

Møte 1-2026

Standardiseringsutvalget for internasjonale e-helsestandarder

Torsdag 19.03.26



Agenda

Sak	Tid	Tema	Type
1/26	10.00 – 10.30	Velkommen / informasjon fra Helsedirektoratet <i>Morten Bakken, Helsedirektoratet</i>	Orientering
2/26	10.30 – 11.00	Status for Xt-EHR og veien videre for de europeiske spesifikasjonene <i>Kerstin Engelhardt, Helsedirektoratet</i>	Orientering
3/26	11.00 – 11.30	EEHRxF Support Center <i>Edyta Tyc, Ernst and Young / EU Commission</i>	Orientering
	11.30 – 12.15	LUNSJ	
4/26	12.15 – 13.00	Nordic HL7 Affiliate Term Server Collaboration <i>Mattias Colliander, E-Hälsomyndigheten</i>	Drøfting
5/26	13.00 – 13.45	DigiDOT – digitalisering av tannhelsetjenesten <i>Jørn Andre Jørgensen, Novari</i>	Drøfting

Status for Xt-EHR og veien videre for de europeiske spesifikasjonene

Møte 1-2026 i Standardiseringsutvalget, sak 02/26

Kerstin Engelhardt, avdeling for informasjonsstyring



Innhold

- Myndighetssamarbeidet Xt-EHR nærmer seg slutten
- Kort oppsummering av deltakelse og involvering i prosjektet
- Xt-EHR Targeted Stakeholder Consultation – *D8.1 Classification and functional profiles of EHR systems Guideline*
- Hva skjer nå? Planer for videre arbeid med EHDS-spesifikasjoner



Deltakelse og sektorens involvering i Xt-EHR

- Xt-EHR leveranser understøtter arbeidet med sentrale EHDS gjennomføringsrettsakter
- 2024-26: informasjon om prosjektet m/åpen invitasjon gjennom Standardiseringsutvalget og Rådsmodellen
- I 2025-2026 ble det gjennomført >30 referansegruppemøter med påmeldte fra >80 organisasjoner
- Gjennomført konsultasjoner for 13 prosjektleveranser i Norge, fulgt opp 838 kommentarer fra norske aktører
- **Stor takk til alle aktører for stort engasjement, aktiv deltakelse og gode bidrag!**



Disse gjennomføringsrettsakter er behandlet av Xt-EHR

Artikkel i helsedata-forordningen	Beskrivelse	Behandlet i Xt-EHR
17	Technical implementation of rights of natural persons conc. primary use of their health data: service for health data access, download, insert/rectify/transmit/restrict access etc.	WP9
15 (1)	Technical specifications for the EEHRxF	WP6+7, WP5
13 (4)	Data quality requirements for registration in EHR-systems, incl. semantics, uniformity, consistency of registration, accuracy and completeness	WP5, WP6, WP7
4 (4)	Technical specifications for interoperable proxy services	WP4
16 (2)	Requirements for interoperable, cross-border identification and authentication for natural persons and HPs	WP5
24 (1)	Technical aspects of MyHealth@EU supplementary services (telemedicine, mobile health etc.)	WP9
24 (2)	Technical aspects of exchange of personal health data with "other infrastructures" (CMS, social security etc.) as authorised participants to MyHealth@EU	WP9
36 (1)	Conformity of EHR systems: common specifications in respect of the essential requirements** laid out in Annex II	WP5, WP8 (WP6+7)
47 (3)	Wellness applications - Format and content of the label	WP8, D8.3

D8.1 Classification and functional profiles of EHR systems Guideline



12 organisasjoner



2 organisasjoner
45 kommentarer

Uklarhet og inkonsistens i begreper, manglende definisjoner

- Sentrale begreper brukes ulikt og må samstemmes med helsedataforordningen/defineres (eks: *intermediation, intended use, støtte*)
- Det samme gjelder *obligations* (shall, should, may) -> bruk definisjoner fra eksisterende standarder, eks. HL7 Obligation Framework
- Uklarhet rundt forhold mellom ulike klassifiseringsdimensjoner og inkonsistent bruk av disse: roller (*produsent, konsument, utveksler*) og operations/handlinger (*view, consume, produce, modify* – det mangler enkle forklaringer/definisjoner)
- Profilene burde vært merket tydelig som foreløpige utkast, som må oppdateres og tilpasses det videre arbeidet med EEHRxF

Utfordringer

- Alle kravene må kunne testes automatisk
- Starte med et lite sett obligatoriske data og utvide gradvis
- Begrens *Consumer*-krav til situasjoner de faktisk kan teste
- Konsumenter har ansvar for validering, men verken validering eller håndtering ved feil er definert
- Profilene omfatter for mye data (eks. legemiddelprofilen): omfattende/kompliserte krav krever ekstra utvikling hos leverandører, mer dokumentasjon og i verste fall nye arbeidsprosesser/merbelastning for helsepersonell
- Behov for en fast prosess for oppdatering/forvaltning av EEHRxF (-> EHDS board)

