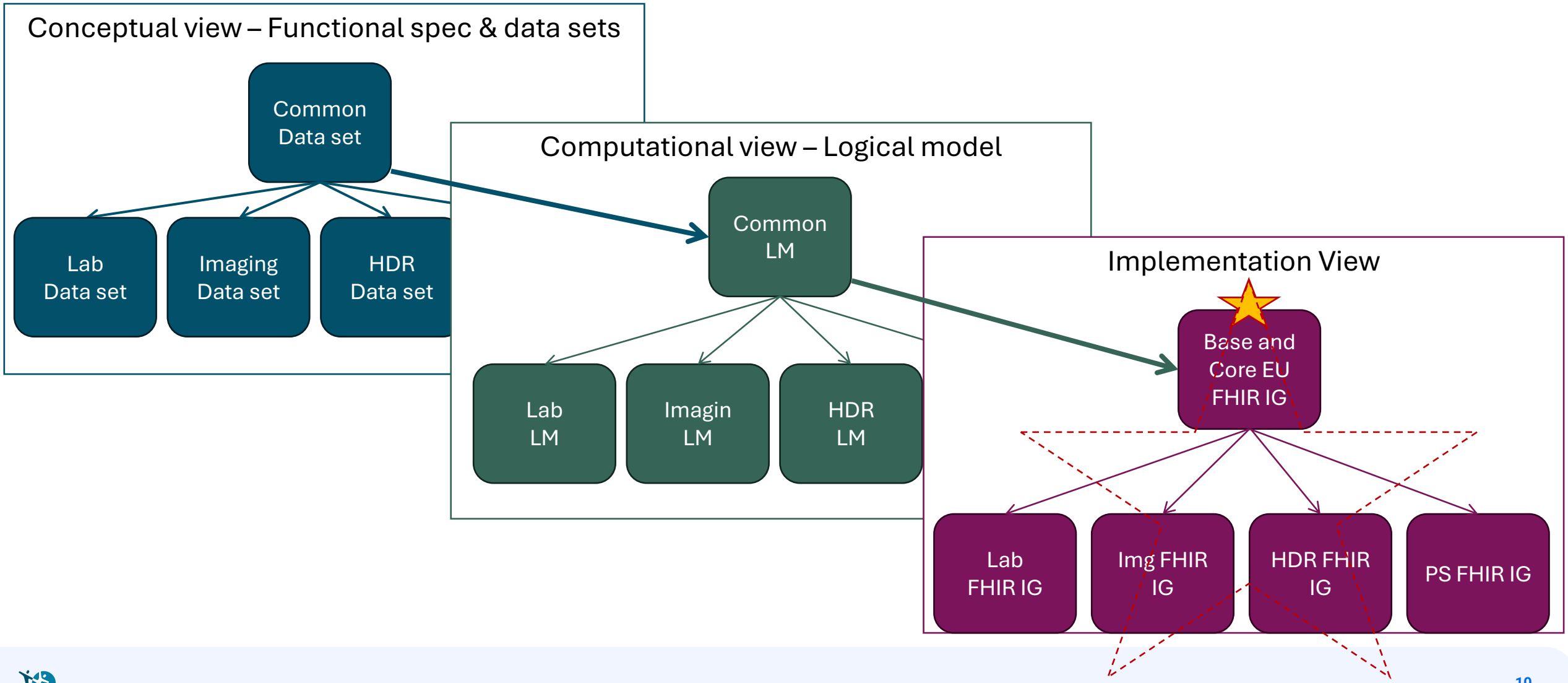
Are the requirements on medication data different across the EEHRxF?

X-eHealth vision

- Data set &
  Logical data model



Artefacts at different levels of the MDA



EHDS-krav til felles format (art. 6)

- Krav om å bruke europeiske formater ved elektronisk utveksling av helseinformasjon
  - ePrescription
  - Patient Summary
  - Lab reports
  - Imaging reports
  - Discharge reports
- Grunnlag for arbeidet: eHN guidelines, MyHealth@EU requirements catalogue, X-eHealth informasjonsmodeller mm.

