XpanDH
Expanding Digital Health through a pan-European EHRxF-based Ecosystem

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2nd European EHR Exchange Format Expert Summit

Session 2: Building up the Format

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The EEHRxF and its initial specifications

Giorgio Cangioli

HL7 Europe Technical Lead

eHMSEG STF Architecture WG leader

XpanDH WP2 leader

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Recap of previous episodes…

...where are we ...

… how to contribute.

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Recap of previous episodes...

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European EHR Exchange Format Expert Summit

In collaboration with the European Commission

Tuesday 12 December 2023
9:00 AM – 6:00 PM CET
Brussels

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HL7 FHIR

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A complex and multiform scenario

Needs and expectations are different …not a one-fits-all solution

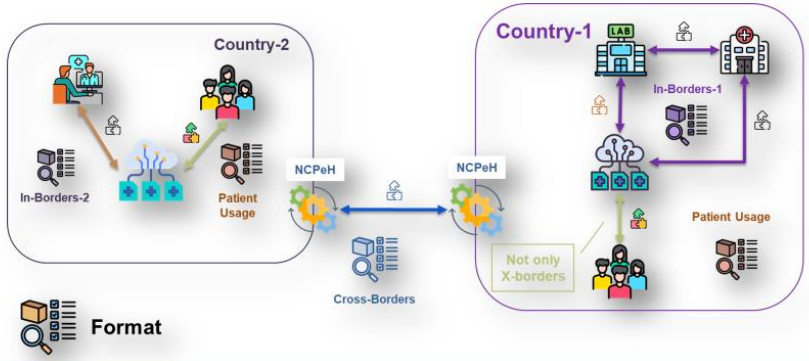
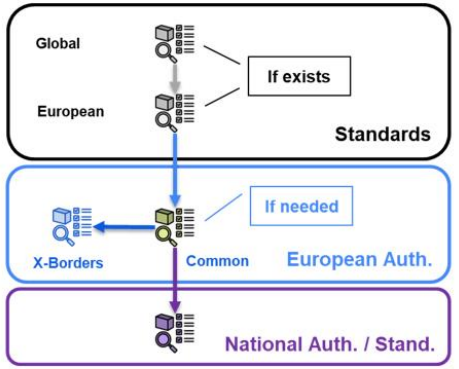


image: Flaticon.com

HL7 FHIR

Which design strategy ?

The strategy



A consistent **system (i.e. a federation) of cooperating, coherent and possibly standard-based specifications**

"The European electronic health record exchange format may have different profiles for its use at the level of EHR systems and at the level of the national contact points in MyHealth@EU for cross-border data exchange" .

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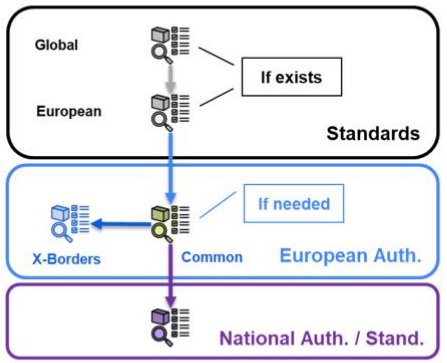
Which design strategy ?

The strategy



A consistent system (i.e. a federation) of cooperating, c
specifications

*"The European
different profile
level of the nat
border data ex*

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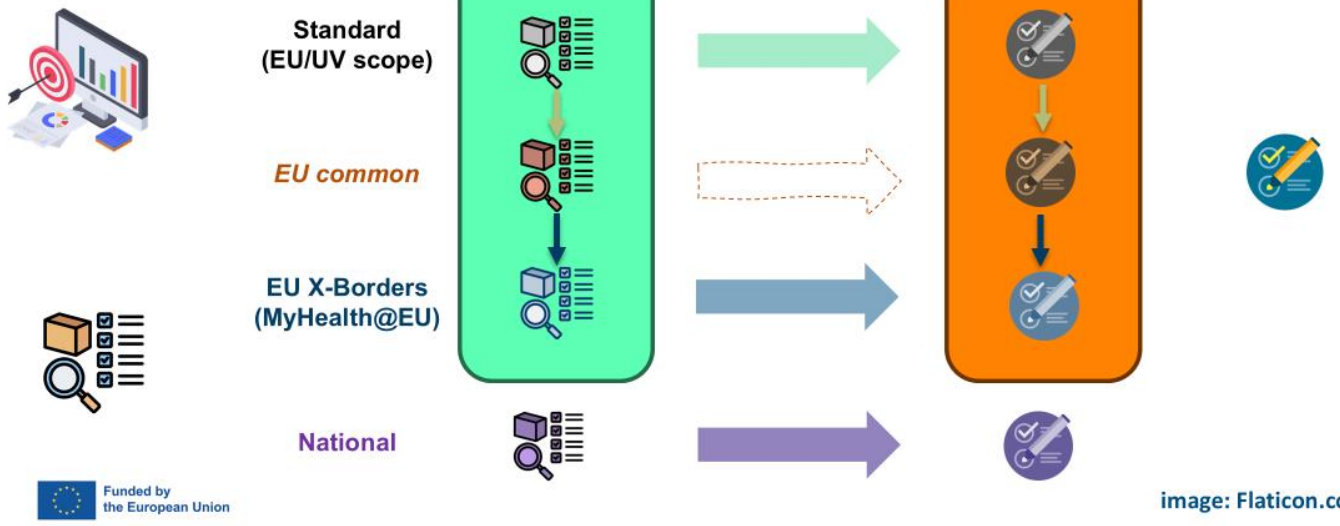
image: Flaticon.com

The strategy



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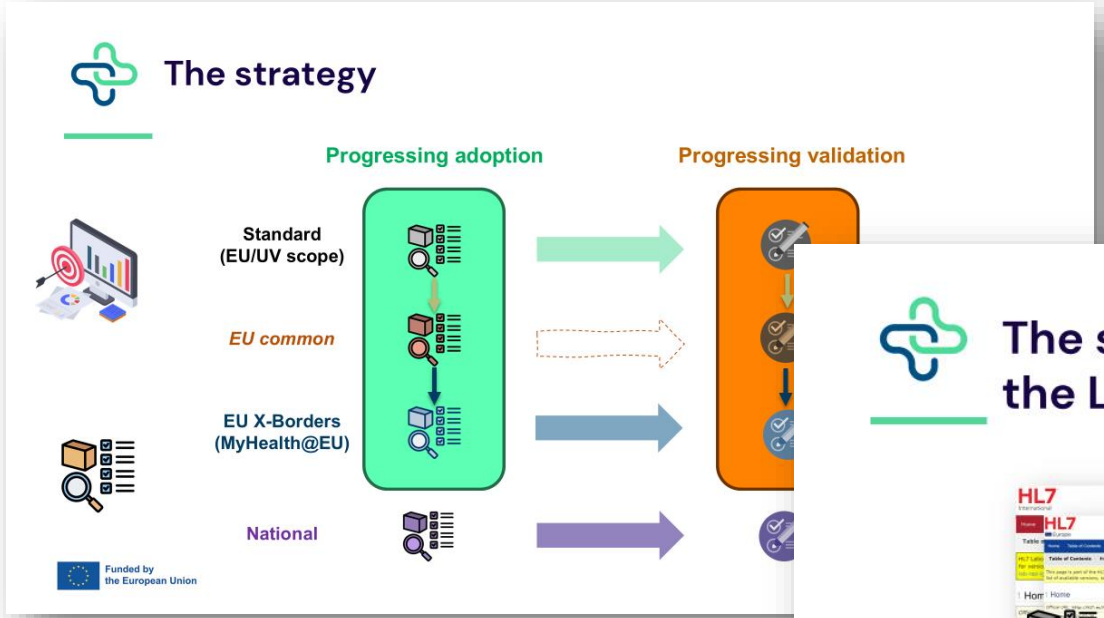

FEB 2024

HL7 Europe Laboratory Report FHIR IG

APR 2024

MyHealth@EU Laboratory Report FHIR IG

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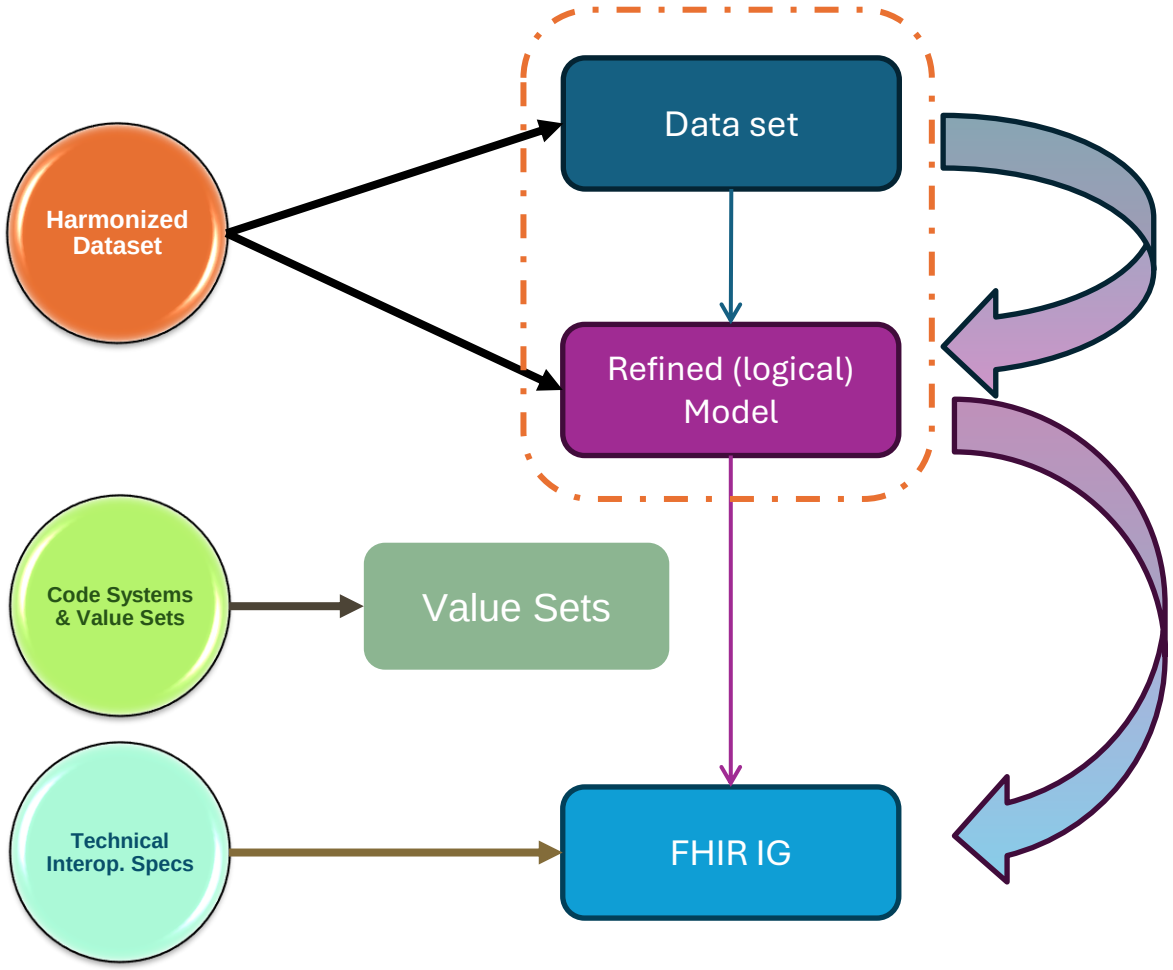
EEHRxF (art. 6): content



Formal model mapping

How is the data set realized in the refined model ?

Formal model mapping

How is the refined model realized in the Tech. specs ?

