

# FHIR-profilering i Norge i lys av EHDS

**FHIR-profiling in Norway in light of EHDS**

Linn Brandt, Directorate of Health in Norway. Senior adviser Dept. Code systems



# EHDS Regulation-on-FHIR?


**No, not directly.....**

*Article 15*

## European electronic health record exchange format

1. By 26 March 2027, 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 14(1), setting out the European electronic health record exchange format. Such format shall be commonly used, machine-readable and allow transmission of personal electronic health data between different software applications, devices and healthcare providers. Such format shall support transmission of structured and unstructured health data and shall include the following elements:

- (a) harmonised datasets containing electronic health data and defining structures, such as data fields and data groups for the representation of clinical content and other parts of the electronic health data;
- (b) coding systems and values to be used in datasets containing electronic health data;
- (c) technical interoperability specifications for the exchange of electronic health data, including its content representation, standards and profiles.

 **FHIR** is a hot candidate for framework to represent these technical interoperability specifications.

# Even if the role of FHIR in EHDS is not clear yet, there are things we know:

- In the current **MyHealth@EU** crossborder service FHIR is chosen as the format for all new developments, and will be piloted for existing CDA formats (Patient Summary, ePrescription/eDispensation)
- **Xt-EHR Joint Action** project are creating suggestions for FHIR profiles for EEHRxF, in an official collaboration with HL7 Europe
- A lot of models and data elements are being discussed (like Giorgio showed)
- We use quite a lot of FHIR in **Norway**: Internally in health organisations (RHFer), National platforms/components (Core records- Kjernejournal, Medication-SFM/PLL, Patient medical results-PPS (Lab, imaging), some data exchange for registries...
- There is a [recommendation on use of FHIR](#) for data exchange in **Norway**, developed by Directorate of e-health (now merged with Directorate of health)

# So IF **FHIR** will be used as technical framework in EHDS – how could it work in Norway?

## *Article 15*

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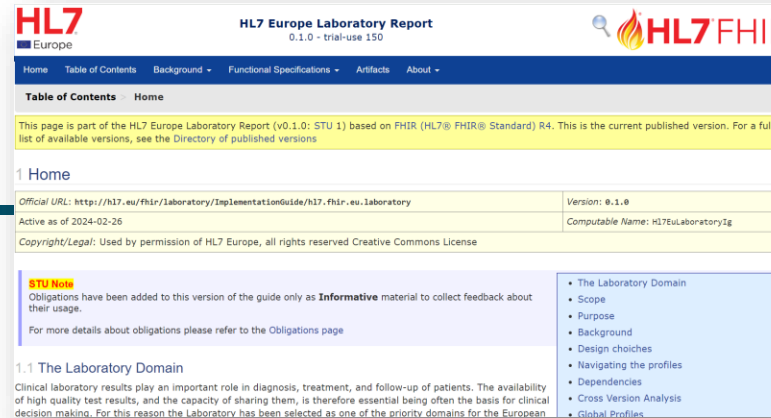
# EEHRxF will support many different use cases