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** –
    - Frist 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.

https://build.fhir.org/ig/Xt-EHR/xt-ehr-common/artifacts.html

Xt-EHR
0.1.0 - ci-build

Home | About | EHDS Use Cases | Artifacts

Table of Contents > **Artifacts Summary**

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.

Contents:

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.

Takk -> over til Linn

Helsedirektoratet

EHDS på norsk?

Deltagelse inn i Europeisk implementasjonsguider og Helse-NIM

Linn Brandt, Helsedirektoratet, avd. Kodeverk

Det gjøres mye arbeid for å spesifisere detaljer i EHDS skal inneholde… skal si litt om noe av det

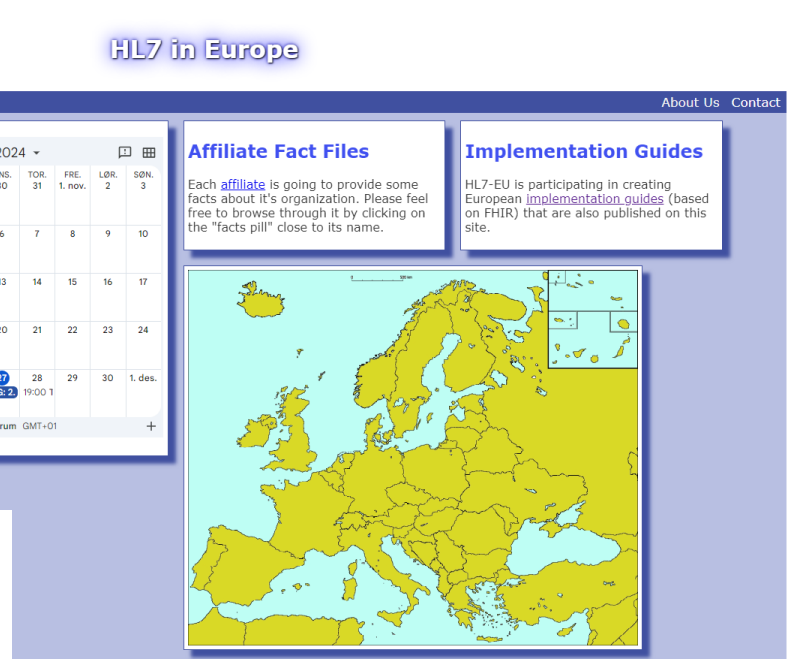
- **Xt-EHR**: myndighetssamarbeid for å jobbe med forslag til implementing acts
- **MyHealth@EU**: cross-border deling av helsedata for pasientbehandling
- Flere EU prosjekter: XpanDH, X-eHealth, X-Share
- Arbeid med Europeiske Implementasjonsguideline i **HL7 Europe**
- **Helse-NIM**: Nasjonale informasjonsmodeller for Helse

Europeiske spesifikasjoner

Utarbeide felles europeiske spesifikasjoner

- ePrescription/eDispensation = **Xt-EHR**, **MyHealth@EU**, **HL7 Europe, Helse-NIM**
- Patient Summary = **Xt-EHR**, **MyHealth@EU**, **HL7 Europe, Helse-NIM**
- Lab = **Xt-EHR, MyHealth@EU**, **HL7 Europe**
- Bilder = **Xt-EHR**
- Epikrise **Xt-EHR**, **MyHealth@EU**, **HL7 Europe**

HL7 Europe



- HL7 Europe Laboratory Report (2023-2024): lenke
- HL7 Europe Medication Prescription and Dispense: lenke
  - Møter annenhver torsdag 16-17
- HL7 Europe Hospital Discharge Report: lenke og HL7 Europe Patient Summary: lenke
  - Møter hver fredag 10-11

I arbeidet i HL7 Europe: Bruker profilene til International Patient Summary (IPS)