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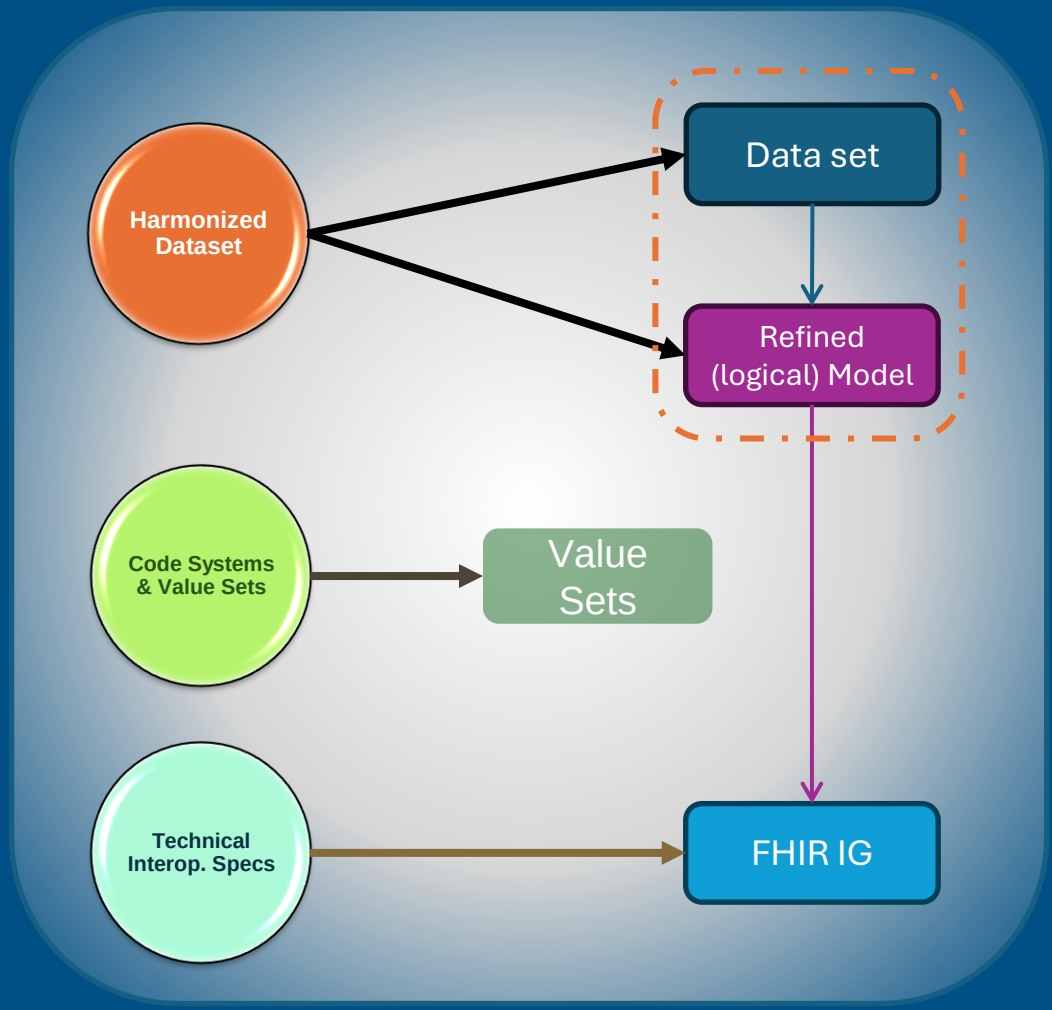
Where are we...



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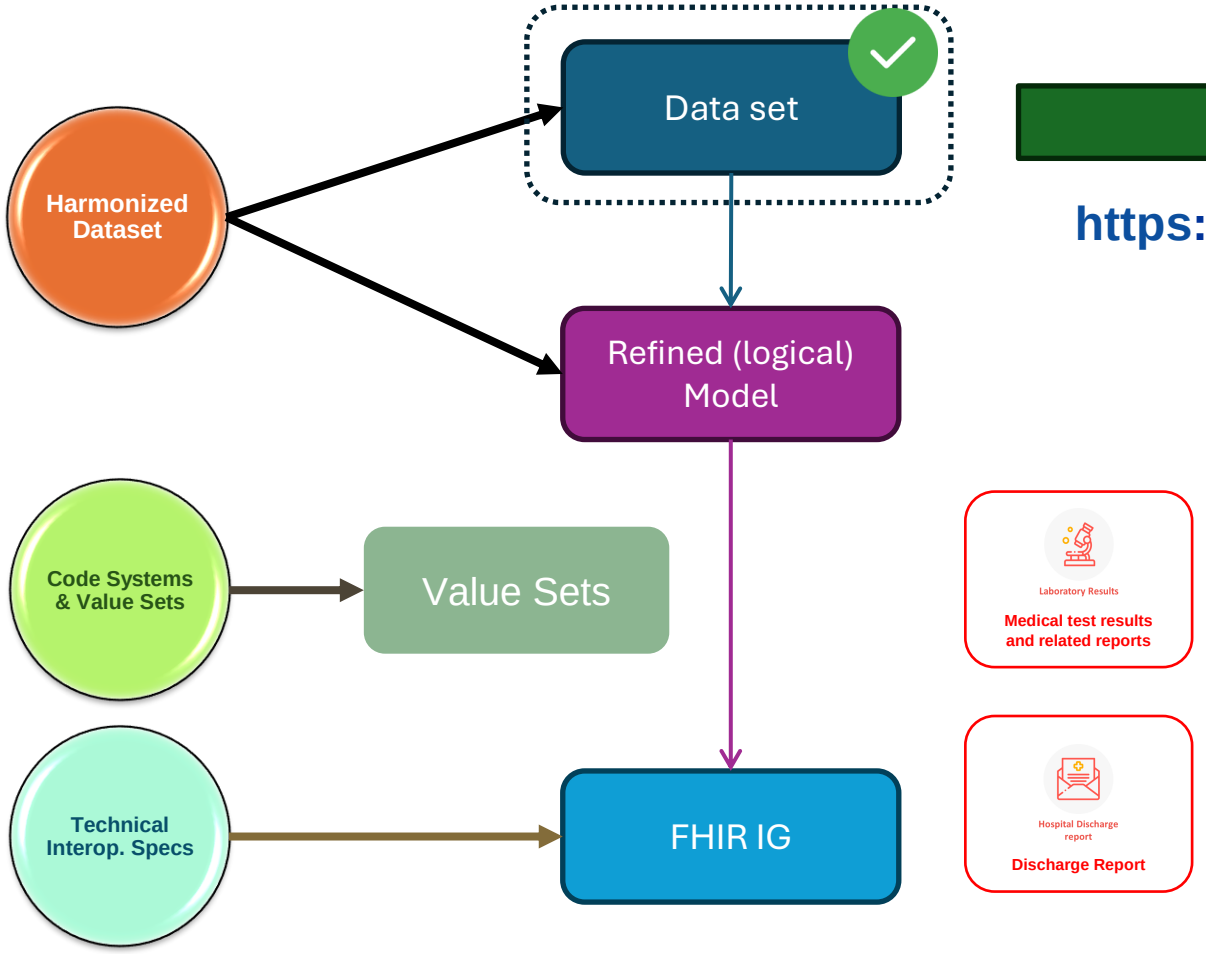
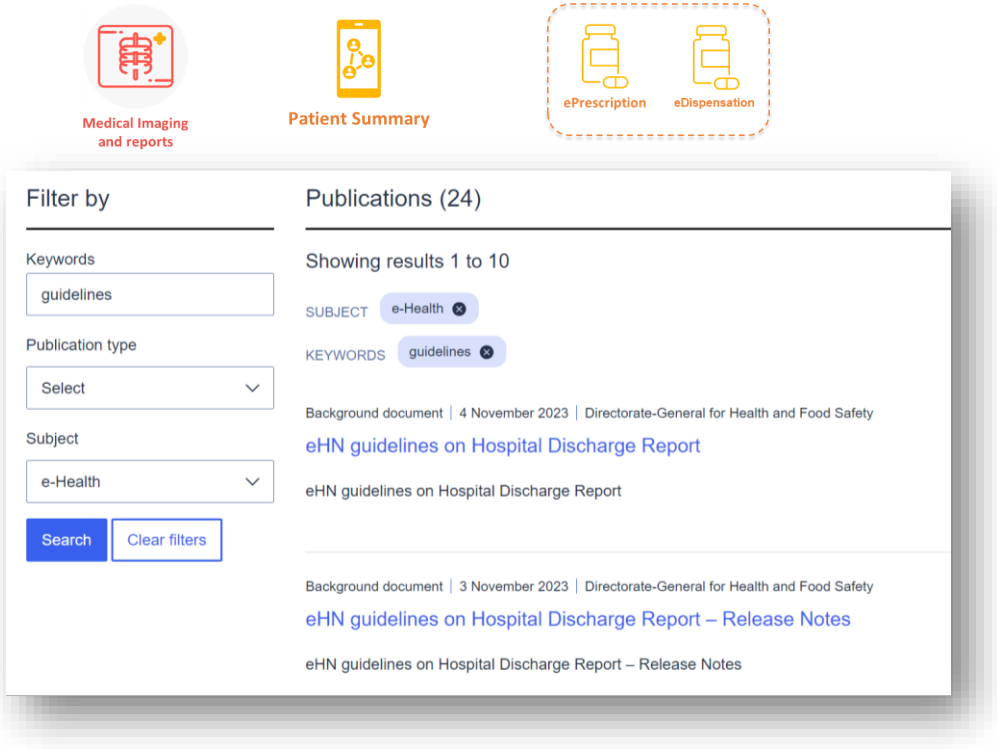


eHN Guidelines – data sets

https://health.ec.europa.eu/publications_en



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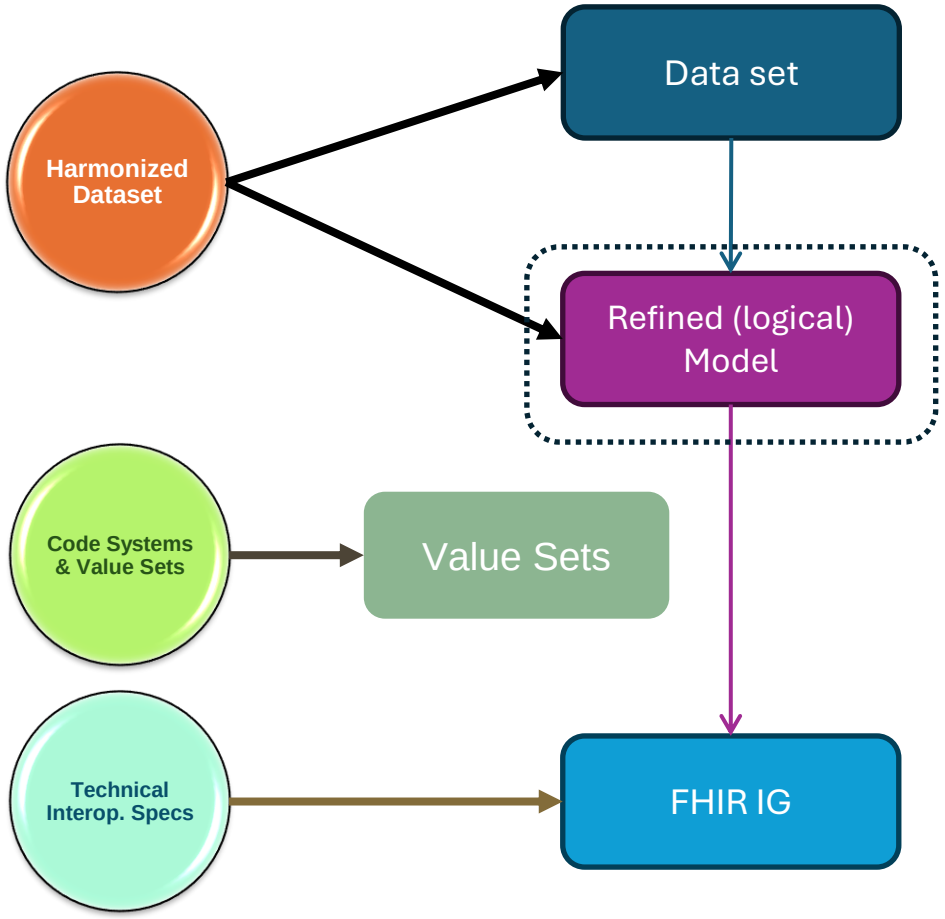
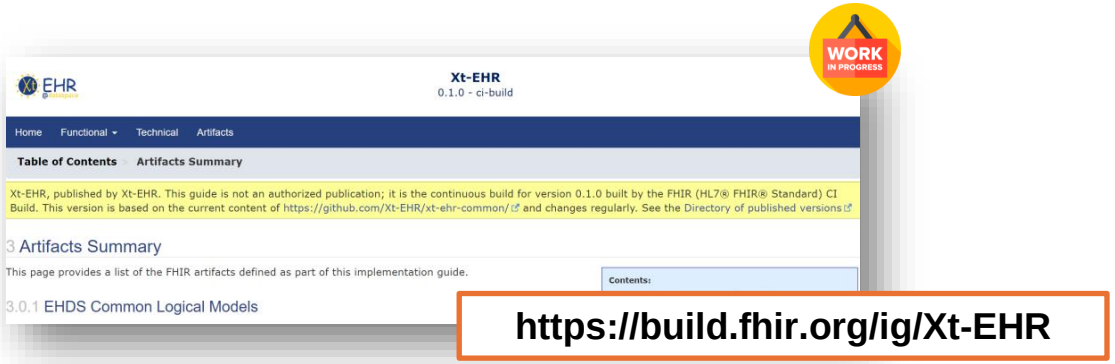