## Top level/ Base/ Flexible EEHRxF IG

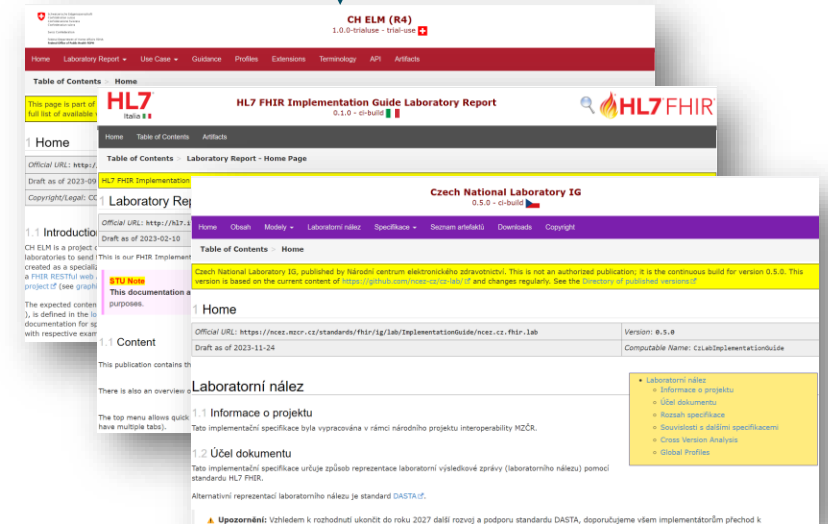
### Crossborder use case



<https://fhir.ehdsi.eu/laboratory/>

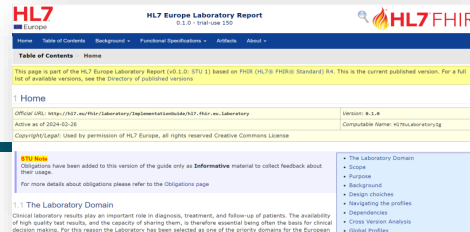


### National use cases

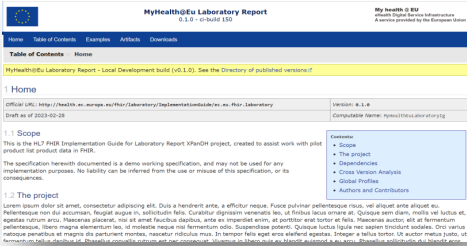


# National vs. Implemented IGs in Norway

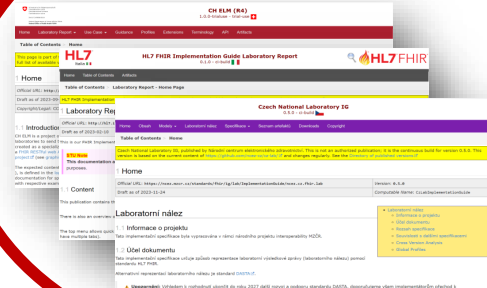
## Top level/ Base/ Flexible EHRx IG



## Crossborder use case



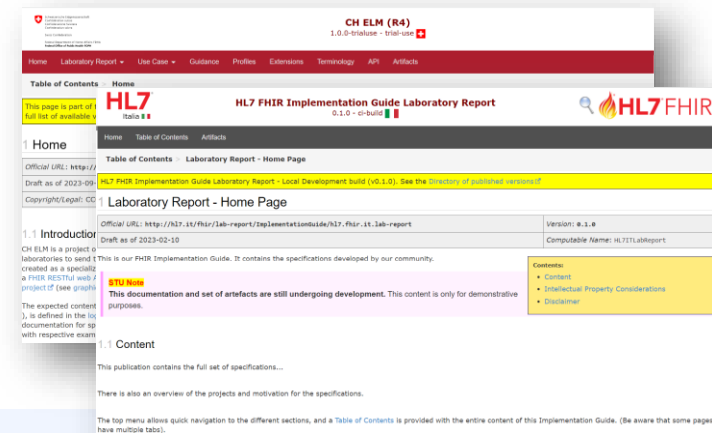
## National use cases



## No-EEHRx (IDs, code systems, additions)?

- Interaction with No-basis
- Role of HL7 Norge?
- Role of government (Directorate of Health+)?
- Role of NHN, RHF and others?

## Implemented IGs



Kjernejournal (core medical record)  
 Pasientens prøvesvar (Patient medical results)  
 A regional data exchange, a new tool... ?

# Government functions to be established as a result of the EHDS Regulation



## Digital helsemyndighet (Digital Health Authority-DHA)

- Nationally responsible for implementing the requirements for primary use of health information
- Appointed: **Helsedirektoratet**

## Markedsovervåkings-myndighet (Market surveillance authority- MSA)

- National supervision of EHR systems\* meeting the requirements of the Regulation
- Appointed: **Helsedirektoratet**