Differential Table | **Key Elements Table** | Snapshot Table | Statistics/References | All

Name	Flags	Card.	Type	Description & Constraints
AllergyIntolerance	C	0..*	AllergyIntoleranceUvIps(2.0.0)	Allergy or Intolerance (generally: Risk of adverse reaction to a substance) **ait-1:** AllergyIntolerance.clinicalStatus SHALL be present if verificationStatus is not entered-in-error. **ait-2:** AllergyIntolerance.clinicalStatus SHALL NOT be present if verification Status is entered-in-error
implicitRules	?! Σ	0..1	uri	A set of rules under which this content was created
Slices for extension				Content/Rules for all slices
modifierExtension	?!	0..*	Extension	Extensions that cannot be ignored
clinicalStatus		0..1	CodeableConceptIPS(2.0.0)	Current allergy or Intolerance status **Binding:** AllergyIntoleranceClinicalStatusCodes (required): The clinical status of the allergy or intolerance.
verificationStatus		0..1	CodeableConceptIPS(2.0.0)	Certainty **Binding:** AllergyIntoleranceVerificationStatusCodes (required): Assertion about certainty associated with a propensity, or potential risk, of a reaction to the identified substance.
type	S Σ	0..1	code	Type of propensity **Binding:** AllergyIntoleranceType (required): Identification of the underlying physiological mechanism for a Reaction Risk.
criticality	Σ	0..1	code	Criticality **Binding:** AllergyIntoleranceCriticality (required): Estimate of the potential clinical harm, or seriousness, of a reaction to an identified substance.
code	S	1..1	CodeableConceptIPS(2.0.0)	Concept - reference to a terminology or just text **Binding:** Allergy Intolerance - IPS (preferred): Type of the substance/product, allergy or intolerance condition or a code for absent/unknown allergy.

I arbeidet i HL7 Europe: Knytter dataelementer til informasjonselementene i EU eHealth Network (eHN) guidelines

Differential Table | **Key Elements Table** | Snapshot Table | Statistics/References | All

Name	Flags	Card.	Type	Description & Constraints
Allergy		0..*	Base	A.2.1.1 - Allergy **Instances of this logical model are not**
description		0..*	BackboneElement	A.2.1.1.1 Allergy description
type		0..*	string	A.2.1.1.2 Type of propensity
manifestation		0..*	CodeableConcept	A.2.1.1.3 Allergy manifestation
severity		0..*	BackboneElement	A.2.1.1.4 Severity
criticality		0..*	CodeableConcept	A.2.1.1.5 Criticality
onsetDate		0..*	CodeableConcept	A.2.1.1.6 Onset date
endDate		0..*	dateTime	A.2.1.1.7 End Date
status		0..*	dateTime	A.2.1.1.8 Status
certainty		0..*	CodeableConcept	A.2.1.1.9 Certainty
agent		0..*	CodeableConcept	A.2.1.1.10 Agent or Allergen