Xt-EHR Logical Models



MyHealth@EU Requirements Catalogue

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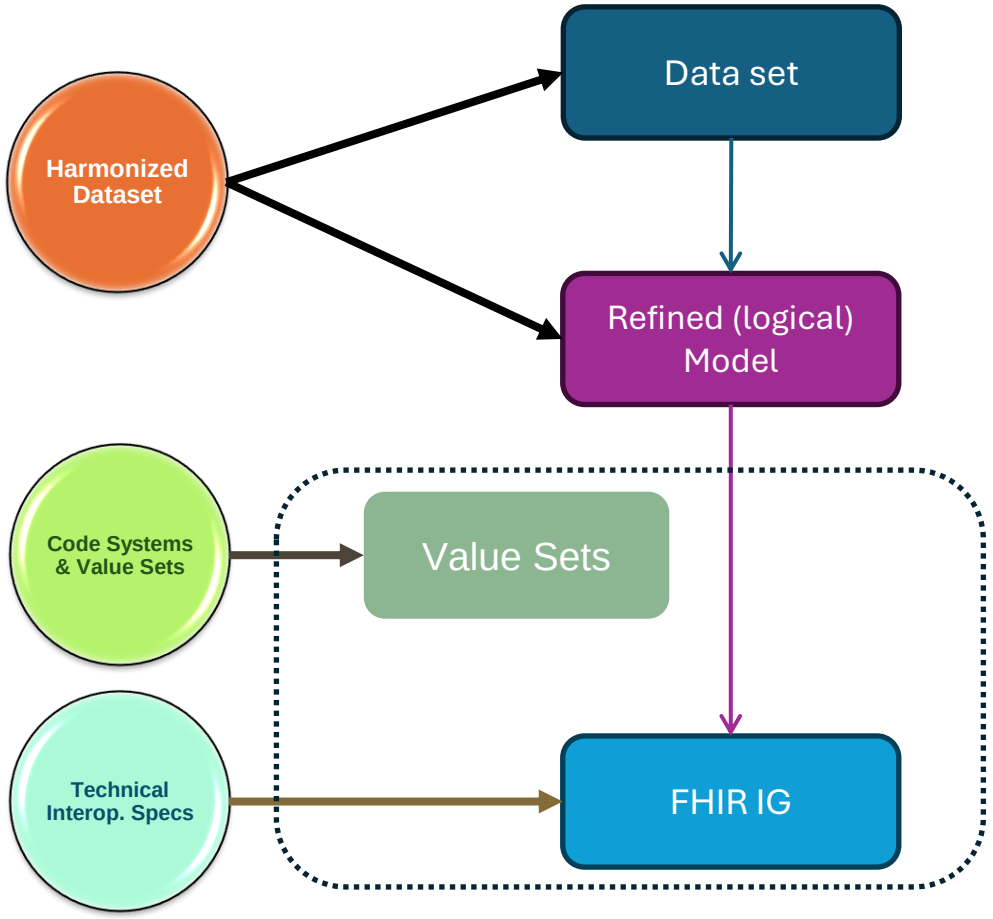

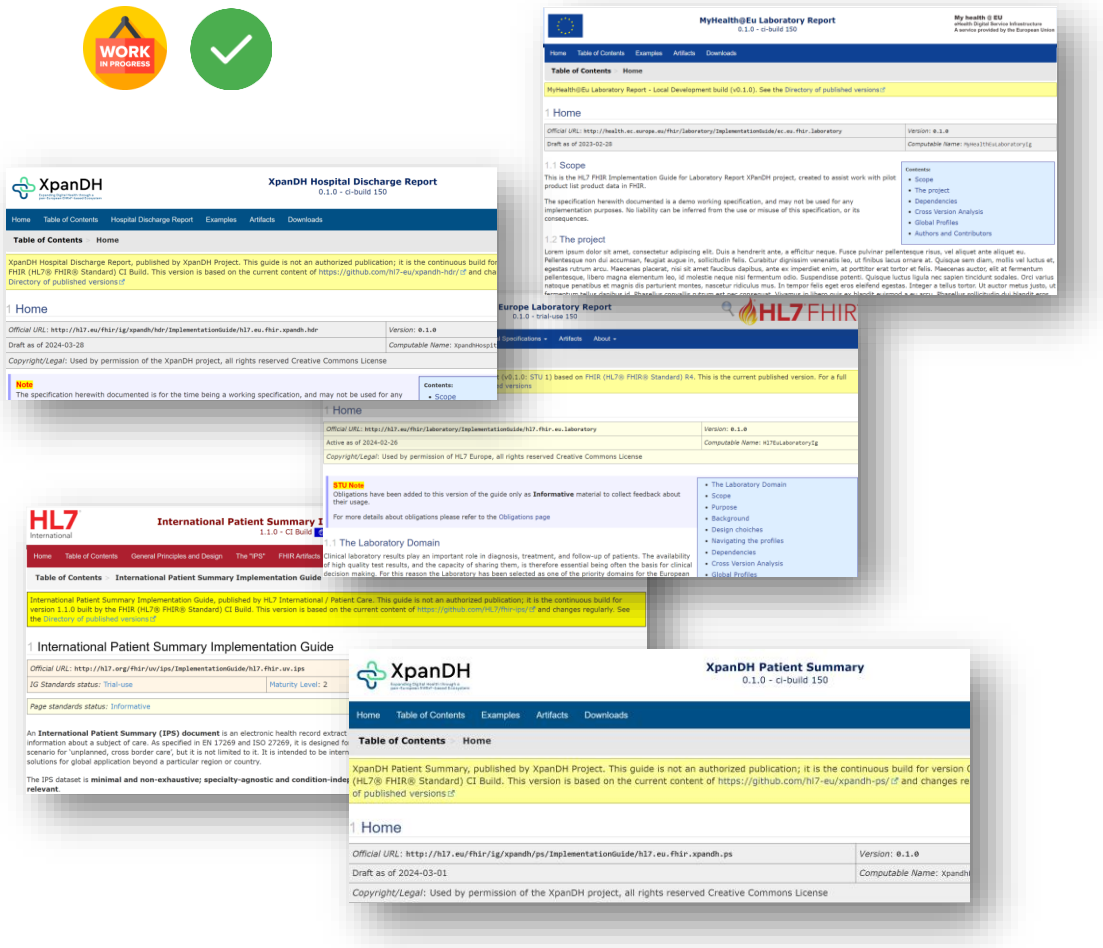

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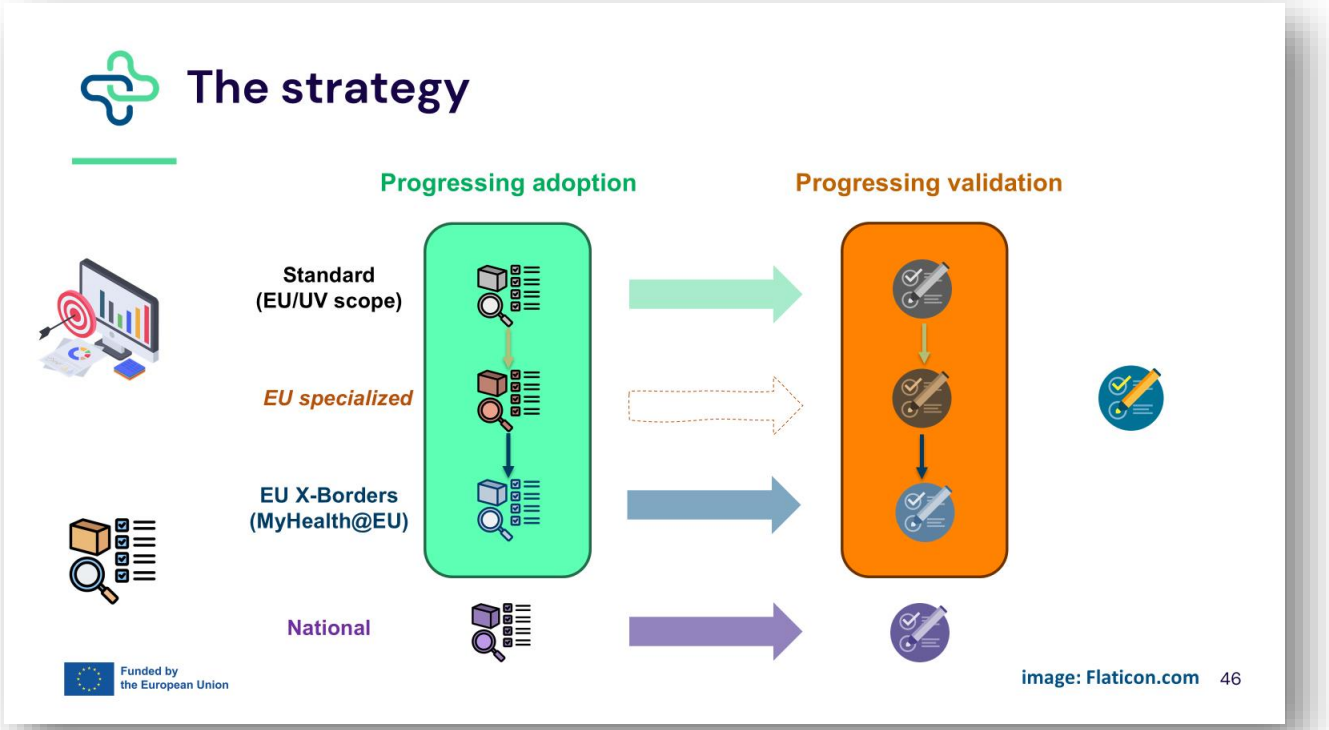
EEHRxF (art. 6)

- Harmonized Dataset
- Code Systems & Value Sets
- Technical Interop. Specs



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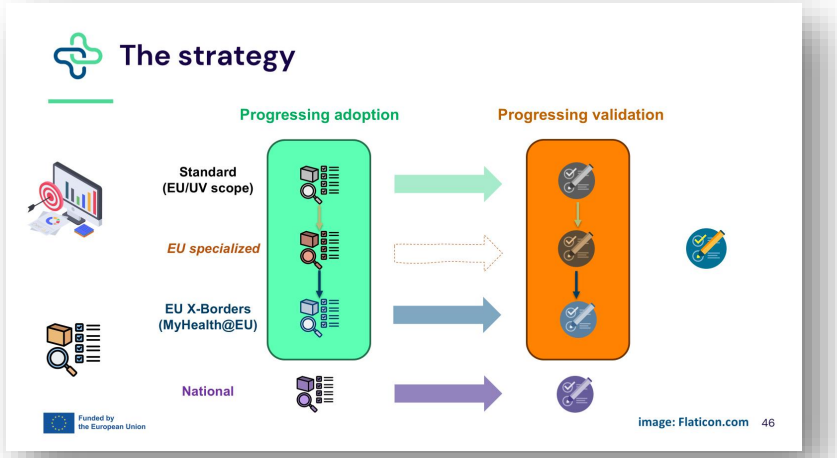