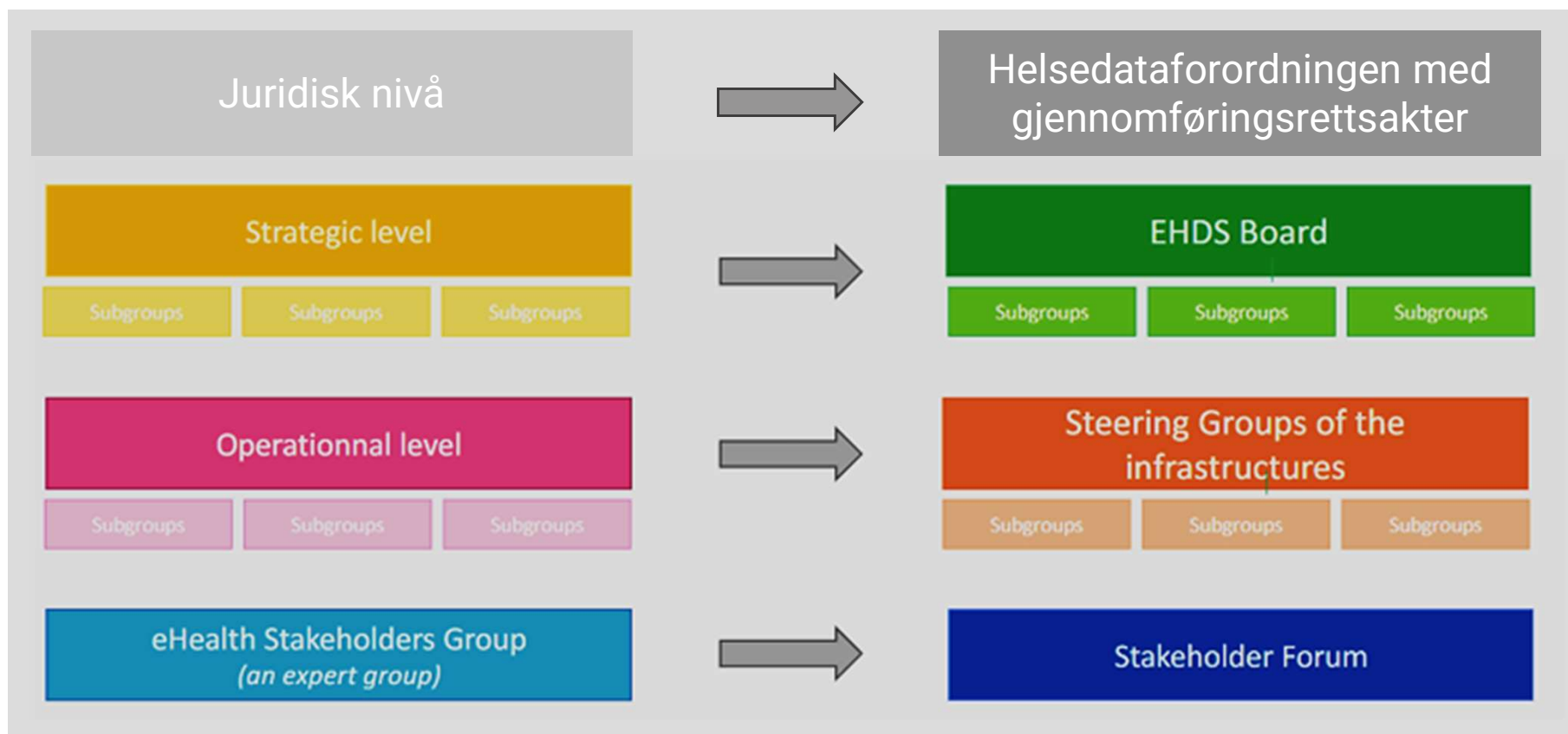


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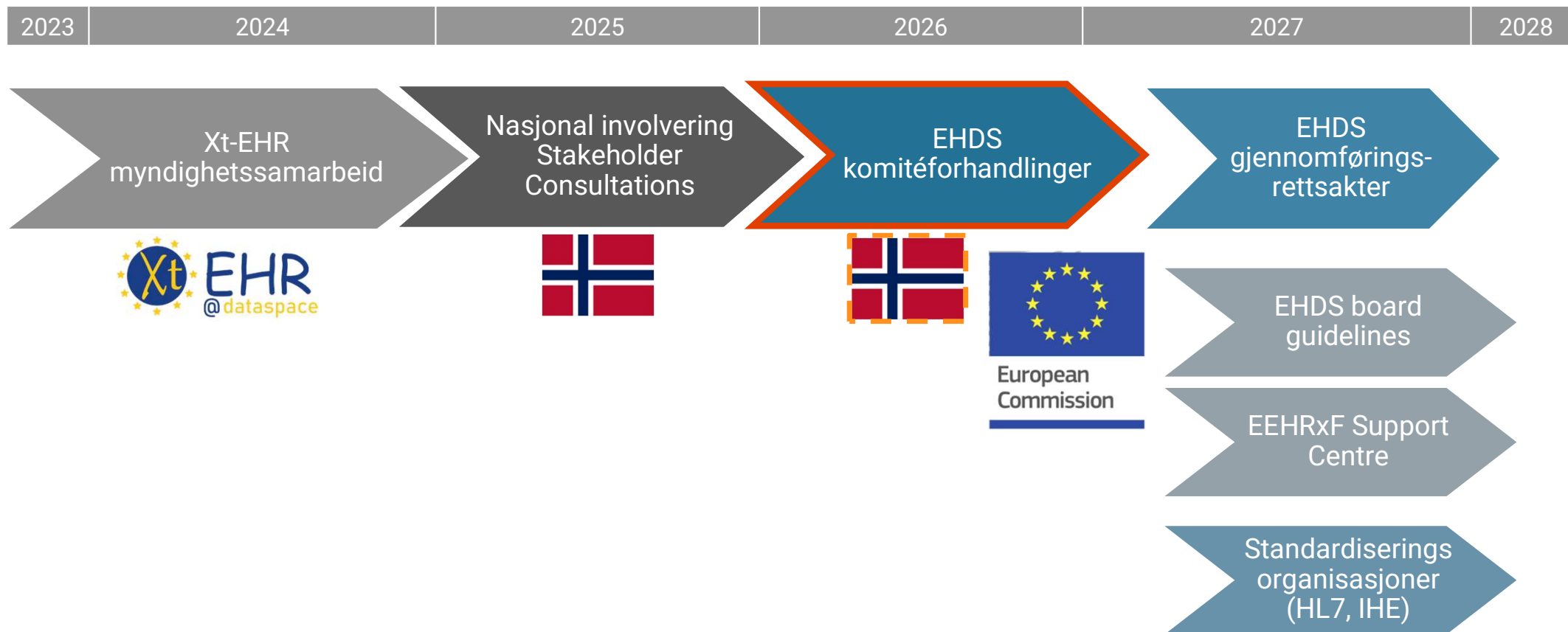
Oversikt over deltakelse av norske helseaktører i Xt-EHR Targeted Stakeholder Consultations 2025-2026

Xt-EHR Targeted Stakeholder Consultations - underlag	Antall påmeldte organisasjoner	Antall organisasjoner som leverte innspill
D5.1 Technical Requirements for EHRs and key system interfaces	23	2
D5.2 Technical requirements for EEHRxF metadata	23	2
D6.1 Patient Summary : Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems	50	10
D6.2 Electronic prescription and electronic dispensation : Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems	23	11
D7.1 Laboratory results and reports : Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems	21	3
D7.2 Medical images and reports : Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems	22	3
D7.3 Discharge reports : Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems	50	9
D8.1 Classification and functional profiles of EHR systems guidelines	12	2
D8.2 EHR Conformity Assessment Scheme assertion document and checklists	12	1
D8.3 Wellness application labelling guidelines	15	2
D9.1 Requirements and use cases on the availability of health data in cross-border telemedicine services	18	2
D9.2 Technical specifications on the availability of health data in cross-border telemedicine services	18	0
D9.3 Requirements for Large-Scale Uptake of Telemedicine Service	18	1

Overgang til nye EHDS styringsstrukturer (europeisk nivå)