4.1 PATIENT SUMMARY HEADER

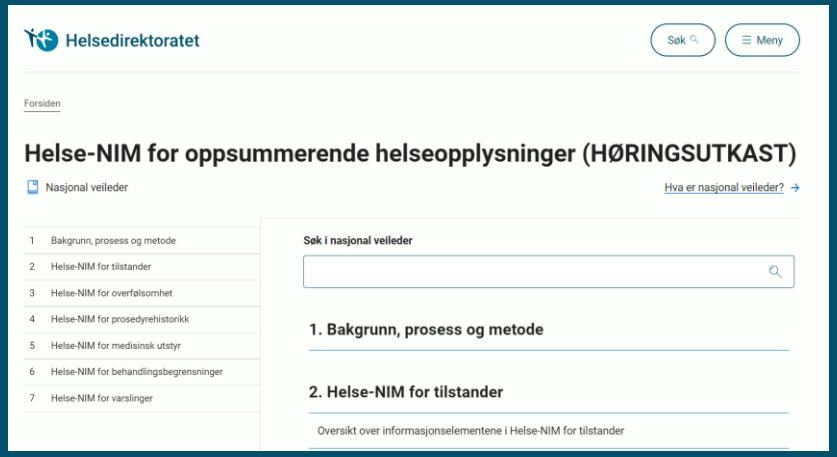
Data Element		Description	Preferred Code Systems * **
A.1 Patient summary header data elements			
A.1.1 Identification of the patient/subject			
A.1.1.1	National healthcare patient ID	Country ID, unique to the patient in that country. Example: ID for Portuguese patient	
A.1.1.2	Family name/surname	The given name/first name of the patient (also known as forename or first name). This field can contain more than one element.	
A.1.1.3	Given name	The family name/surname/last name of the patient. This field can contain more than one element or multiple fields could be present.	
A.1.1.4	Date of birth	The date of birth of the patient [ISO TS 22220]. As age of the patient might be important for correct interpretation of the test result values, complete date of birth should be provided.	Complete date, without time, following the ISO 8601
A.1.1.5	Gender	This field must contain a recognised valid value for "administrative gender". If different, "physiological gender" should be communicated elsewhere.	HL7 Administrative Gender

HL7 Europe arbeidet

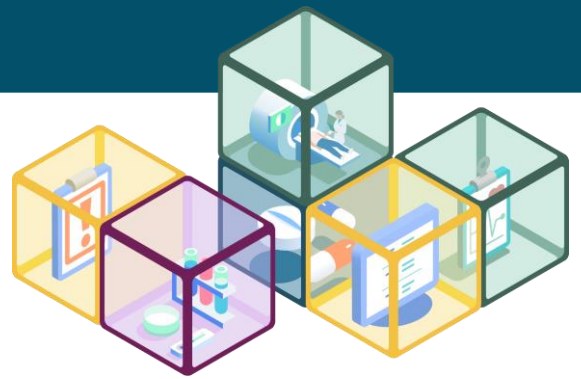
- Er viktig underlag for både Xt-EHR og MyHealth@EU, derav også den endelige EHDS forordningen med implementing acts.
- Er åpent tilgjenglig for deltagelse
- Viktig diskusjonsforum
- Mange deltagere fra hele Europa, alle med sin erfaring i bagasjen. Deltagelse fra Norge kan være viktig for å dele våre erfaringer