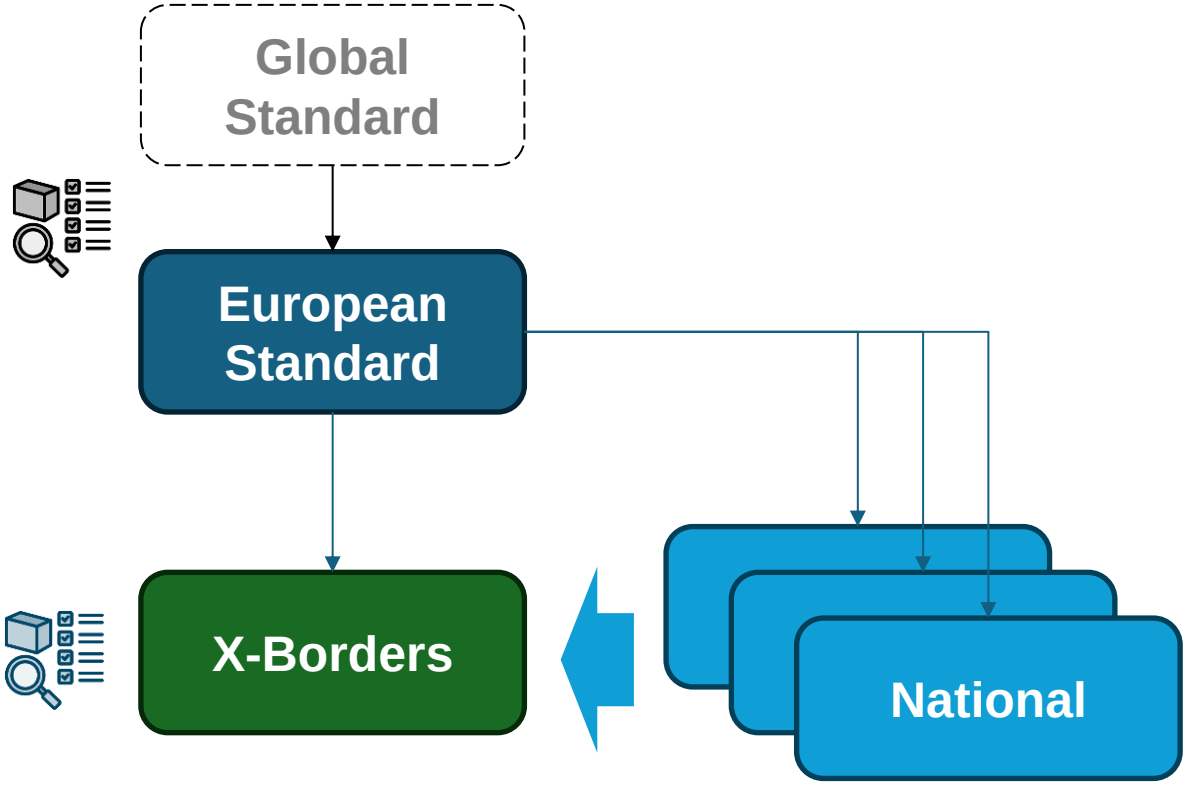

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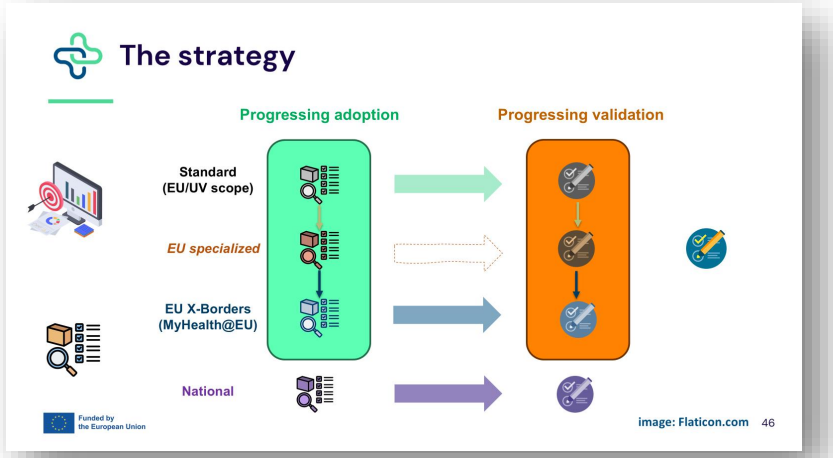

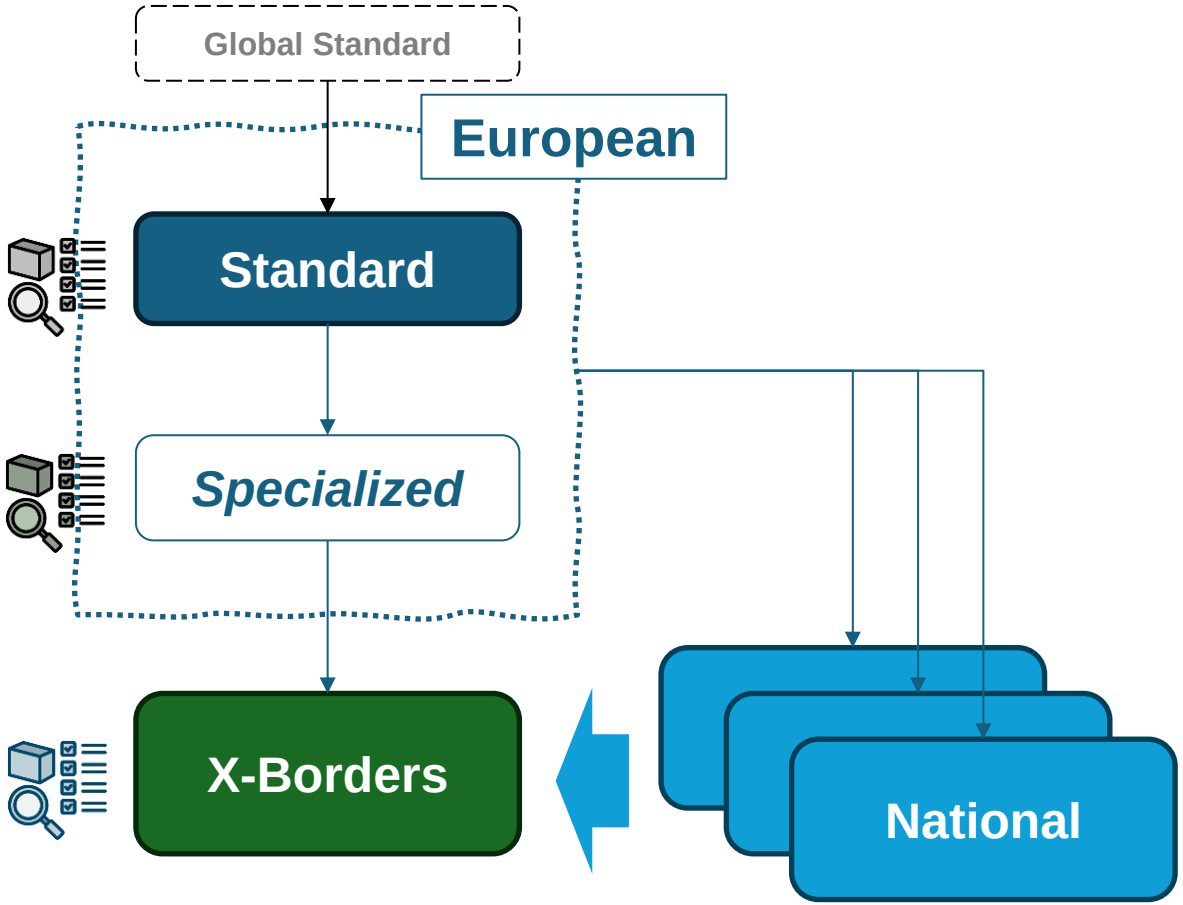

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Data Set/Logical Models overview

	Patient Summary	Laboratory Results	Hospital Discharge report	ePrescription	Medical Imaging and reports	BASE
Global Standard	✓	?	?	✓ WORK IN PROGRESS	?	?
European Standard	✓ ?	?	?	?	?	?
European *Specialized*	✓ WORK IN PROGRESS	✓ WORK IN PROGRESS	✓ WORK IN PROGRESS	✓ WORK IN PROGRESS	✓ WORK IN PROGRESS	WORK IN PROGRESS
European X-border	✓	✓	WORK IN PROGRESS	✓	WORK IN PROGRESS	?

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HL7 FHIR IGs overview

	Patient Summary	Laboratory Results	Hospital Discharge report	ePrescription	Medical Imaging and reports	BASE
Global Standard	✓ WORK	WORK		WORK	WORK	
European Standard	WORK	✓	WORK	WORK	?	WORK
European *Specialized*	IF...	IF...	IF...	IF...	IF...	IF...
European X-border		✓	WORK			?

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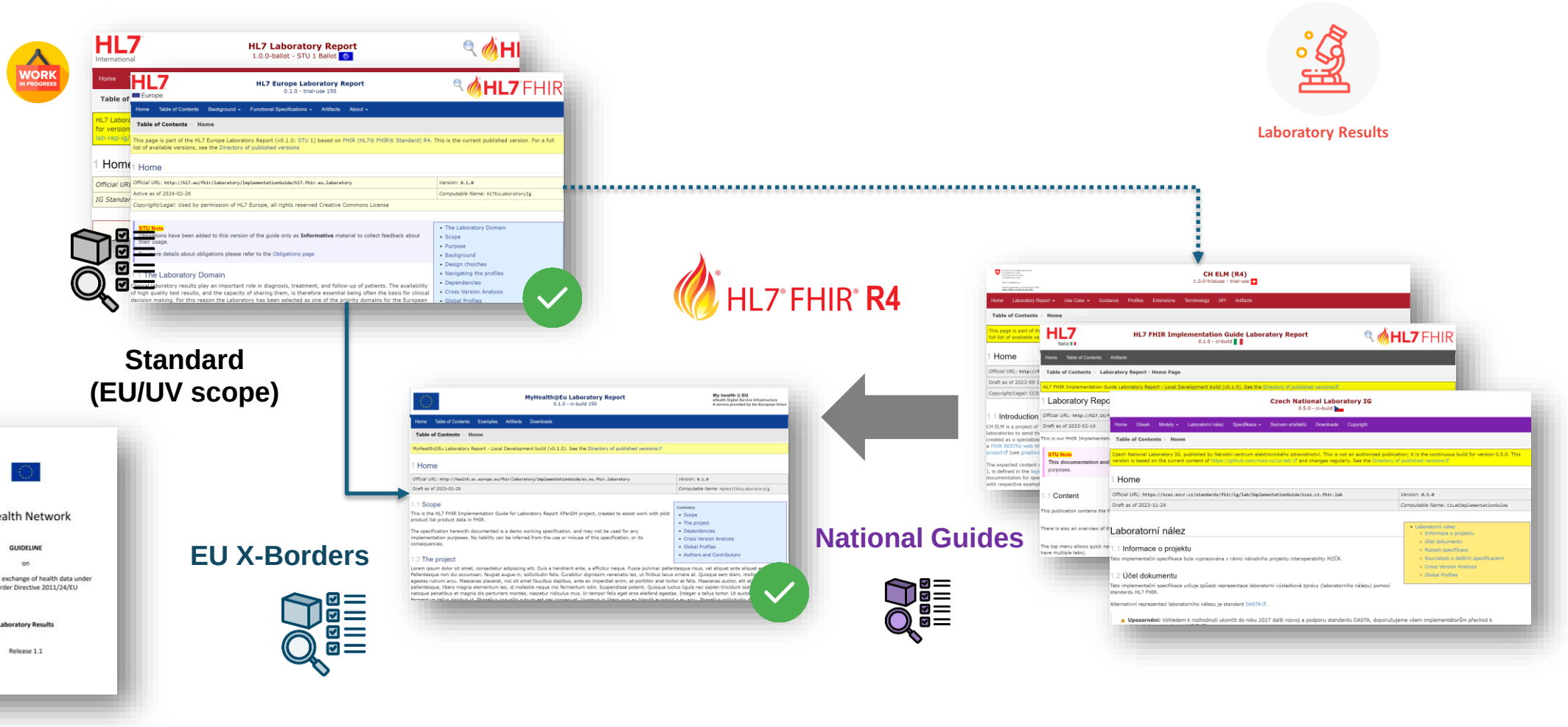
Laboratory Report