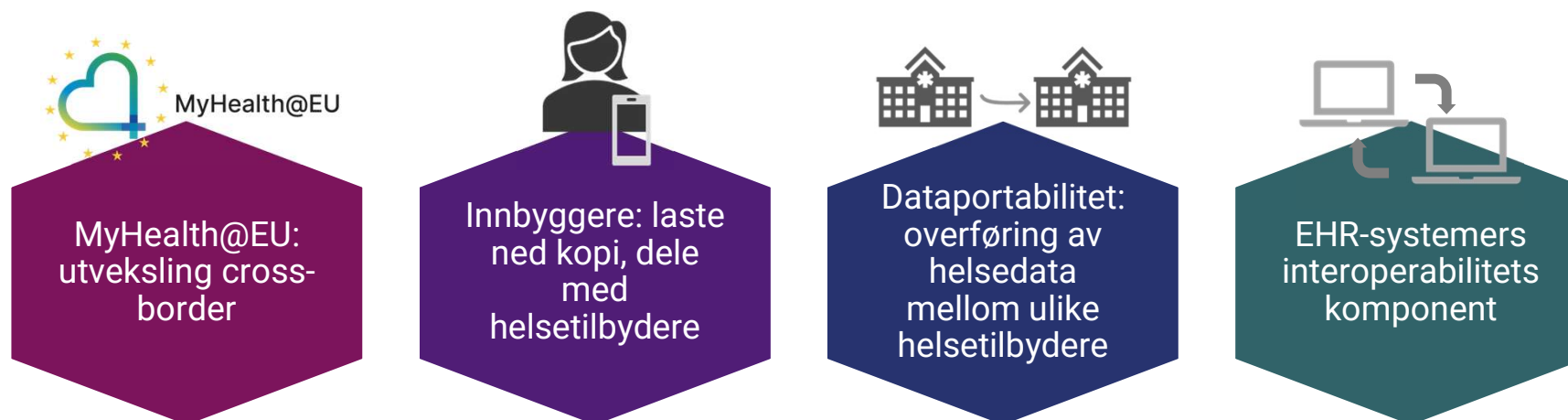


Xt-EHR avsluttes – hva skjer med EHDS spesifikasjonene etterpå?



Videre arbeid med EHDS spesifikasjoner - EEHRxF

- Grunnleggende prinsipper:
- Formatet må støtte ulike use cases (ulike «kontekster» i EHDS):



- Formatet i seg selv må være overordnet nok for å kunne gjelde alle use cases
 - Mer detaljerte krav i implementeringsprofiler per use case
- Kravene er avhengig av kategori (oppsummerende pasientopplysninger, e-resepter mm.)

Forvaltning og videreutvikling av EEHRxF



EU-kommisjonen

- Spesifikasjoner i implementing acts
- Medlemsland påvirker via komitéforhandlinger



EHDS board

- Myndighetssamarbeid, rådgivende/strategisk
- Enhetlig implementering og samordning
- Teknisk støttedokumentasjon/guidelines



Videreutvikling av spesifikasjoner

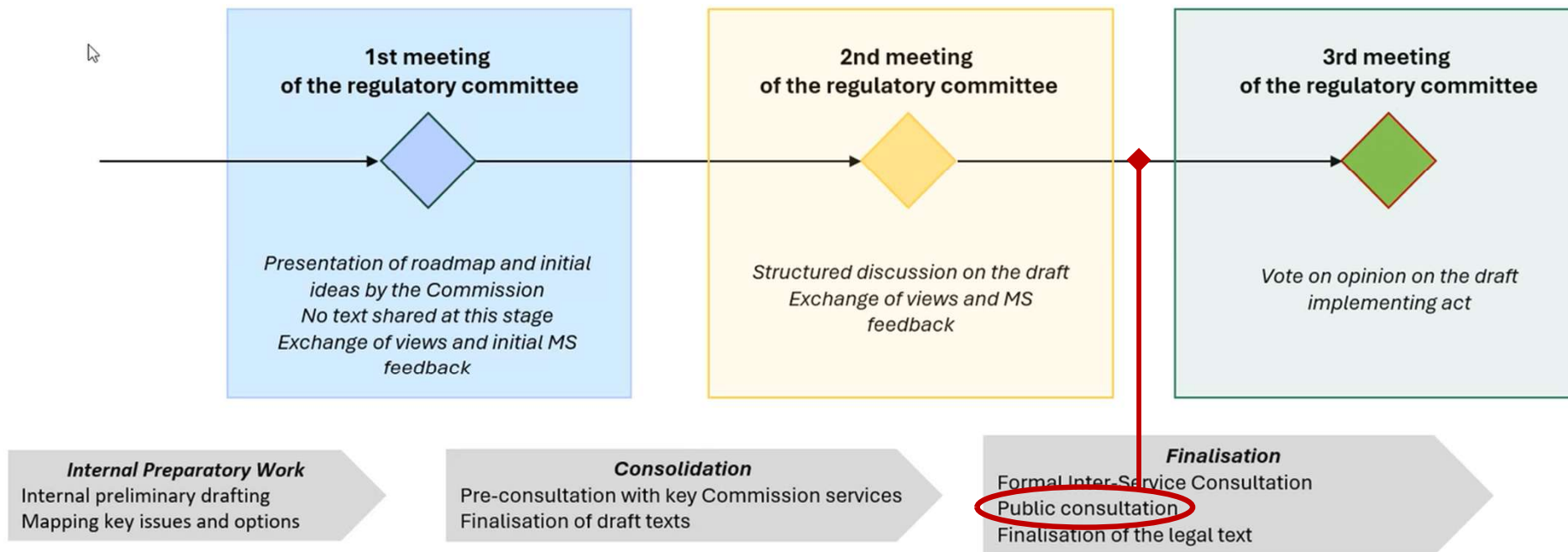
- SDOs: tekniske artefakter og profiler
- MyHealth@EU, EU-prosjekter og piloter
- Nasjonale myndigheter
- Leverandører og fagmiljøer



Åpne spørsmål

- Detaljert, permanent forvaltningsprosess
- Samspill med SDOs
- Revisjonsfrekvens
- Plattform/offisiell repository for tekniske artefakter

EHDS gjennomføringsrettsakter – offentlige høringer



- Høringer publiseres [her](#):



Law

Have your say - Public Consultations and Feedback



HelseDirektoratet



Support Centre for EEHRxF and Interoperability of Electronic Health Record Systems

19 March 2026

Support Centre for EEHRxF and Interoperability of EHR Systems

Scope and Key Objectives

Scope

- Drive the **adoption of the Format**, ensuring a unified approach to **cross-border** health data exchange
- Establish a pan-European **Support Centre as the central hub** for guidance and resources
- Unified **framework of services and tools** to enable the implementation of the Format across Member States
- Mandate by the European Commission/HaDEA