Helsedirektoratet

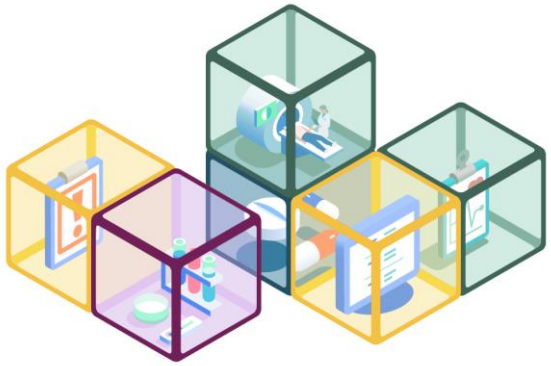
Helse-NIM



Nasjonale Informasjonsmodeller for helse

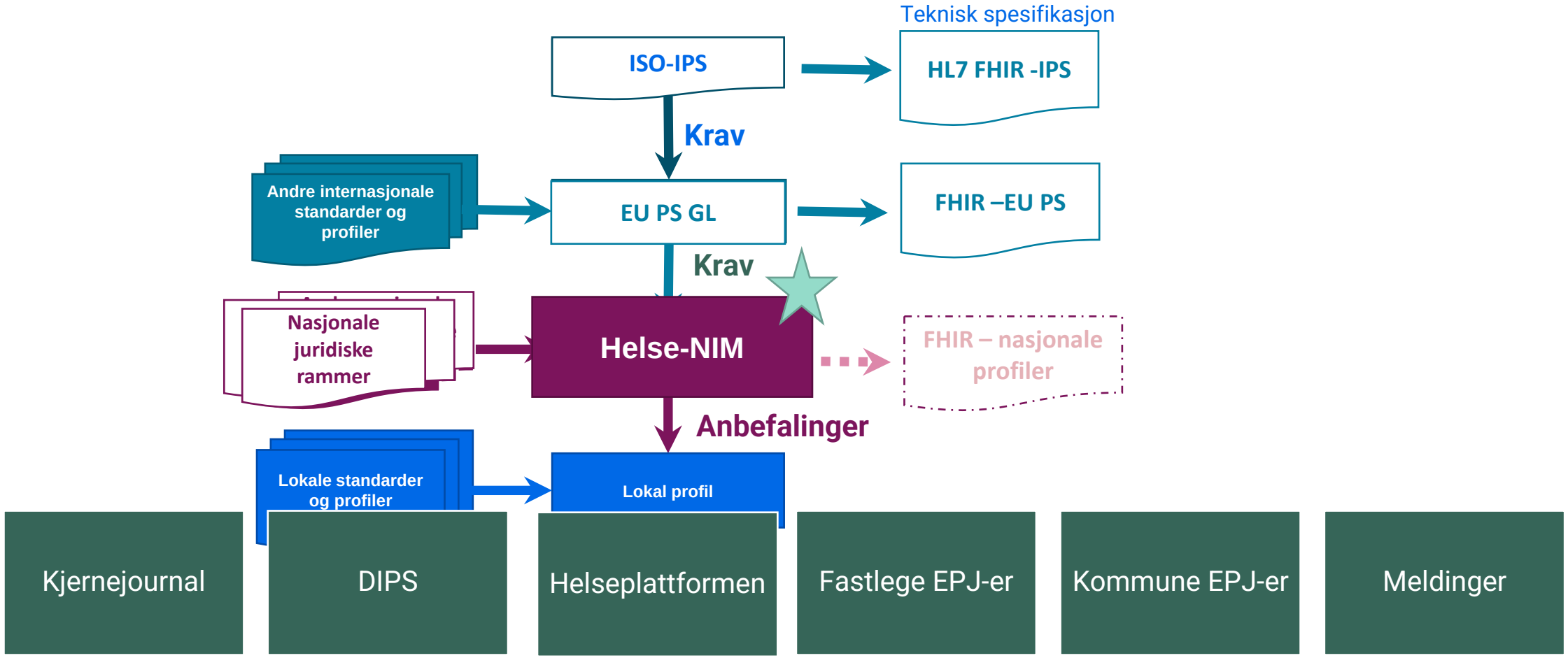


Hva er Helse-NIM?



- En Helse-NIM beskriver et utvalg informasjonselementer som er felles for et visst område
- Definerer informasjonselementer og hvilke kodeverk og terminologier som foreslås
- Tar utgangspunkt i BÅDE internasjonale krav og nasjonale behov
- Det vil si at krav gjennom EHDS vil være førende, men klinisk praksis, eksisterende løsninger, lover og regler og div andre ting også må tas hensyn til…
- Beskriver ikke hvordan informasjonen teknisk sett skal implementeres i IT-løsninger. Dvs, er ikke FHIR-profiler (eller arketyper, eller annet…). Tabell og tekst.