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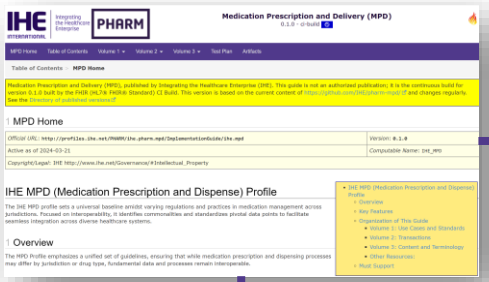
Medication Prescription & Dispense

IHE INTERNATIONAL Integrating the Healthcare Enterprise

HL7

GEMINI



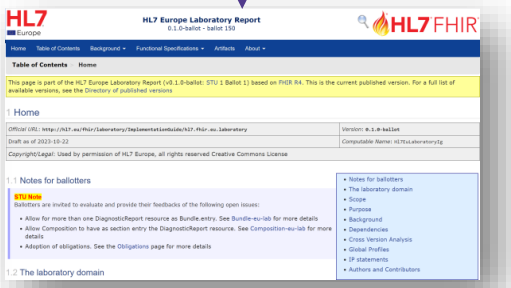
ePrescription

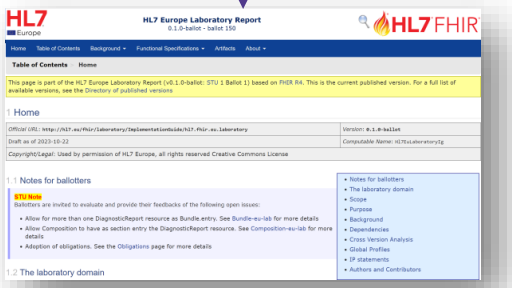
aligned

derived

WORK IN PROGRESS

HL7 Europe





HL7 FHIR R5

HL7 FHIR R4

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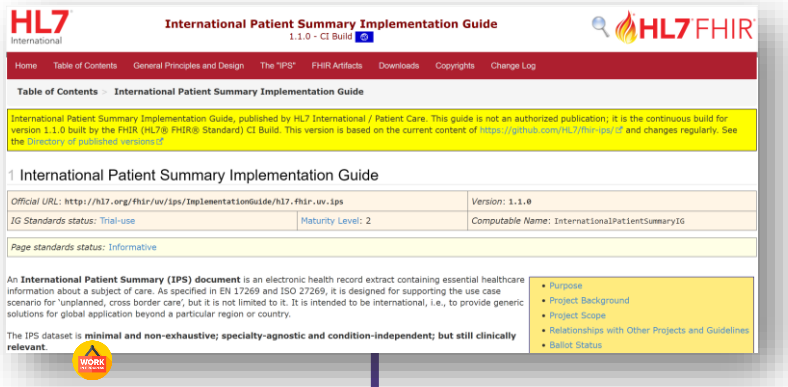
Patient Summary

Patient Summary



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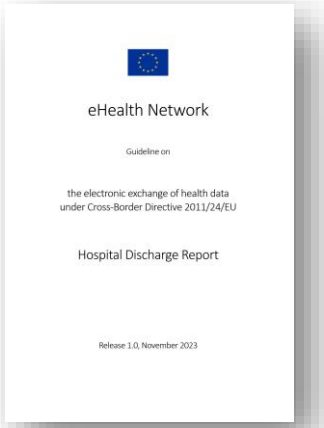
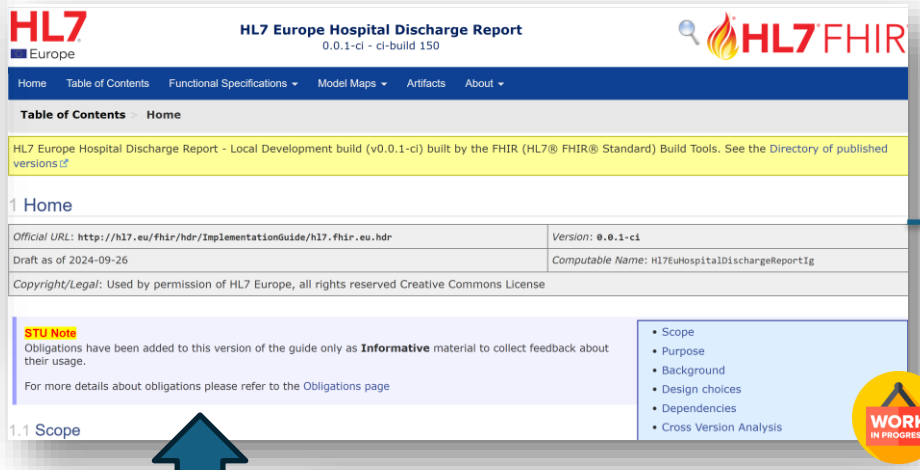
Hospital Discharge Report

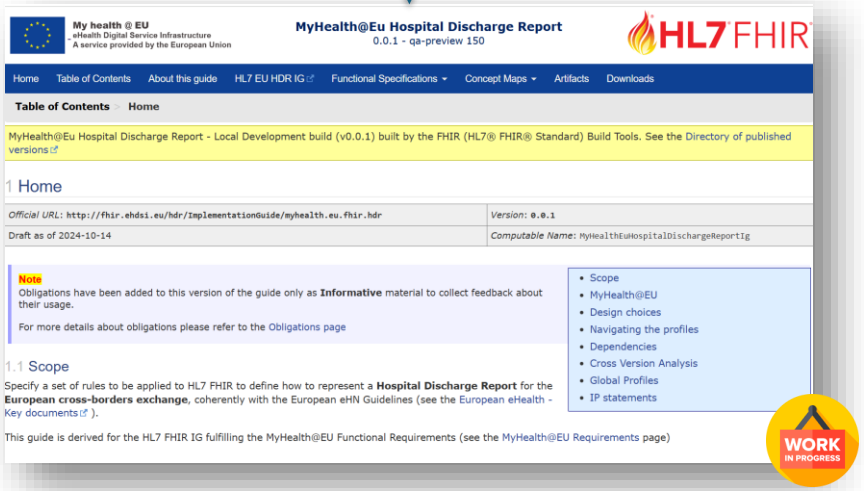




HL7 Europe

HL7 FHIR R4

Hospital Discharge report



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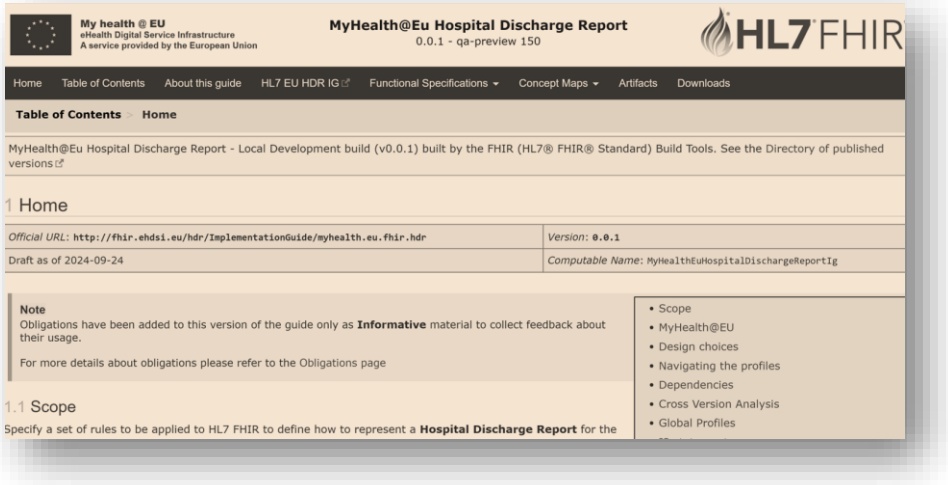
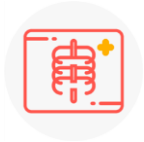
Medical Imaging Report





- Scheduled for MyHealth@EU Wave 9
- IHE Radiology activity on going (HL7 FHIR R6)
- HL7 Europe activity under evaluation

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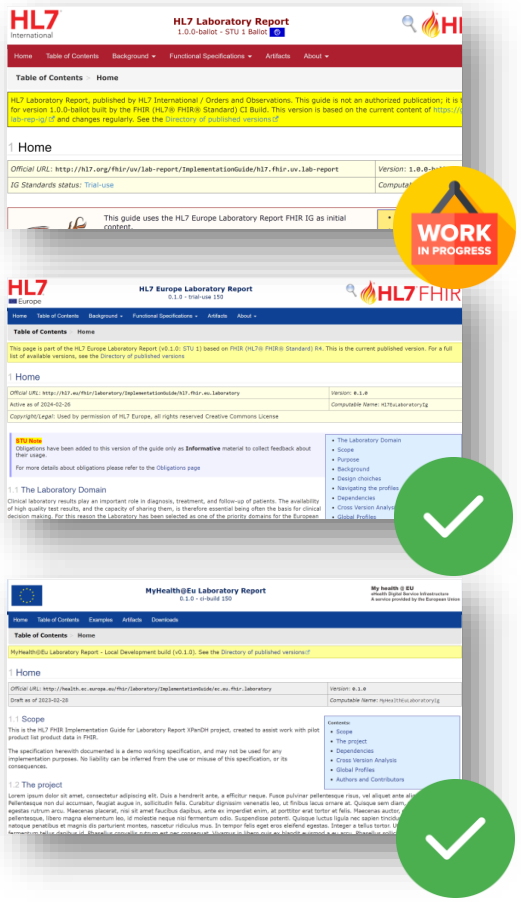
Laboratory Report



https://build.fhir.org/ig/HL7/uv-lab-rep-ig/

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https://build-fhir.ehdsi.eu/laboratory/

Laboratory Results

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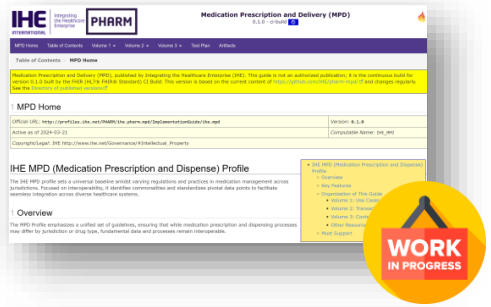
Medication Prescription & Dispense

ePrescription



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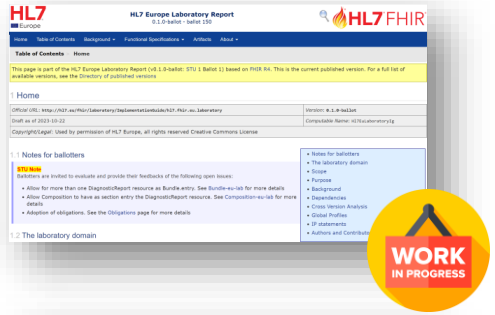

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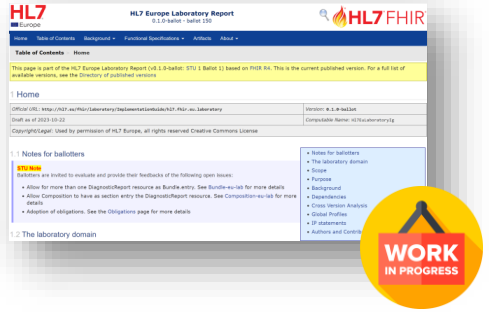