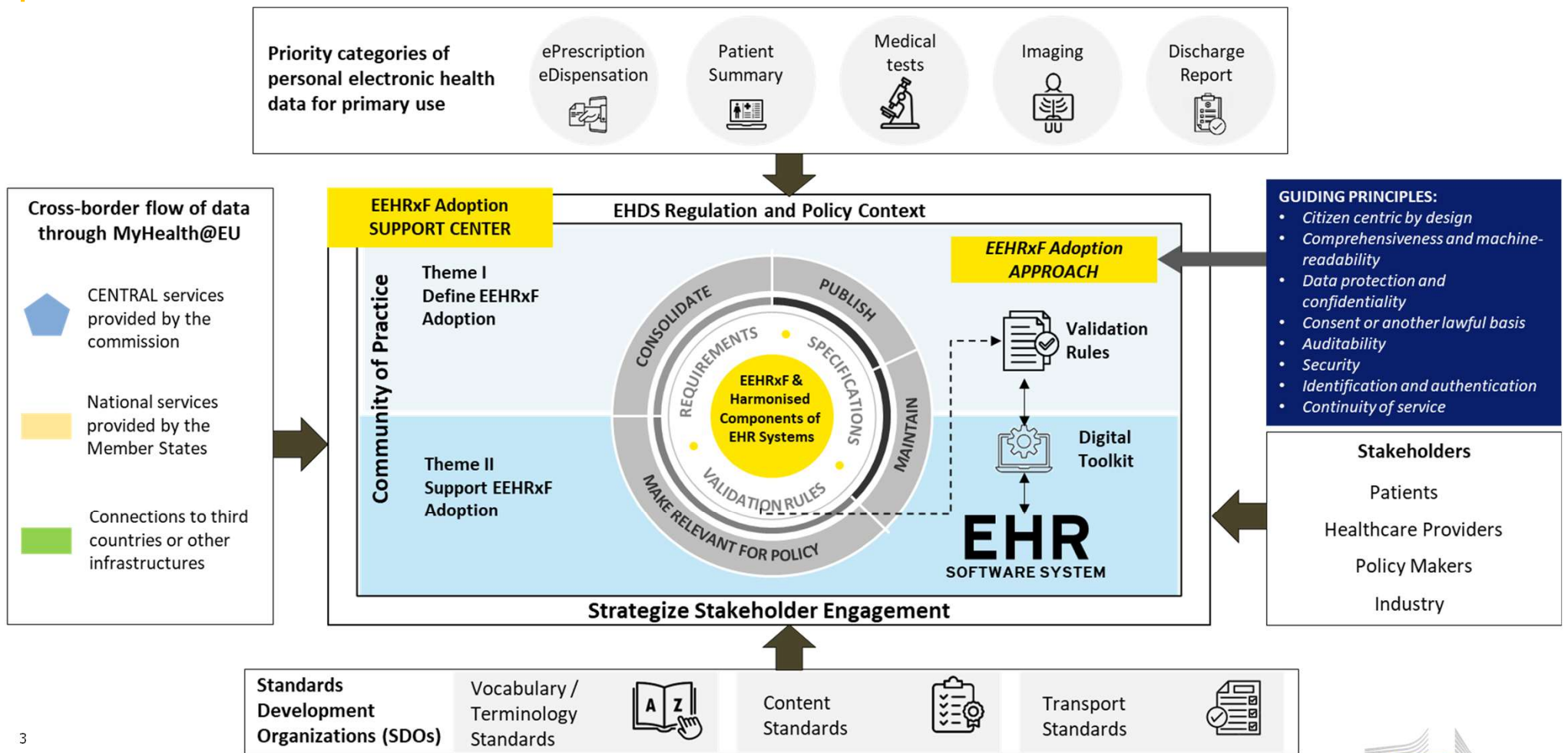
General objectives

- To set up and operate a **support centre for stakeholders to advance in the adoption of the Format** and in key aspects such as the interoperability and security of EHR systems towards the implementation of the EHDS.
- The support centre will **facilitate the adoption of the Format** by providing services to relevant stakeholders in healthcare environment intending to ensure compatibility of their systems with the EHDS requirements.

Specific objectives

- **SO1** - Establish and operate a **Support Centre** for relevant stakeholders (SPOC).
- **SO2** - Create, manage, support and moderate a **Community of Practice for the Exchange Format (COPEF)**.
- **SO3** - Consolidate, publish and maintain **requirements and specifications** for the **Format** and the **harmonised components** of EHR systems and define **validation rules** for the **assessment** of harmonised components of electronic health record systems.
- **SO4** - Develop an integrated **digital toolkit** for the harmonised components of EHR systems.

Support Centre for EEHRxF and Interoperability of EHR Systems Methodology



Support Centre for EEHRxF and Interoperability of EHR Systems

Stakeholder Groups

ENGAGEMENT SCOPE

- Stakeholder engagement covers **12 Stakeholder Groups (SGs)** with a **priority focus on implementers and industry actors**.
- The SPOC surveys, interviews and thematic workshops are open to **all interested stakeholders**.
- The COPEF consists of **~200 active participants**, focusing **mainly on EHDS-related industry representatives**. **EHR vendors and IT suppliers (SG4) and pharma/medtech industry (SG6) will comprise ≥80 % of COPEF.**

Stakeholder Groups

- SG1 – Patients & representatives
- SG2 – Healthcare providers
- SG3 – Healthcare professionals
- SG4 – EHR vendors & IT suppliers
- SG5 – Health insurers
- SG6 – Pharma & Med-Tech industry
- SG7 – Academia & research institutions

- SG8 – Regulators, policymakers & national authorities
- SG9 – Cross-border health initiatives
- SG10 – Standards/certification bodies and IGOs
- SG11 – EC expert groups
- SG12 – Horizontal organisations dealing with identity management, Cybersecurity, Data Protection, AI

Support Centre for EEHRxF and Interoperability of EHR Systems

Stakeholder Engagement Modalities

OBJECTIVES

- **Support implementation:** Provide guidance, shared resources and practical solutions
- **Facilitate collaboration:** Bring together implementers, industry and experts
- **Ensure regulatory alignment:** Aligning activities with EHDS requirements
- **Promote best practices:** Identify and disseminate successful approaches
- **Enable continuous knowledge sharing:** Maintain active platform for dialogue and learning
- **Engage stakeholders:** Actively involve users and experts



Structured Consultations (SPOC)

- Targeted surveys (evidence collection)
- Thematic workshops (focused discussions)
- Expert interviews (in-depth clarification)



COPEF-based engagement

- COPEF Thematic Groups / Work Strands
- Expert panels
- Peer exchange on real-world use cases



Continuous Support Channel (SPOC)

- Questions, clarifications, and follow-ups
- Ensures no input is lost between sessions
- Routes issues to experts when needed



Confluence Wiki

- Single collaborative workspace
- Hosts agendas, meeting outputs, working documents & FAQs
- Supports asynchronous input (comments, polls)



LinkedIn

- Public visibility of COPEF activities
- Promotion of calls for participation & EOIs
- www.linkedin.com/company/eehrxfsupportcentre



EU Academy

- Training modules linked to COPEF outputs
- Forum discussions linked to consultation topics
- Scalable access to guidance and learning materials