Hvor er Helse-NIM i hierarkiet av standarder: Eksempel Patient summary



Kunnskapsgrunnlag: Gap-analyser og oversikter

Datapunkt	ISO-IPS Problems	ISO-IPS History of past problems	FHIR IPS IG	EU-PS GL	EU myhealth@eu	Kjernejournal
			obligatoriske å støtte.			
Innholdsstatus	**Problems content status** (innholdsstatus) [C] The patient has no problems to be reported or the problem information is unavailable		Inkl i **code**		Et av kodeverkene i <value>: eHDSIAbsentOrUnknownProblem	
Tilstand	**Diagnosis** Et kodet element. (R)	**Diagnosis** Et kodet element. (R)	**Code** [1..1] [S] "Code for a clinical problem that is selected from SNOMED CT or a code for absent/unknown problem"	**A.2.3.1.1 Problem / diagnosis description** "Health conditions affecting the health of the patient and are important to be known for a health professional during a health encounter." [ICD-10* SNOMED CT GPS, Orphacode]	The **<value>** is the condition that was found. This element is **required**. While the value may be a coded or an un-coded string, the type is always a coded value (xsi:type='CD'). If coded, the code and codeSystem attributes shall be present. The value set to be used when this template is specialized for describing adverse reaction is eHDSIReactionAllergy. The value of @code should be drawn from value set 1.3.6.1.4.1.12559.11.10.1.3.1.42.5 eHDSIIllnessandDisorder (DYNAMIC) or The value of @code should be drawn from value set 1.3.6.1.4.1.12559.11.10.1.3.1.42.50	Diagnose: - ICD-10 - Absoluttlisten: https://www.nhn.no/tjenester/kjernejournal/dokumentasjon-for-kjernejournal/nyttig-dokumentasjon-for-helsepersonell/Absoluttliste%20-%20nettversjon%200721.pdf (KJ 7512 Kritisk medisinsk tilstand)
Start dato	**Onset date** Dato-Tid (RK)					
Kategori	**Problem type** (RK). Kodet element. Kategorier som "sykdom", "c risk", "medical alerts" [Kritisk med. tilstan være en slik type, selv om det ikke gis som e teksten]					

Tilstander/ Condition/ Problem	ISO-IPS	FHIR-IPS	MyHealth@EU	Klinisk praksis	Kjerne-journal	EEHRxF
Innholdsstatus	**Ja** [C].	**Ja**	**Ja**	**Nei**	**Nei**	**Ikke klarlagt**
Kategori	**Ja** [RK].	**Ja** [0..*] [S]	**Ja** [1..1] [R].	Ja [Ulikt]	Tja [Ulikt]	**Ikke klarlagt**
Tilstandskode	**Ja** [R].	**Ja** [1..1] [S]	**Ja** [1..1] [R].	Ja [Likt, ICD]	Tja [Ulikt]	**Ikke klarlagt**
Kommentar	**Ja** [R]	**Ja** [0..1] (2 felt)	**Ja** [0..*] [O].	**Nei**	Ja	**Ikke klarlagt**
Alvorlighetsgrad	**Ja** [RK]	**Ja** [0..1] [S]	**Ja** [0..1] [R].	**Nei**	**Nei**	**Ikke klarlagt**
Startdato	**Ja** [RK]	**Ja** [S] [0..1]	**Ja** [0..1] [R].	**Nei**	**Nei**	**Ikke klarlagt**
Sluttdato	**Ja** [RK]	**Ja** [0..1]	**Ja** [0..1] [C].	**Nei**	**Nei**	**Ikke klarlagt**
Verifikasjons-status	-	**Ja** [0..1]	**Ja** [0..1] [R].	**Nei**	**Nei**	**Ikke klarlagt**
Klinisk status	**Ja** [O]	**Ja** [0..1] [S]	**Ja** [0..1] [R].	**Nei**	Ja [Likt]	**Ikke klarlagt**
Dokumentasjonsdato	-	**Ja** [0..1]	-	Ja	Ja	**Ikke klarlagt**

Underveis sendte vi ut forslag og gap-analyser for hvert tema, hadde innspillsmøter (demo) med diskusjon

- Mer enn 70 påmeldte til demoene
- Virksomheter (Helseforetak, kommuner)
- Leverandører
- Interesseorganisasjoner
- Standardiseringsorganisasjoner
- Flere etater

18. Januar kl 14:00-15:00
- **Tema**: Hva er arbeidet med nasjonal informasjonsmodell for kritisk info? Hva er IPS?
- **Relevante kategorier:**
  - Alle