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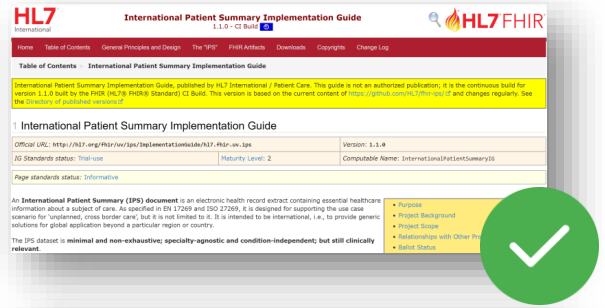
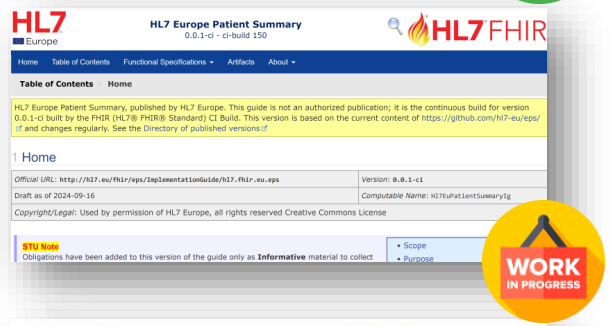
Patient Summary



https://hl7.org/fhir/uv/ips/
https://build.fhir.org/ig/HL7/fhir-ips



https://build.fhir.org/ig/hl7-eu

Patient Summary

https://build.fhir.org/ig/hl7-eu/xpandh-ps/ (POC)

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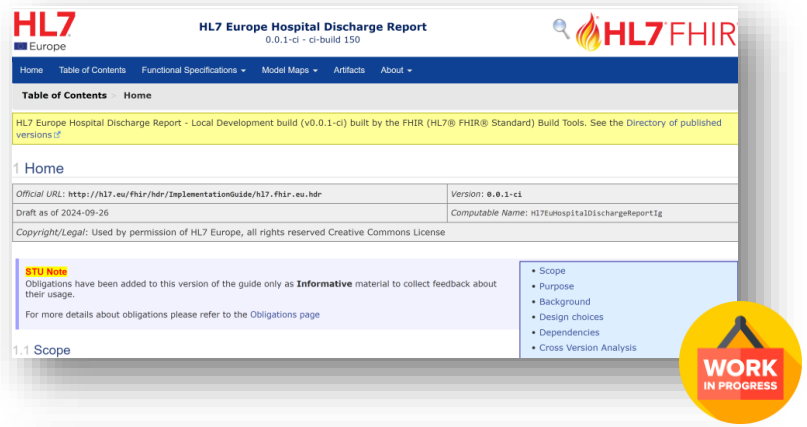
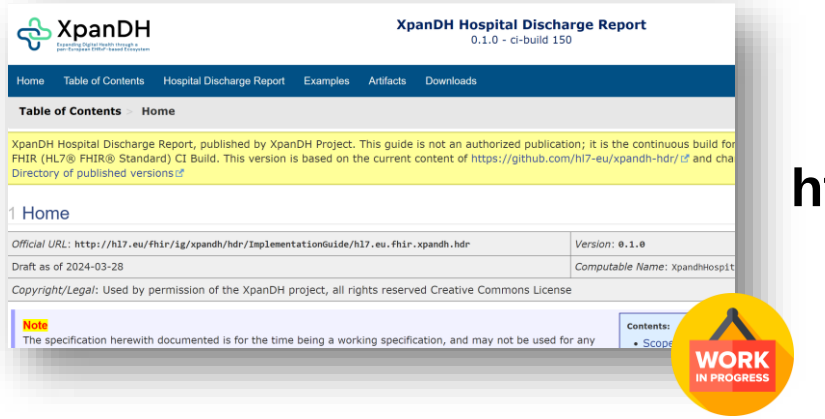
Hospital Discharge Report



https://build.fhir.org/ig/hl7-eu/hdr/



https://build.fhir.org/ig/hl7-eu/xpandh-hdr/

Hospital Discharge report

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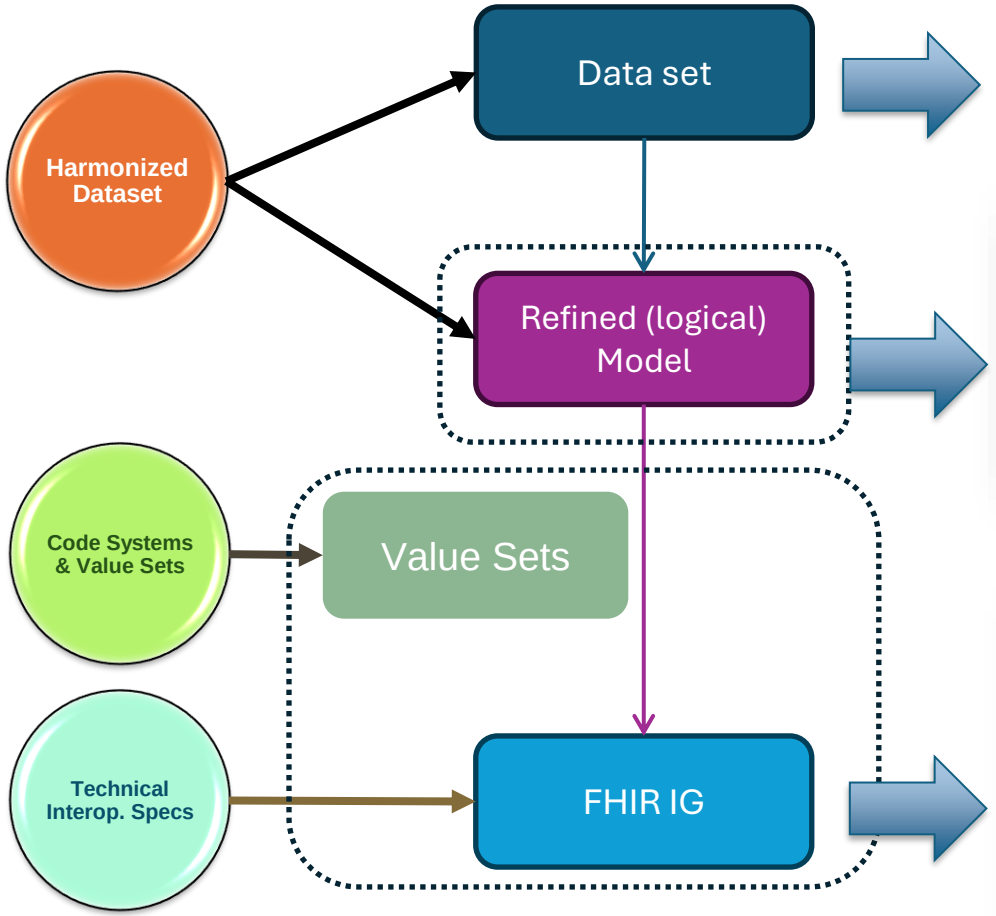
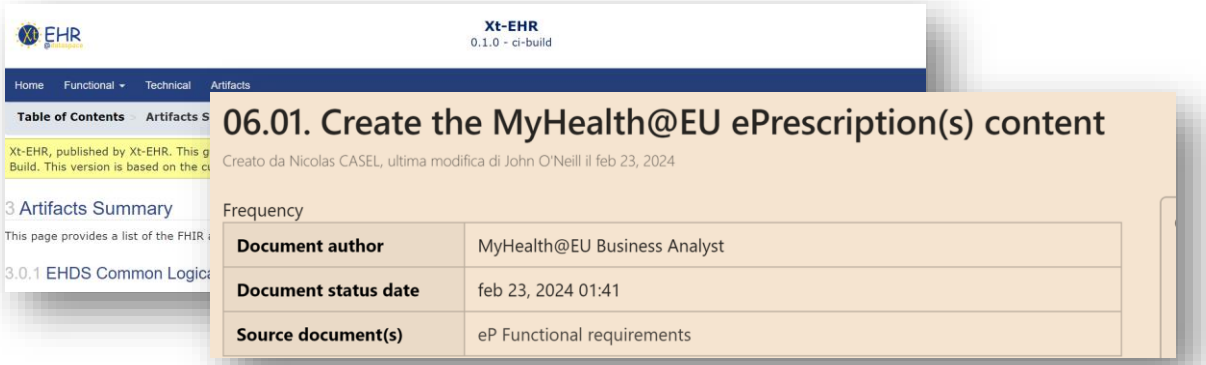
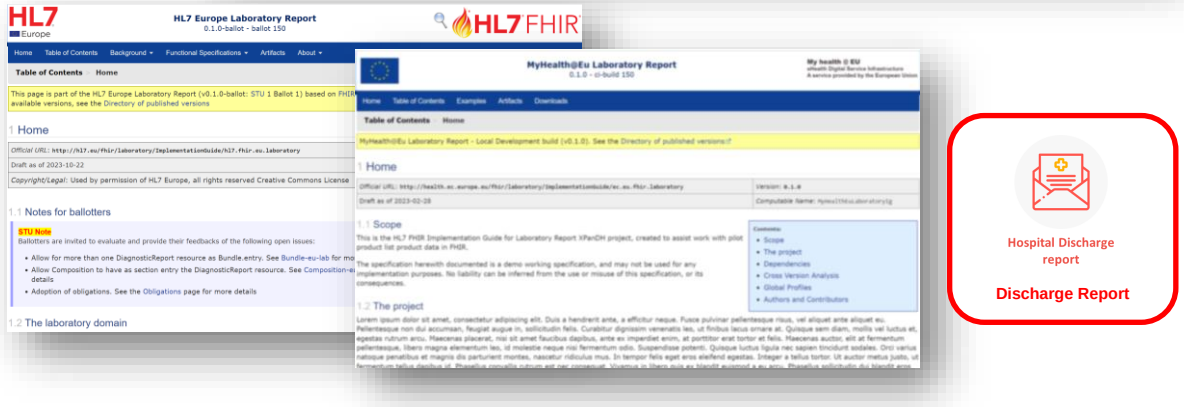
EEHRxF (art. 6): content



eHN Guidelines – data sets





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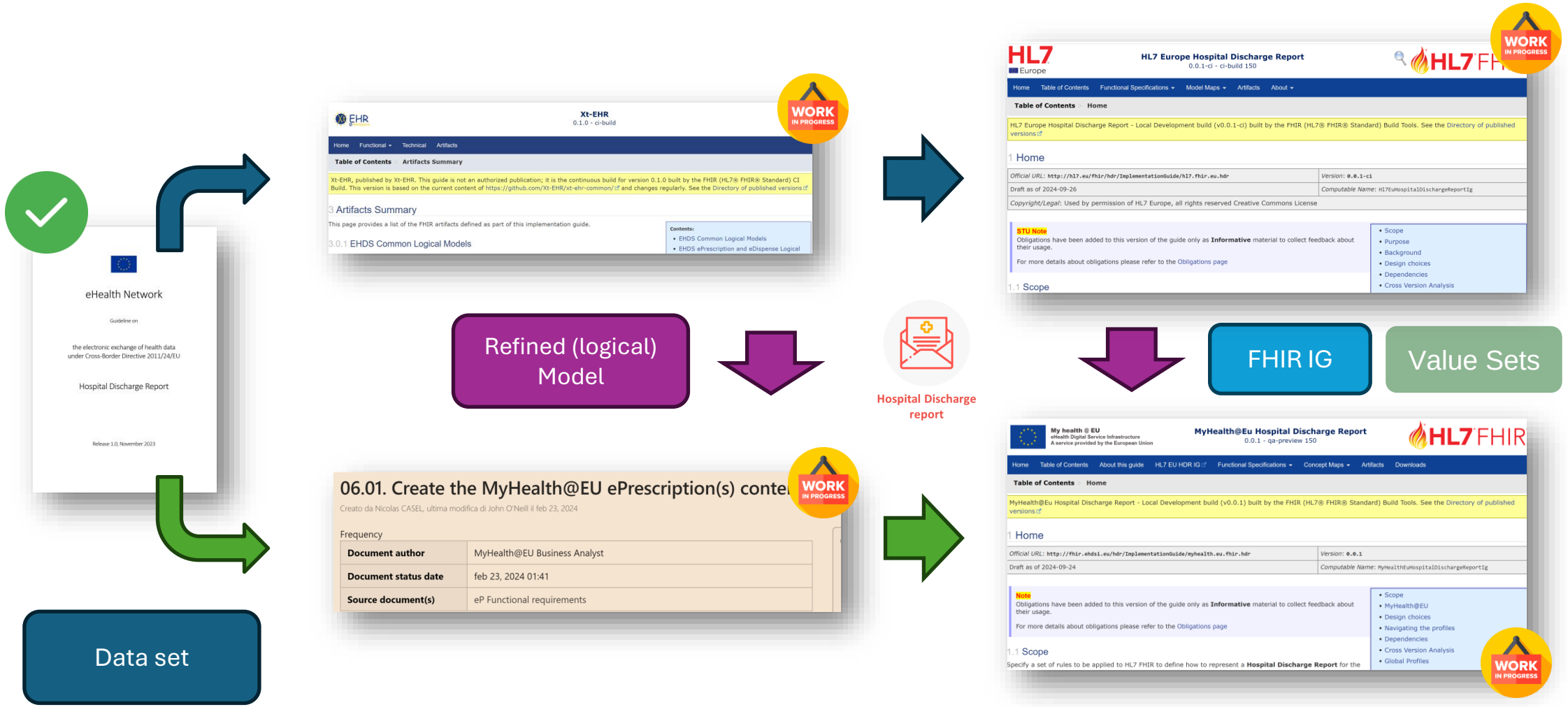