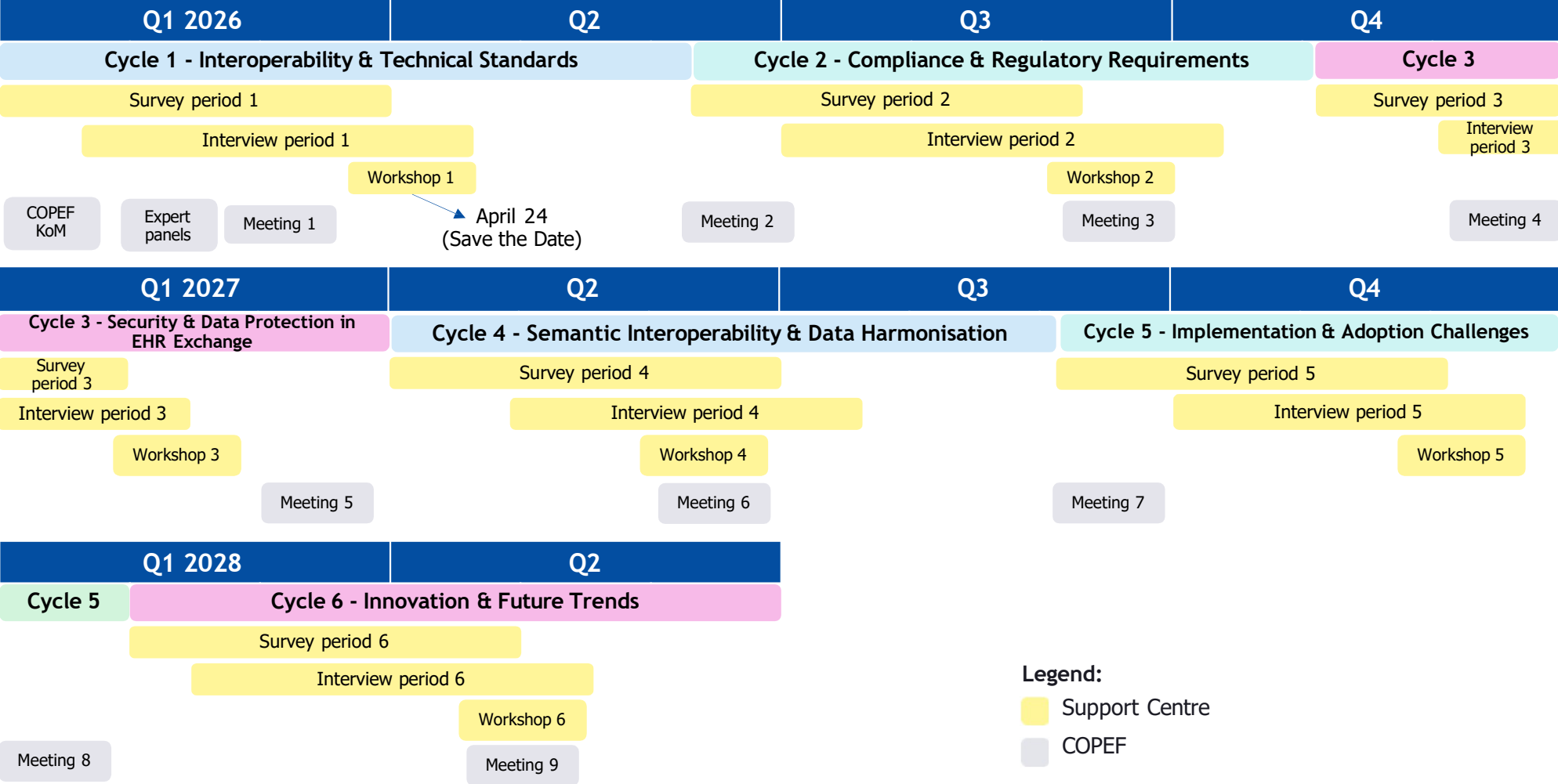
Support Centre for EEHRxF and Interoperability of EHR Systems Ongoing Survey – Call for Action

Respond and share with your network



Support Centre for EEHRxF and Interoperability of EHR Systems

Workplan and Timeline



Support Centre for EEHRxF and Interoperability of EHR Systems Workshop Agenda (Friday, 24 April 2026)

Time	Agenda item	Content
09:30 - 09:40 (10')	Welcome and setting the scene	<ul style="list-style-type: none"> • Introduction to the EEHRxF Support Centre • Opening remarks by HaDEA / European Commission • Workshop objectives
09:40 - 10:00 (20')	State-of-the-art of EEHRxF involvement	<ul style="list-style-type: none"> • Stakeholder engagement • EEHRxF Technical development status
10:00 - 11:00 (60') Parallel Session	EEHRxF Interoperability	<ul style="list-style-type: none"> • Benefits, best practices, challenges the interoperability of EHRs • Use cases
10:00 - 11:00 (60') Parallel Session	EEHRxF Technical Standards	<ul style="list-style-type: none"> • Technical standards for interoperable EHR systems, their importance, challenges and improvement actions • Use cases
11:00 - 11:15 (15')	Recap, next steps and closing remarks	<ul style="list-style-type: none"> • Summary of key points • Timeline and expectations for the next stages of the Support Centre • Closing remarks

Support Centre for EEHRxF and Interoperability of EHR Systems Workshop Registration (Friday, 24 April 2026)

Register and share with your network



Support Centre for EEHRxF and Interoperability of EHR Systems

Requirements and Specifications of the Format - Objectives

SCOPE

- **Methodology for the consolidation and maintenance of requirements and specifications of the Format**
- Delivers the **technical backbone** for adopting the EEHRxF by consolidating requirements and specifications for the Format and the harmonised components of EHR systems, and by defining validation rules that enable assessment of the harmonised components of EHR Systems.