15. Februar kl 14:00-15:00
- **Tema**: Tilstander
- **Relevante kategorier:**
  - Smitte
  - Kritiske medisinske tilstander
  - Komplikasjoner ved anestesi

21. Mars kl 14:00-15:30
- **Tema**: Revidert informasjonsmodell for overfølsomhetsreaksjoner etter høringsrunde i 2023
- **Relevante kategorier:**
  - Overfølsomhet

18. April kl 14:00-15:30
- **Tema**: Implantert medisinsk utstyr og prosedyrer
- **Relevante kategorier:**
  - Implantater / pågående behandling

15. Mai kl 14:00-15:30
- **Tema**: Endring i behandlingsrutiner
- **Relevante kategorier:**
  - Endring i behandlingsrutiner

14. Juni kl 12:00-13:30
- **Tema**: Annen varslingsinformasjon, Oppsummering
- **Relevante kategorier:**
  - Alle

3. Helse-NIM for overfølsomhet

Helse-NIM for overfølsomhet er en liste som inneholder informasjon om unormale reaksjoner, symptomer eller funn initiert av eksponering for en definert stimulus i en dose som normalt tolereres av andre. Informasjon om en pasients overfølsomhet er relevant i mange situasjoner, som ved vaksinasjon, kost på institusjon, rekvirering og utlevering av legemidler, herunder inkludert muligheten til å dele informasjon om en avkreftet overfølsomhet.