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Joint Action Formalization

X-eHealth
Exchanging Electronic Health Records in a common framework

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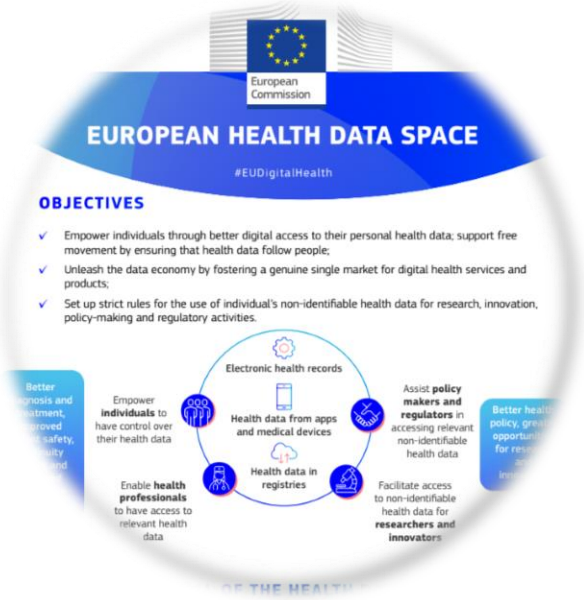
Share EHR Xchange Format



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eHMSEG

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A service provided by the European Union

Innovation, Experimentation

Cross-Border Services Infrastructure, Deployment

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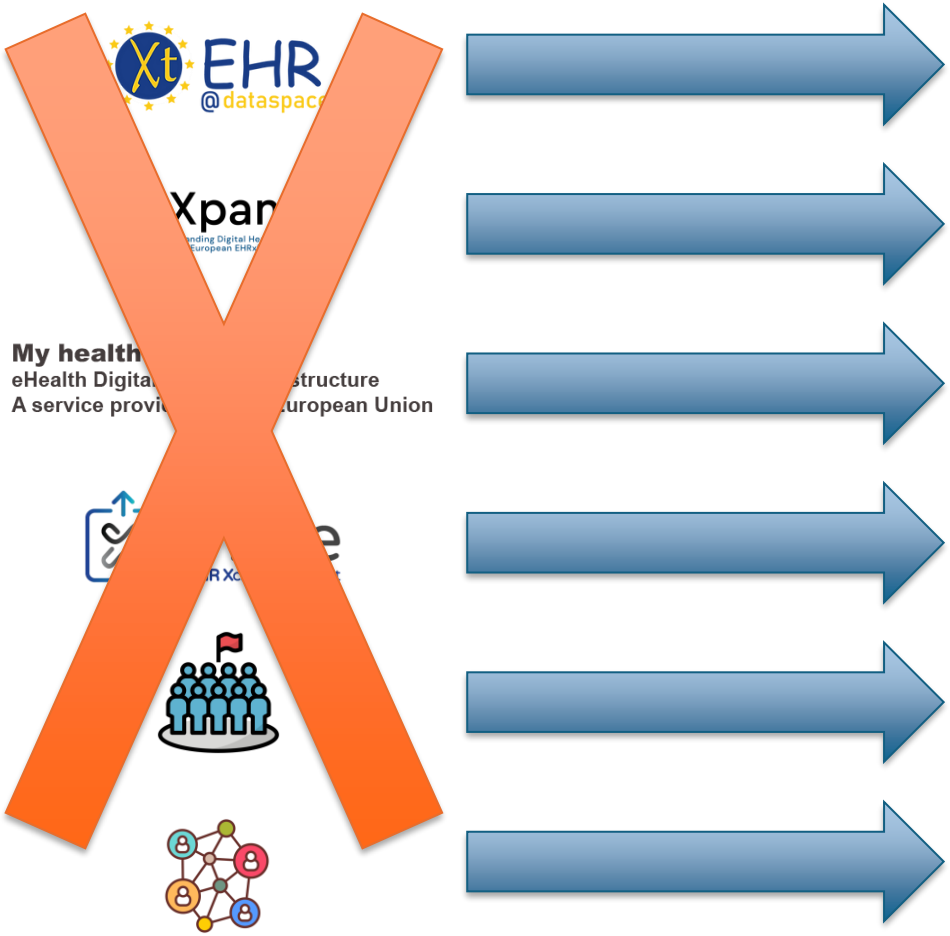
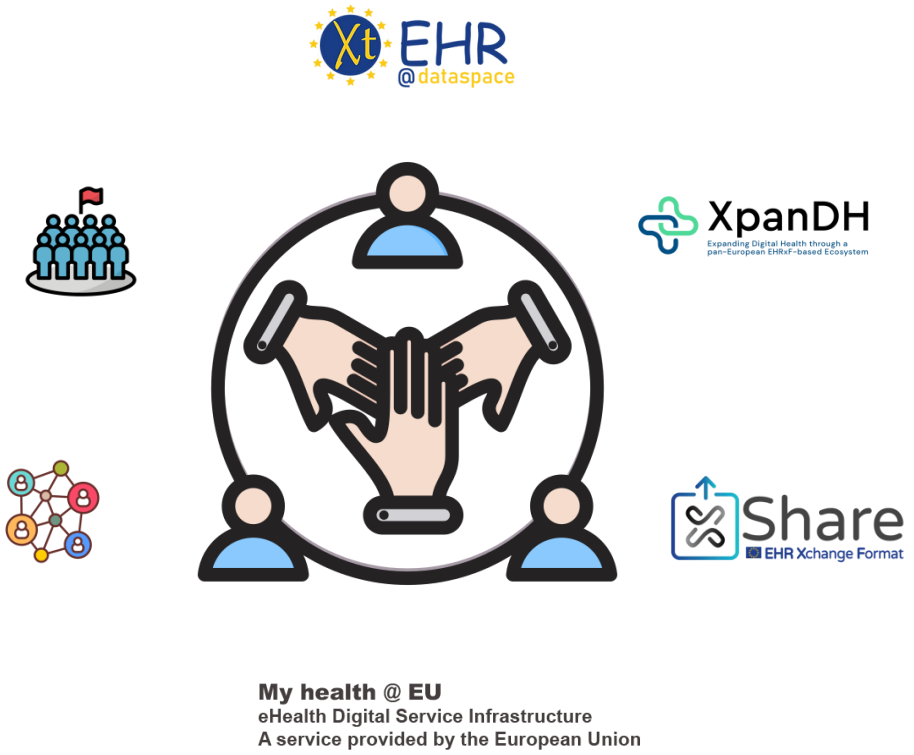


Only do the job once !



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..How to contribute

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Some Facts..

- The **standardization work** is a result of a highly **participated multi-stakeholder effort**..
- ..including, but not limited to, the **most relevant European projects and initiatives**..
- ..with a relevant **country coverage** (beyond the European Union)

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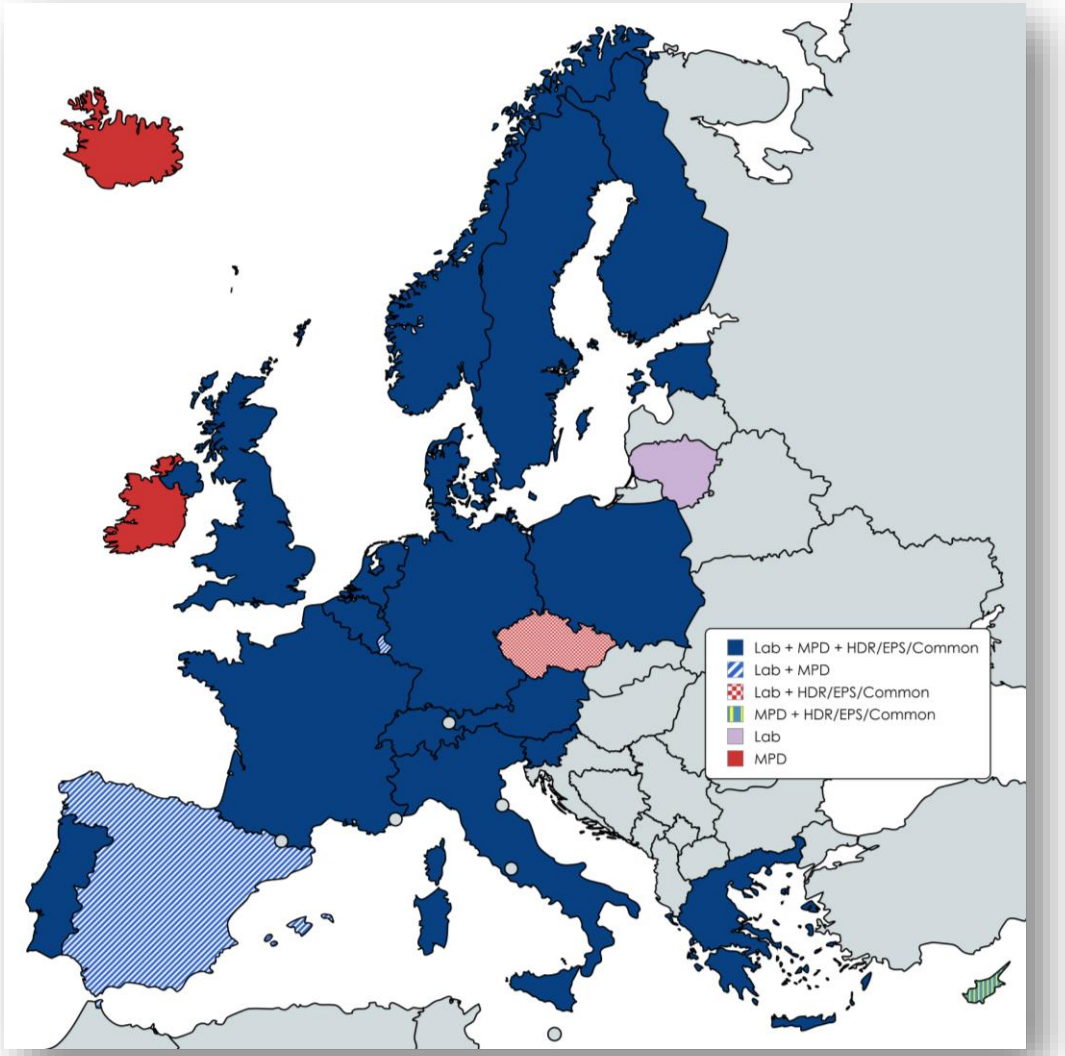

Some Facts..

- **Laboratory Report**: **113 distinct participants** from **22 countries** (including USA) and EC Solution Providers [average ~30 attendees]
- **MPD**: **114 distinct participants** from **26 countries** (including USA) and EC Solution Providers [average ~30 attendees]
- **HDR/EPS/Common**: **118 distinct participants** from **22 countries** (including Sri Lanka, United Arab Emirates and Saudi Arabia) and EC Solution Providers [average 66 attendees]

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How to be engaged ...