Objectives

Consolidation of Requirements & Specifications

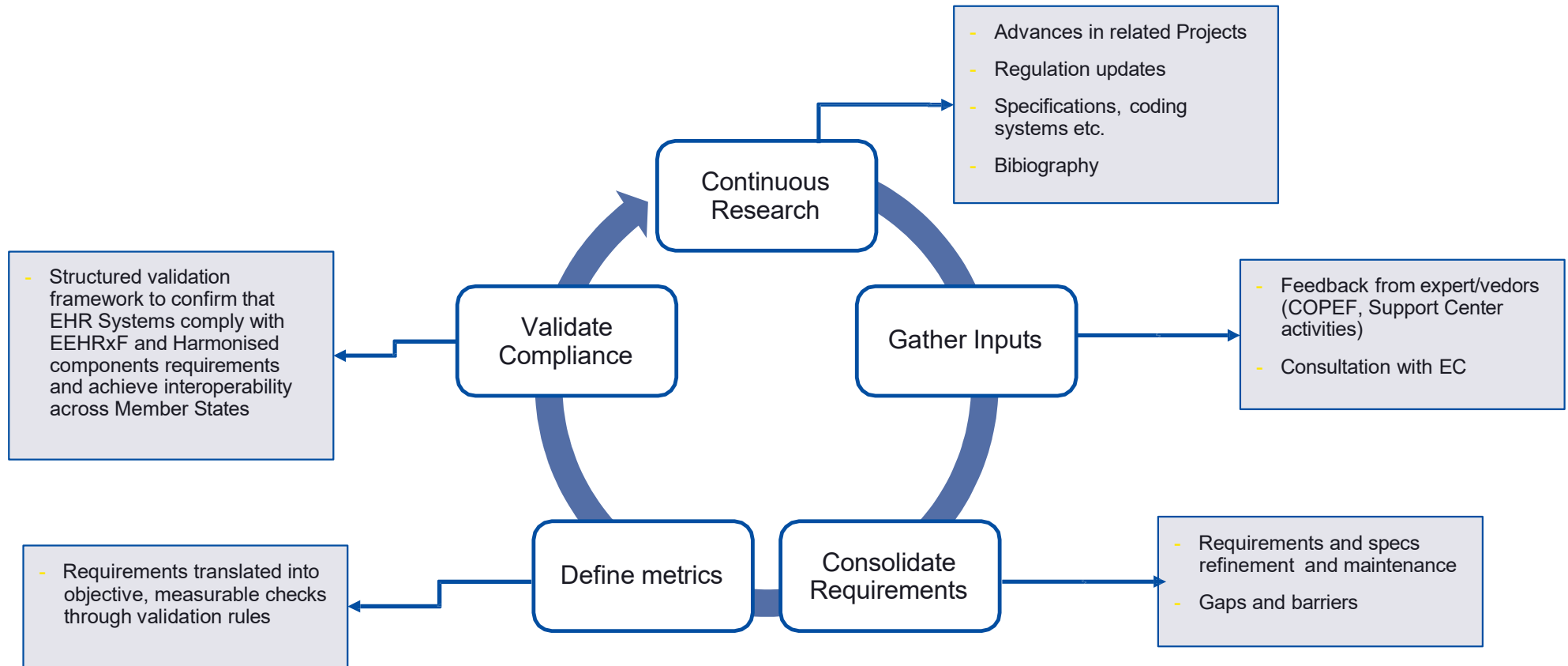
- **Desk research and analysis** of resources across EU initiatives (e.g., Xt-EHR, X-eHealth, xShare, XpanDH, MyHealth@EU) and relevant standards
- **Consolidation** in a unified, user-friendly requirements and specifications catalogue
- **Publishing and maintenance**

Definition of Validation Rules

- Define machine-checkable **validation rules** for the harmonised components to support conformance assessment
 - Data Format, Terminology and Coding Systems, API and Protocol Compliance, Security and Logging, Regulatory Frameworks
- Executed by **testing tools** (ITB) and reused by stakeholders (vendors, implementers, authorities)

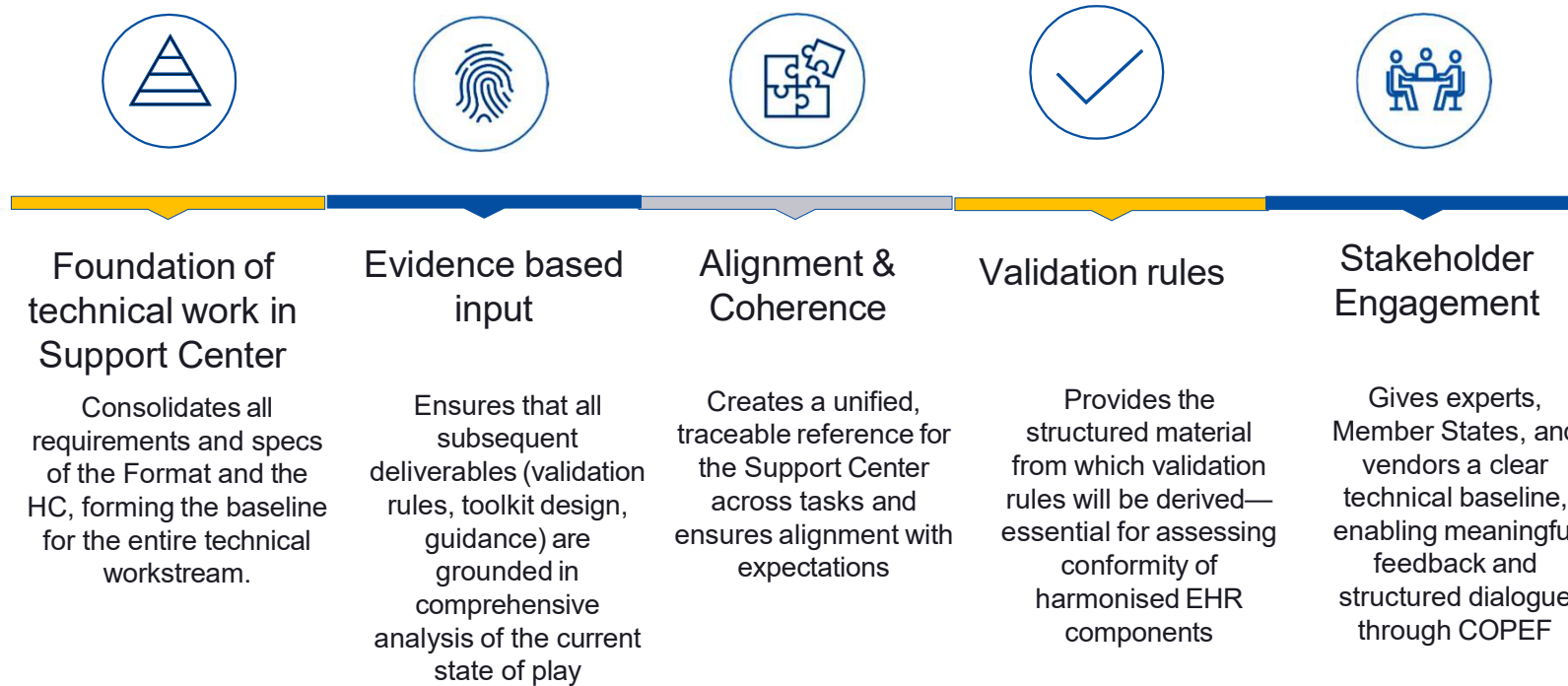
Support Centre for EEHRxF and Interoperability of EHR Systems

Requirements and Specifications of the Format - Methodology



Support Centre for EEHRxF and Interoperability of EHR Systems

Requirements and Specifications of the Format - Roadmap



TASK-05 – Development of an integrated digital toolkit for the harmonised components of EHR systems

- Develop and test with stakeholders the integrated digital toolkit for the harmonised components of EHR systems designed and developed to assist stakeholders in checking compliance of their systems with Format and harmonised components of Electronic Health Record (EHR) systems
- Requirements and technical specifications of the integrated digital toolkit
- Development of an integrated digital toolkit and documentation
- Collection of at least 10 digital tools (e.g. downloadable executables, web tools, etc.)
- Health data structuring, Data quality improvement, Classification of EHR systems, Format conversion, Synthetic data generation, Ensuring cybersecurity
- Open source
- Agile, 5 iterations

Initial tools

EHR classification and compliance tool

- Help a vendor or authority quickly understand if an EHR system is in scope of EEHRxF, and what requirements apply, without needing patient data.
- Provide tailored obligations and practical evidence templates/checklists to support planning and quality assurance.