## Tilgangsforvalter av sekundærbruk av helsedata (Health Data Access Bodies-HDAB)

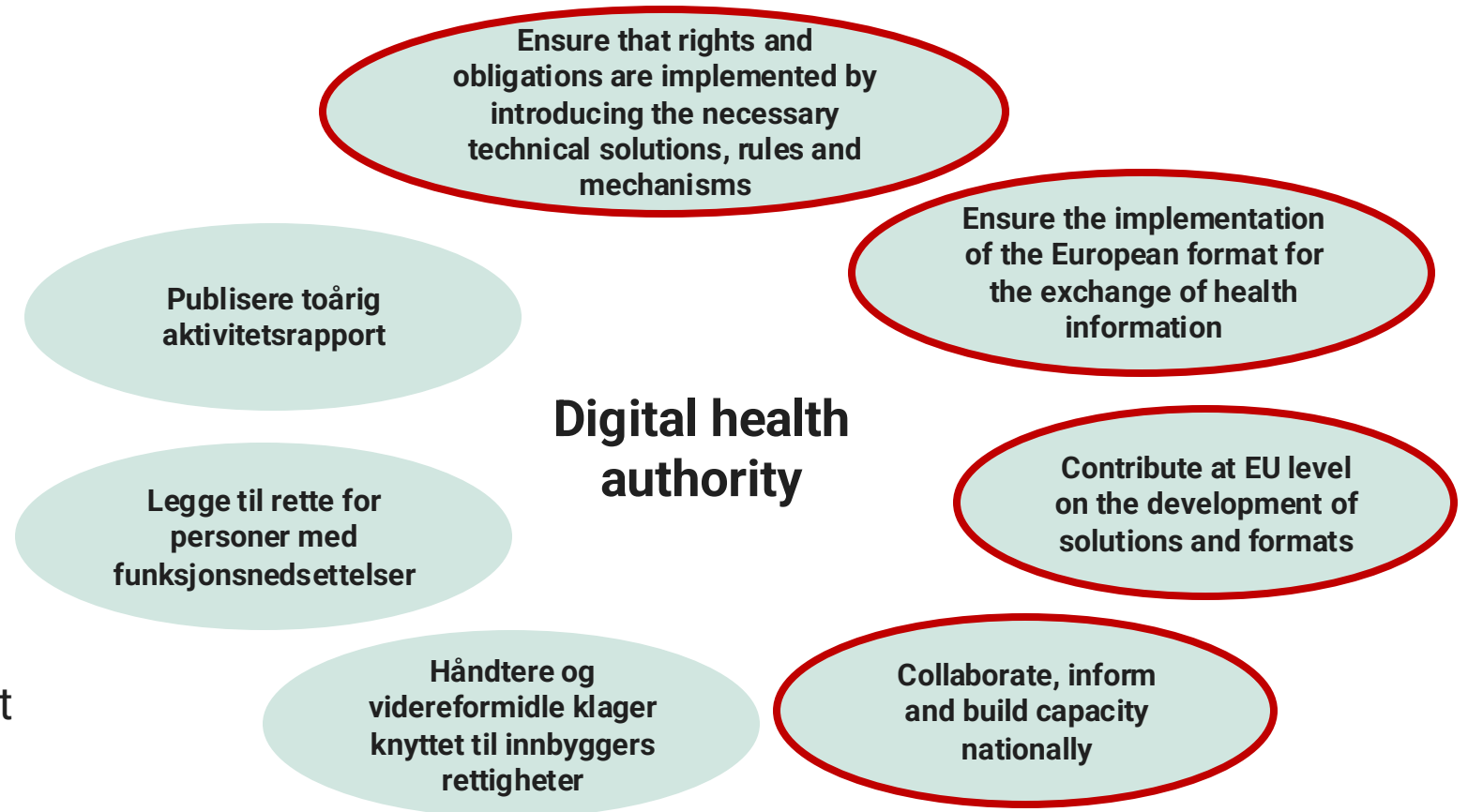
- National or regional bodies that provide access to and facilitate the use of health data for secondary purposes
- Appointed as coordinating HDAB: **Folkehelseinstituttet**

\* Patient records and other treatment-oriented health registries that process one or more of the prioritised health data for the purpose of providing healthcare

# 1.1 Establish a Digital Health Authority (DHA)

Krav i forordningen:

- Art.19: Digital Helsemyndighet
  - Art.20: Rapportering
  - Art.21: Håndtere klager
  - Art.22: Samarbeid med Datatilsynet
- 
- Oppgavene faller for en stor del naturlig under Helsedirektoratets eksisterende myndighetsansvar, men det vil være behov for å videreutvikle og tydeliggjøre rollen i samsvar med EHDS
- 
- Flere av oppgavene vil forutsette tett samarbeid med andre myndigheter, samt egne oppdrag til NHN

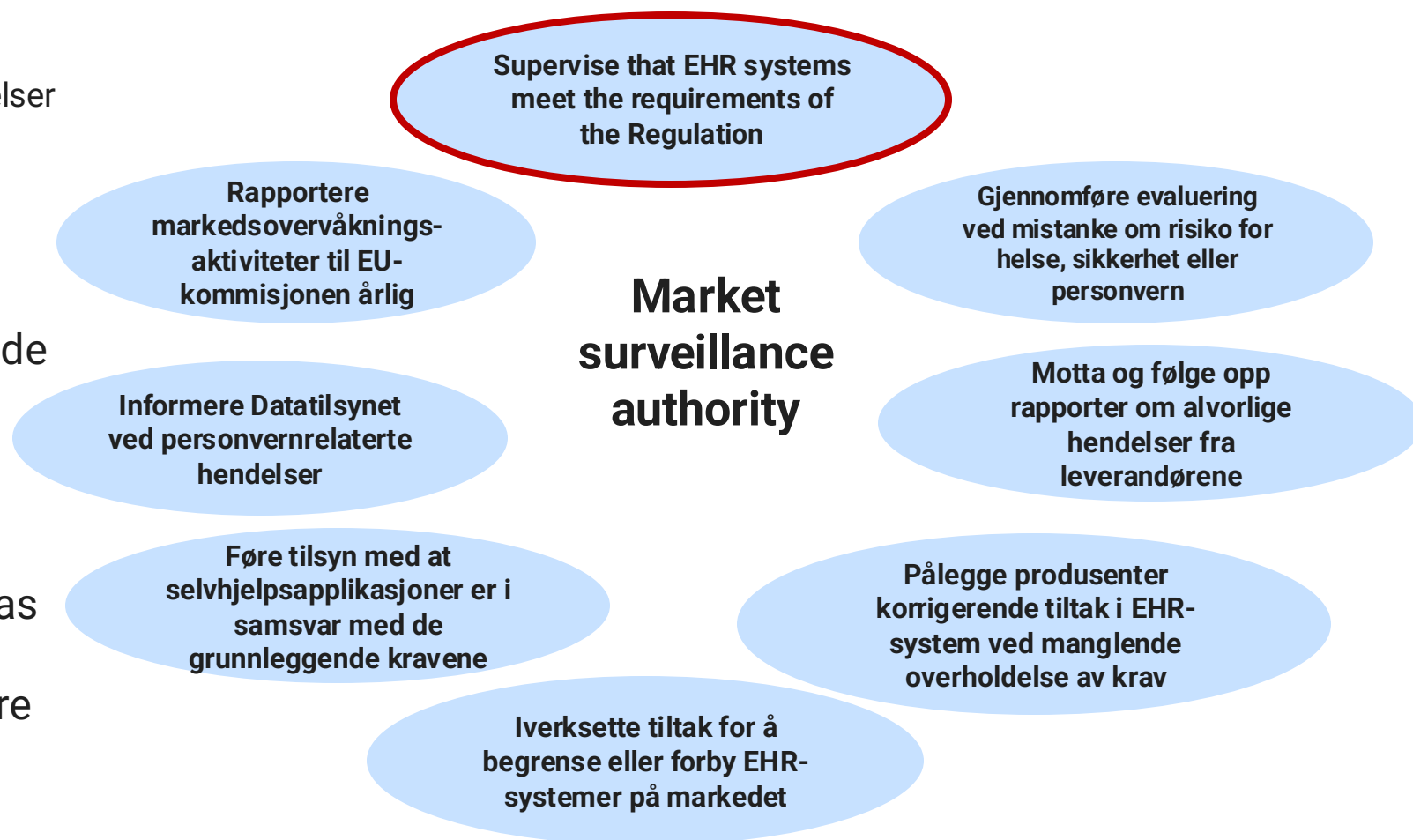




# 1.2 Establish Market surveillance authority (MSA)

Krav i forordningen:

- Art.43: Markedsovervåkingsmyndighet
  - Art.44: Håndtering av risiko og alvorlige hendelser
  - Art.45: Manglende overholdelse av krav
  - Art.46: Union safeguard procedure
  - Art.47: Selvhjelpsapplikasjoner
  - Art.99: Bruk av sanksjoner
- Norge har ikke en funksjon tilsvarende markedsovervåkingsmyndighet for EHR-systemer i dag.
  - Nye oppgaver må etableres, og rolleklarhet DHA / MSA må hensyntas
  - Forutsetter tett samarbeid med andre myndigheter



# Directorate of Health

- Will have some new functions and tasks in relation to DHA and MSA
- Maintain the current messaging standards (ePrescription, Discharge summary, Health care dialog and others)
- Maintain and publish many national code systems (ICD, Procedure code systems, Lab codes, SNOMED CT, codes used in messaging standards)
- There are many relevant tasks in «[Satsning Digital samhandling](#)»
- BUT... Directorate of Health **do not publish FHIR profiles.**
- However, There is a [recommendation on use of FHIR](#) for data exchange in **Norway**, developed by Directorate of e-health (now merged with Directorate of health)- which points to no-basis profiles

# HL7 Norway

- DO publish FHIR profiles, notably no-basis profiles
- Are official Norwegian representative in the international standardisation of HL7 and are responsible for the Norwegian adaptation of FHIR profiles
- Non-profit and based on volunteer work – no employees
- Have membership and some government funding for courses and some activities
- No official role in the standardisation processes in the Directorate of health, or when developing national infrastructure, but are parttaking in hearings, meetings and many collaborators have roles in key organisations.

# Norsk HelseNet (NHN)

- DO publish FHIR profiles for national infrastructure systems (Kjernejournal, Pasientens prøvesvar, Pasientens legemiddelliste)
- Use no-basis from HL7 Norway where relevant
- Is responsible for setting up the National contact point for MyHealth@EU cross border exchange. (in collaboration with the Directorate of Health)

## Other health care actors

- Health regions, Municipalities, Vendors, Public institutions (e.g DMP, NAV)...
- Many publish their own FHIR profiles, using no-basis where relevant
- openEHR Archetype community has a lot of experience with modelling

# Samarbeidsmodellen for internasjonale standarder

## (Collaboration model for international standards)

**Health care organisation:**  
Participate with experience, testing, use

- Bestilling, utprøving og kvalitetskontroll
- Brukerinvolvering
- Erfaringsdeling
- Bidra til utvikling av av standarder

**Government:**  
Participate with coordination, guidance, regulation..

- Lov & forskrift
- Normering
- Nasjonal koordinering
- Veiledning
- Overnasjonale føringer og samarbeid

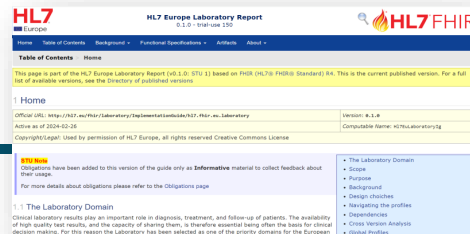


**Vendors:**  
Participate with experience

**SDOs (HL7 Norway)**  
Participate with development, maintainance, guidance

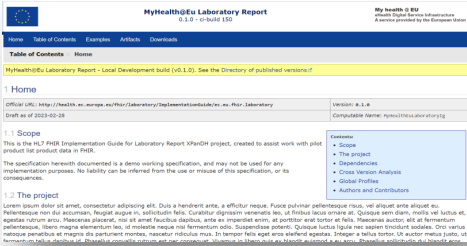
# National vs. Implemented IGs in Norway

## Top level/ Base/ Flexible EEHRxF IG

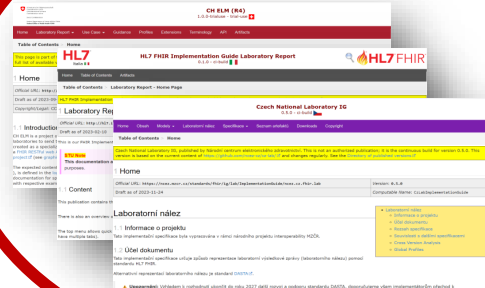


NB! Regular updates!