Oversikt over informasjonselementene i Helse-NIM for overfølsomhet

UML-diagram for Helse-NIM for overfølsomhet

Innholdsstatus

Klinisk status

Startdato

Sluttdato

Verifikasjonsstatus

Type

Kategori

Alvorlighetsgrad av overfølsomheten

Agens

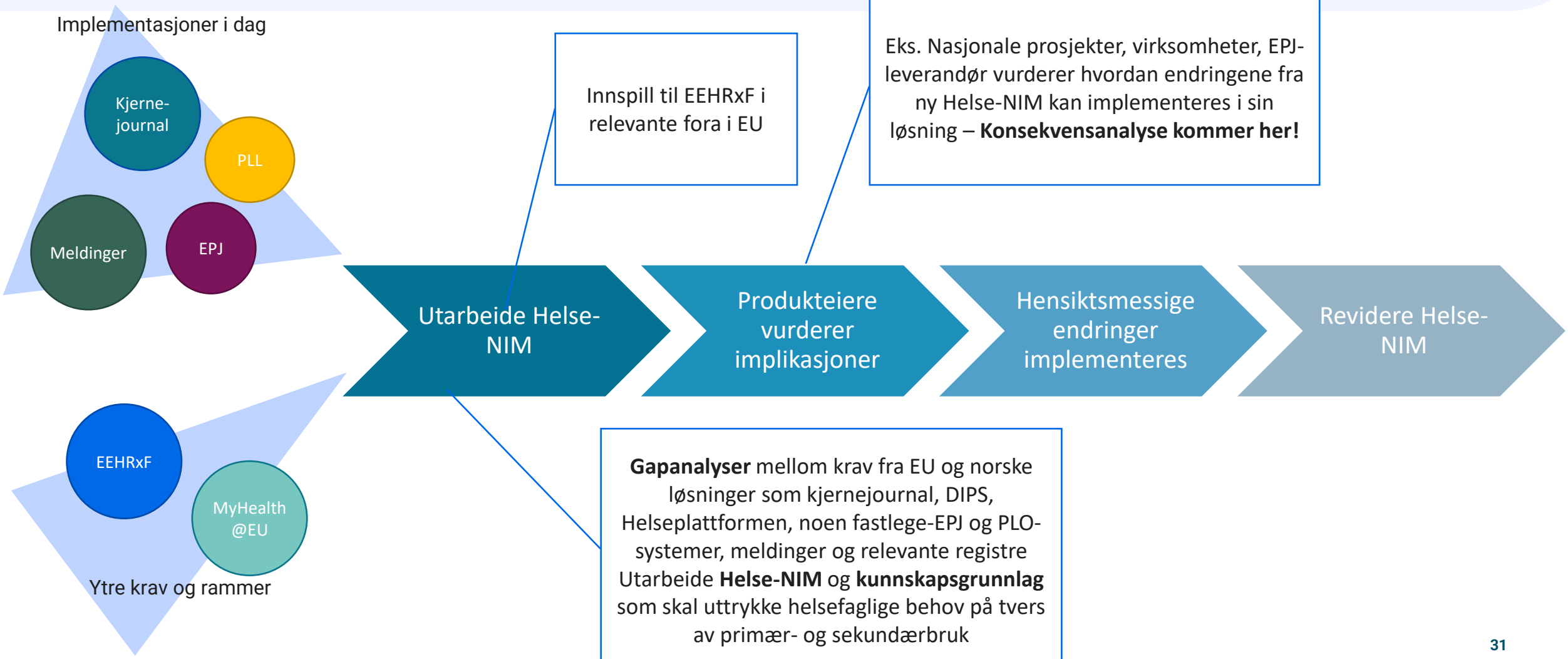
Kommentar

Dokumentasjonsdato

Reaksjon

Informasjonselement	Beskrivelse	Forslag til kodesystem
Overfølsomhet	Liste	
Innholdsstatus	Forklaring på eventuell manglende informasjon Informasjon om ingen kjente allergier eller om allergi-informasjon mangler	Kodet HL7 verdisett: Absent or unknown allergies
Overfølsomhet		
Klinisk status	Om overfølsomheten er aktiv	Kodet HL7 verdisett: AllergyIntoleranceClinicalStatusCodes
Startdato	Tidspunkt da overfølsomheten eller den uønskede reaksjonen ble konstatert. Tidspunkt kan være spesifikk (dag-tidspunkt) eller uspesifikk (årstall, tiår).	Dato
Sluttdato	Tidspunkt da overfølsomheten eventuelt sluttet. Tidspunkt kan være spesifikk (dag-tidspunkt) eller uspesifikk (årstall, tiår).	Dato
Verifikasjonsstatus for overfølsomhet	Om overfølsomheten er bekreftet eller hvor sannsynlig den antatte sammenhengen er mellom agens og pasientens reaksjon	Kodet HL7 verdisett: AllergyIntoleranceVerificationStatus
Type	Underliggende mekanisme som forårsaker reaksjonen	Kodet HL7 verdisett: AllergyIntoleranceType
Kategori	Hvilken kategori av agens som kan knyttes til overfølsomheten	Kodet HL7 verdisett: AllergyIntoleranceCategory

Hvordan går vi fram?



Helse-NIM har flere formål

Legge grunnlaget bedre samhandling internt i Norge

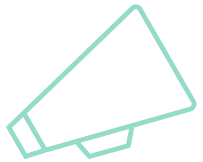
- Støtte samhandling internt i Norge gjennom at virksomheter kan bruke Helse-NIM til å strukturere informasjon og kodeverk likt i ulike løsninger, på tvers av primær- og sekundærbruk

Vise retning for kravene fra EHDS

- Ved å se til Helse-NIM når valg skal tas i løsninger / profilering vil leverandører unngå å ta valg som går på tvers av kommende krav i EU-formatene

Støtte implementering uavhengig av type format

- Helse-NIM er formatuavhengig og skal kunne brukes både for de som skal lage formater for lagring, deling og for registre



Spille inn til pågående arbeid i EU

- Xt-EHR-prosjektet med utvikling av formatene – vi spiller inn det vi plukker opp som del av arbeidet (inkl høringssvar)
- Dere kan også spille inn gjennom å delta i standardiseringsorganisasjoner, som HL7 og IHE

2 kommende relevante Helse-NIM