How it works

- Users answer a guided set of questions about their system and its capabilities, and the tool outputs a tailored set of obligations plus an evidence pack.
- The output is advisory and non-binding (guidance and signposting, not a certification decision).

Synthetic data generator

- Generate synthetic but clinically meaningful test files for development, validation, training and demos, without using real patient data.
- Start with an MVP focus on patient summary and prescriptions, with scope expanding over time.

How it works

- Users choose a scenario/profile and the tool produces datasets plus a provenance/manifest so results can be reproduced and referenced.
- Outputs are clearly labelled as synthetic to avoid misunderstanding, and designed to be usable in automated testing workflows.

Thank you!



• support.eehrxf@be.ey.com



• www.linkedin.com/company/eehrxfsupportcentre/



Lunsj

Starter igjen 12.15



Nordic HL7 Term Server Collaboration

Mattias Colliander

2026-02

Mattias Colliander

- HL7 Sweden, board member
- The Swedish E-Health Agency, architect
- EHDS, national/international standardisation
- FHIR, terminology
- Before that: Lif/FASS



Nordic HL7 Term Server Collaboration

About term servers

FHIR term servers

tx-nordics

About Term Servers

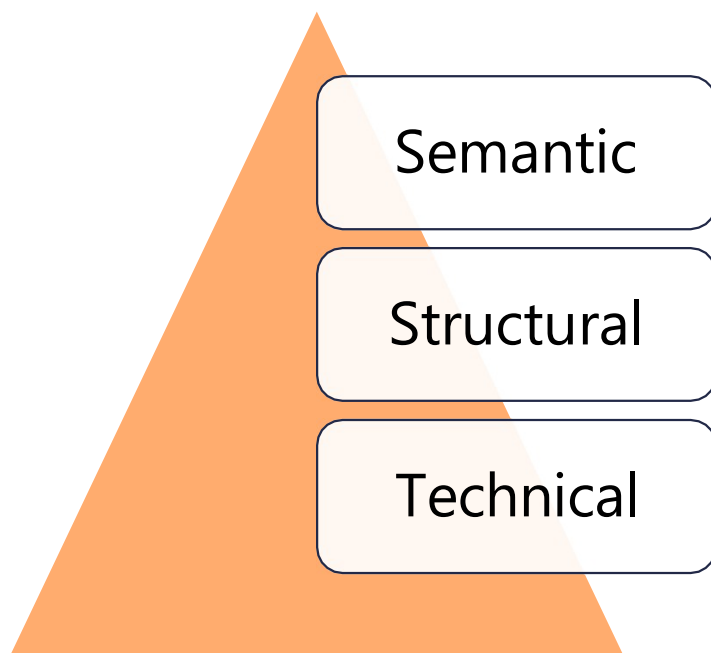
- Why term servers
- What can they do?
- Roles in an landscape

Health data everywhere!

- More organisations involved in caregiving
- People are mobile, within and across national borders
- EHDS!



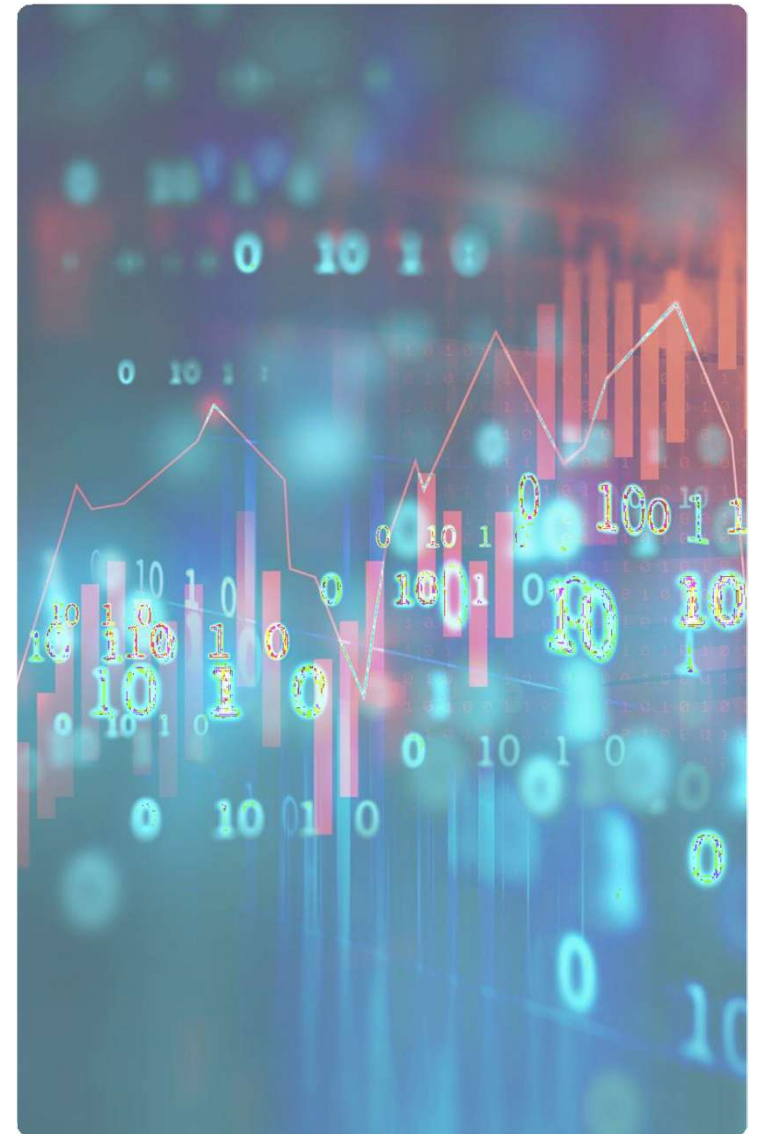
Terminology, ontology, taxonomy...



- Semantic Interoperability
- **Transfer of information with preserved meaning**
- Code systems – shared definitions
- Term servers make code systems usable!

What does it do?