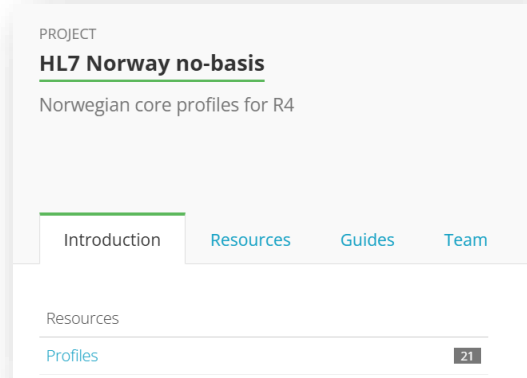
## Crossborder use case



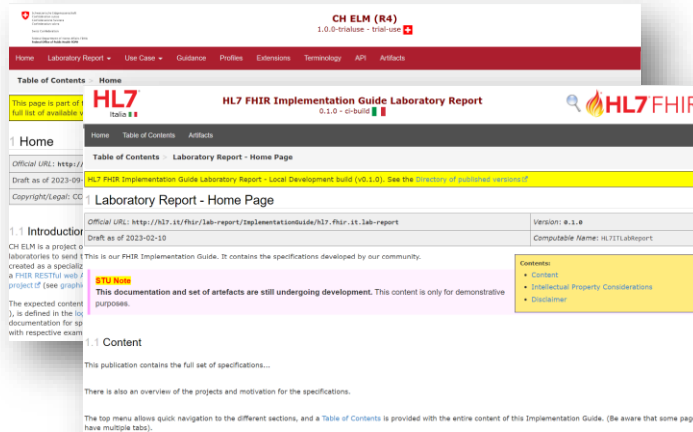
## National use cases



No-EEHRxF?



## Implemented IGs



- No-basis = No-EEHRxF?
- Make No-EEHRxF a «domain profile?»
- Who makes and maintain No-EEHRxF?
  - Collaboration a la «Samarbeidsmodell»?

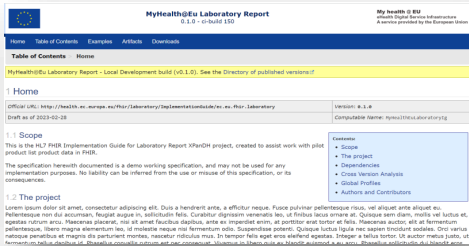
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Top level/ Base/ Flexible EEL

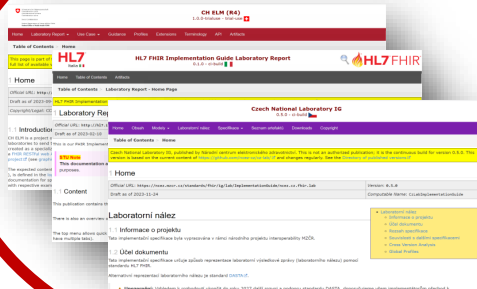


**Important! Participants needed on European level!**

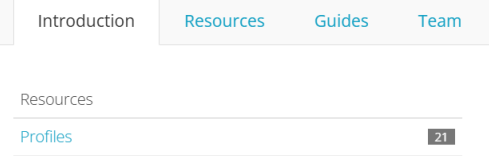
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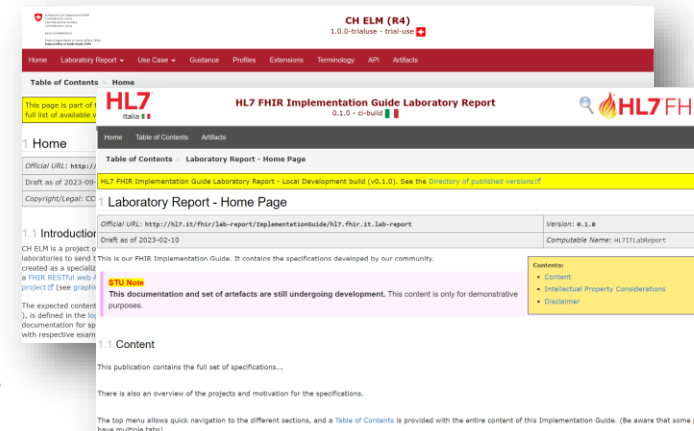
**National use cases**



**No-EEHRxF?**



**Implemented IGs**



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# Participating in HL7 Europe EU-core/EU-basis

- [Open meetings](#).
- HL7 Norway coordinate ballots
- BIG issues and small issues. Some critical to all, and some to a few. Examples:
- How to represent «the printable document, PDF»: Extension, «normal» FHIR composition ....
- Which code system to use for different information elements, and strength: Preferred, Extensible, Example, Required?

Use case	Published version URL	Build version	Balloting/publishing information	Related information	Comments
ePrescription eDispensation	R4: <a href="https://hl7.eu/fhir/mpd">https://hl7.eu/fhir/mpd</a> R5: <a href="https://hl7.eu/fhir/mpd-r5/">https://hl7.eu/fhir/mpd-r5/</a>	<ul style="list-style-type: none"><li>• <a href="#">Web Build</a></li><li>• <a href="#">GitHub</a></li></ul>	Ballot R4/R5 ended 31.08.2025	<ul style="list-style-type: none"><li>• <a href="#">WG meeting minutes</a></li><li>• <a href="#">Jira Dashboard*</a></li><li>• <a href="#">Xt-EHR models</a> (build)</li></ul>	Xt-EHR Consultation 15.06-15.09.2025
Laboratory Report	Patient Summary		<ul style="list-style-type: none"><li>• <a href="#">Web Build</a></li><li>• <a href="#">GitHub</a></li></ul>	<ul style="list-style-type: none"><li>• <a href="#">WG meeting minutes</a></li><li>• <a href="#">Xt-EHR models</a> (build)</li></ul>	Xt-EHR Consultation 14.07-15.09.2025
	Hospital Discharge Report	R4: <a href="https://hl7.eu/fhir/hdr/">https://hl7.eu/fhir/hdr/</a>	<ul style="list-style-type: none"><li>• <a href="#">Web Build</a></li><li>• <a href="#">GitHub</a></li></ul>	Ballot R4 ended 31.08.2025	<ul style="list-style-type: none"><li>• <a href="#">WG meeting minutes</a></li><li>• <a href="#">Jira Dashboard*</a></li><li>• <a href="#">Xt-EHR models</a> (build)</li></ul> Xt-EHR Consultation 31.07-11.09.2025
Imaging Report Imaging Study	European Base/Core	R4: <a href="https://hl7.eu/fhir/base/">https://hl7.eu/fhir/base/</a> R5: <a href="https://hl7.eu/fhir/base-r5/">https://hl7.eu/fhir/base-r5/</a>	<ul style="list-style-type: none"><li>• <a href="#">Web Build</a></li><li>• <a href="#">GitHub</a></li></ul>	Ballot R5 ended 30.06.2025	<ul style="list-style-type: none"><li>• <a href="#">WG meeting minutes</a></li><li>• <a href="#">Jira Dashboard*</a></li></ul> Xt-EHR all Consultations apply
	Extensions	R4/R5: <a href="https://hl7.eu/fhir/extensions/">https://hl7.eu/fhir/extensions/</a>	<ul style="list-style-type: none"><li>• <a href="#">Web Build</a></li><li>• <a href="#">GitHub</a></li></ul>	Ballot R5 ended 30.06.2025	<ul style="list-style-type: none"><li>• <a href="#">Jira Dashboard*</a></li></ul> Discussions during other WG meetings



# Discussion and comments...