- Find the right code
 - By name, code, value set
 - For data entry
- Validation
 - Is the code I have valid for this context?
- Display/learn
 - Give me more info about this code
- Mapping
 - I have code A, in set X. Give me a related code in set Y.
- Authoring
 - I need my own code system, value set, mapping

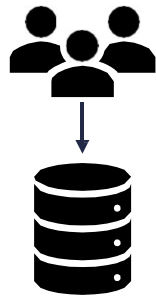


Roles of a term server

National term server



Authoring



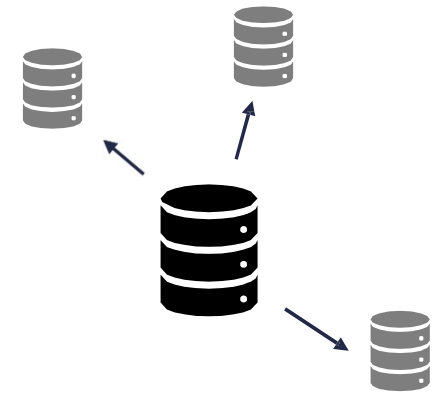
Healthcare



State



Source of truth



Infrastructure

Authoring



Apps



Insurance



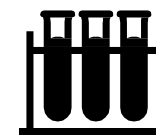
Web forms



Lab systems



EHRs



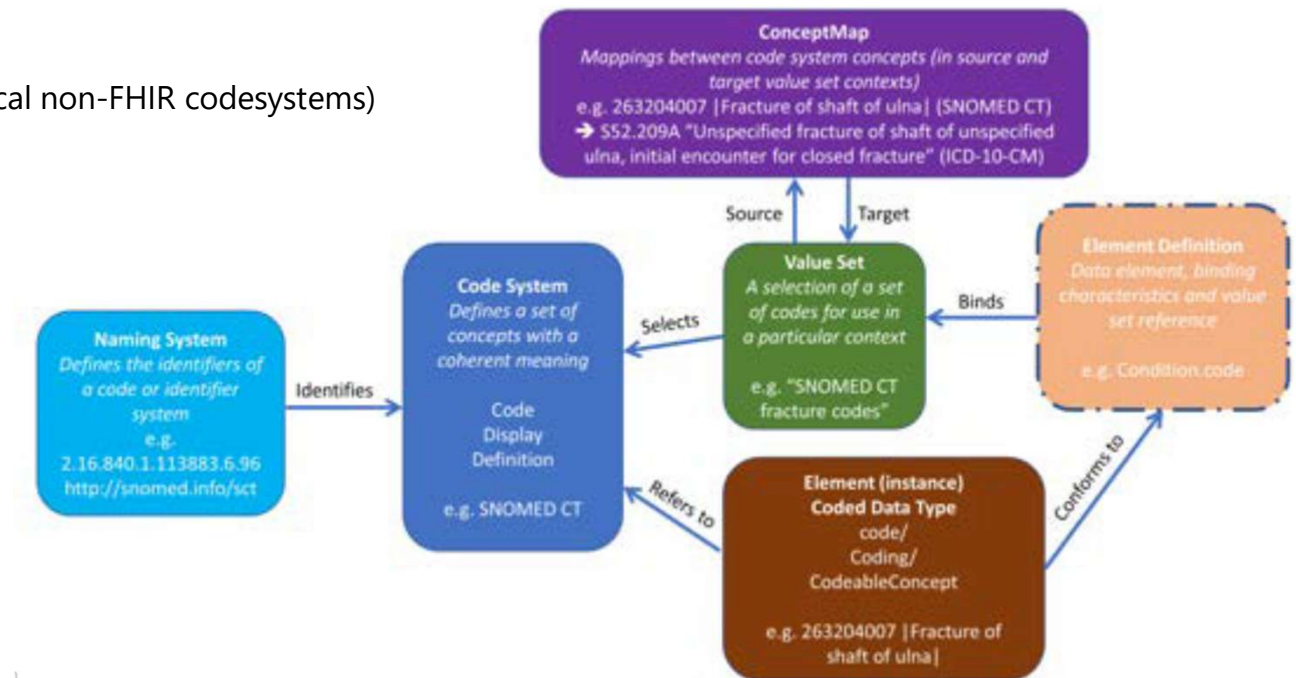
SnomedCT RF2, Loinc, ICD-10
(ICD-11?)

FHIR Term Servers

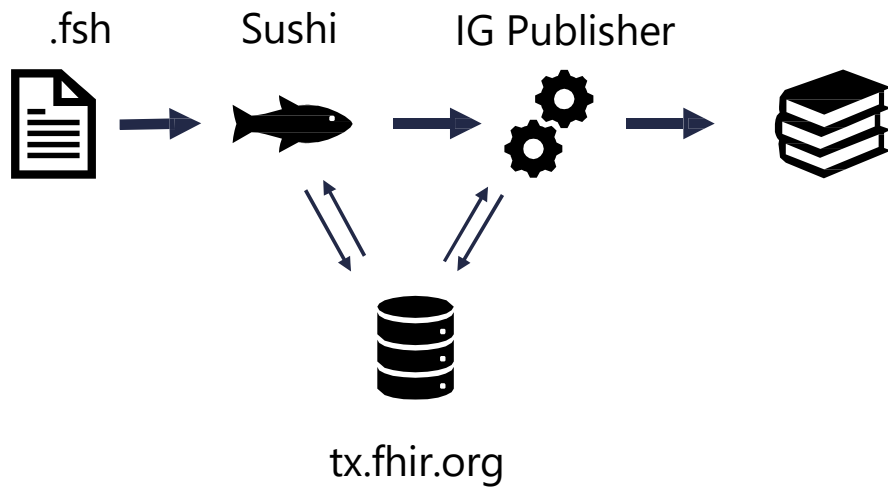
Too much information, not enough time

FHIR Term Servers

- FHIR Terminology Module API
- Outside the standard
 - Specialized import (Snomed, LOINC, ICD, local non-FHIR codesystems)
 - GUI: Authoring, browsing
 - Roles, access management...
 - Federation/synchronization of content
 - Specialized API
- Don't make your own!



FHIR IG Development



- Default term server: tx.fhir.org
- Contains all HL7 code systems, Snomed Int., LOINC...

FHIR Term Server Ecosystem

- Recent, starting in early 2025
- <https://hl7.org/fhir/uv/tx-ecosystem/index.html>
- Federated system of term servers
- tx.fhir.org is central controlling node
- Servers need to match requirements and be approved to join
- <https://tx.fhir.org/tx-reg>

Examples of language handling in IGs

- <https://hl7.dk/fhir/core/ValueSet-sor-organization-type.html>
- Swedish base profile example

Multi language IGs (early work!)

- <https://build.fhir.org/ig/FHIR/ig-guidance/languages.html>

tx-nordics, the details

- Csiros Ontoserver
- HL7 Affiliate license (modified)

“The Client may use the Software, and allow Permitted Users to use the Software with the Client’s systems or products, for the sole purpose of developing interoperability standards.”

“The Client may also use the Software for internal research and development purposes.”

“The Client may use the Software, and allow Permitted Users to use the Software with the Client’s systems or products, for the sole purpose of developing interoperability standards for the countries of **Sweden, Denmark, Norway and Finland.**”



Tack!

mattias.colliander@ehalsomyndigheten.se

References

FHIR Term Server Ecosystem (mainly for building FHIR IGs, and exploring/learning):

- <https://hl7.org/fhir/uv/tx-ecosystem/index.html> (what it is)
- <https://tx.fhir.org/tx-reg> (servers and code systems in the ecosystem)

Terminology in FHIR:

- [Terminology-module - FHIR v5.0.0](#)

Nordic HL7 Affiliate term server:

- <https://tx-nordics.fhir.org/fhir>
- [Shrimp/🔥](#) (Link to Norwegian Snomed in "Shrimp", the Ontoserver code system browser app)



E-hälsomyndigheten