STAYING TUNED (WEBINARS, TUTORIALS; HANDS-ON EVENTS)

JOINING THE X-NETS (E.G. HOSPITALS ON FHIR)

PROVIDING YOUR FEEDBACK (JIRA, GITHUB)

JOINING THE MEETINGS

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European Commission

How to be engaged ...

mailto:xpandh@iscte-iul.pt

- **Laboratory Report**: (*Semantic*) **Every other Friday 13-14.30 CET**
- **MPD**: **Every other Thursday 16-17 CET**
- **HDR/EPS/Common**: **Every Friday 10-11 CET**

JOINING THE MEETINGS

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EEHRxF Adoption: Current Landscape and Future Directions

Maria Marques

UNINOVA

XpanDH WP4 leader | xShare WP3 co-leader

Email: mcm@uninova.pt

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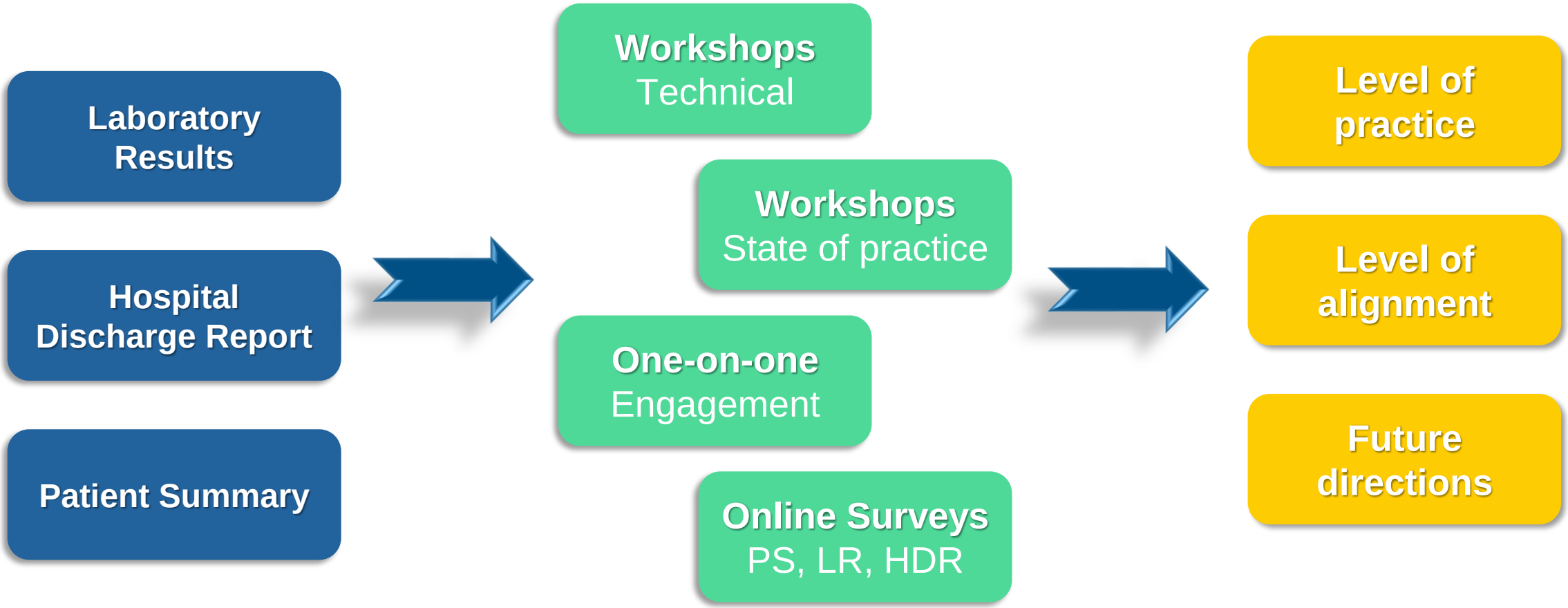
Methodology



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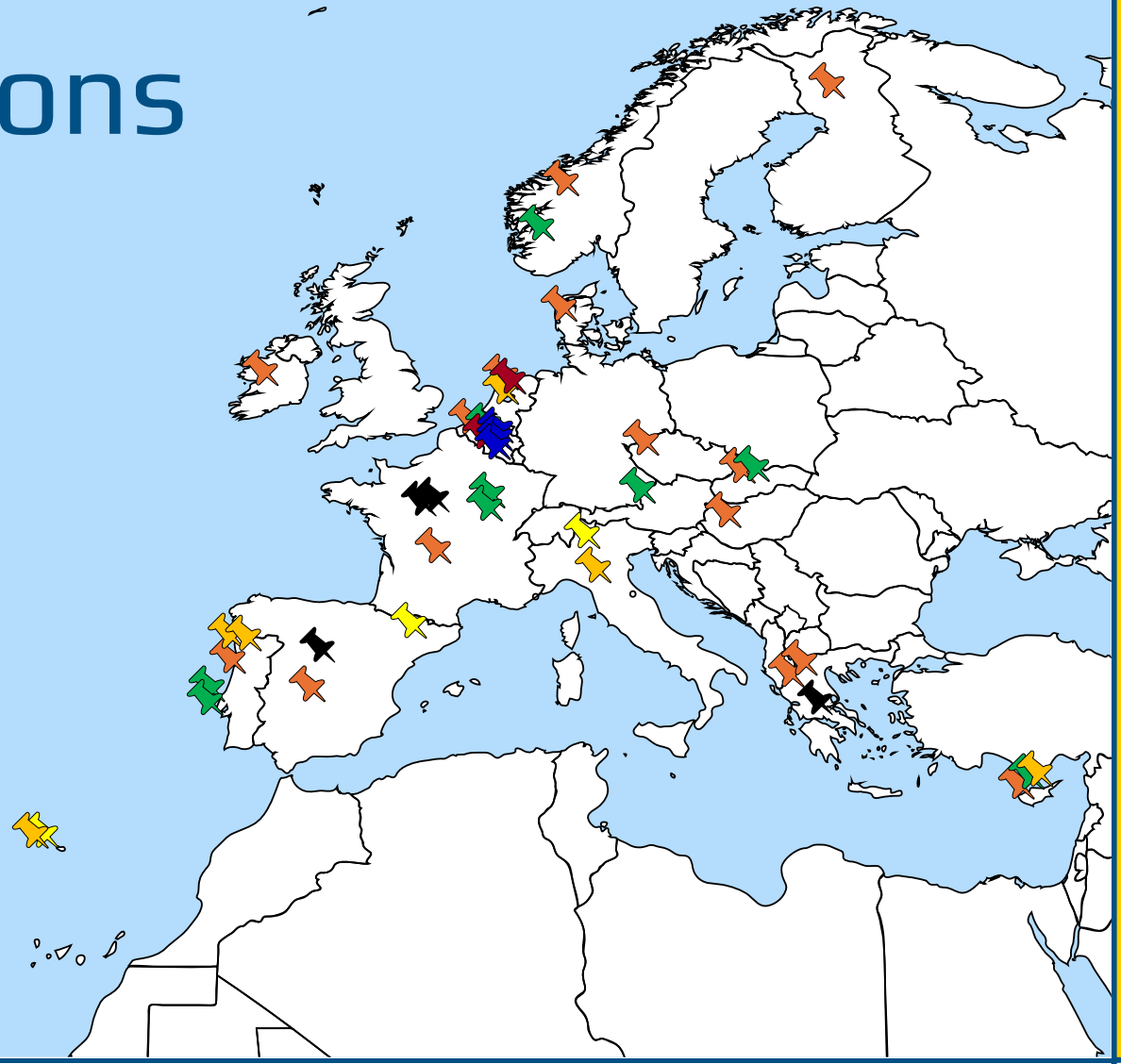
Involved Organisations

- National agencies - 15
- Regional agencies - 3
- Academic and research - 9
- Healthcare providers - 6
- IT/EHR vendors - 5
- SDOs - 3
- Industry/Health associations - 3



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Involved Nacional Agencies

Spain

- NCP implemented (regions)
  - PS (12/18), eD/eP (15/18)
- National Digital EHR system
  - EU PS and Medical Summary Report structured
  - Others unstructured

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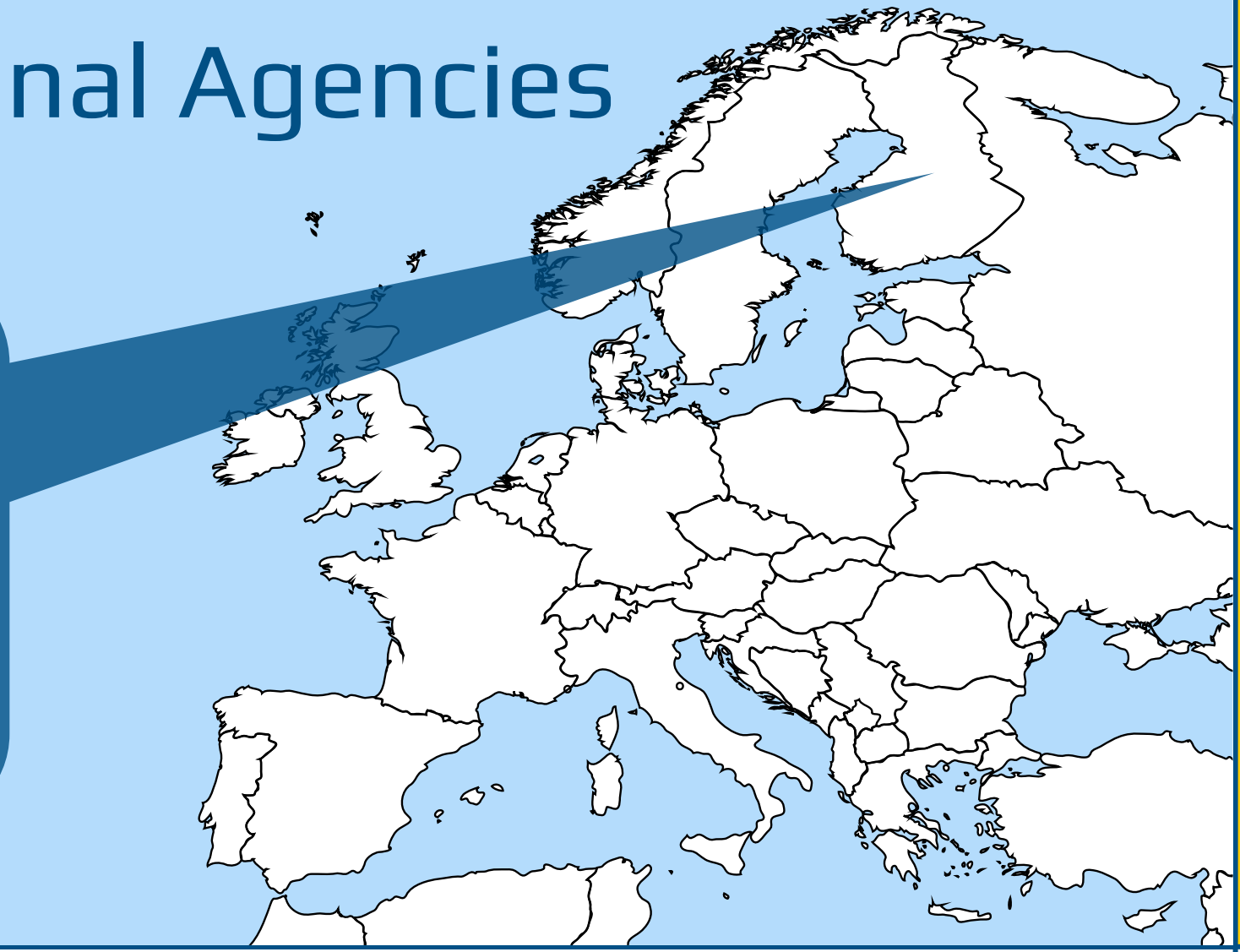
Involved Nacional Agencies



Finland

- NCP implemented
- CDA and FHIR standards used, but there are differences in the structures and datasets compared to EEHRxF
- Mapping to/from code system used on national level
- PS not include all information (e.g vaccination).

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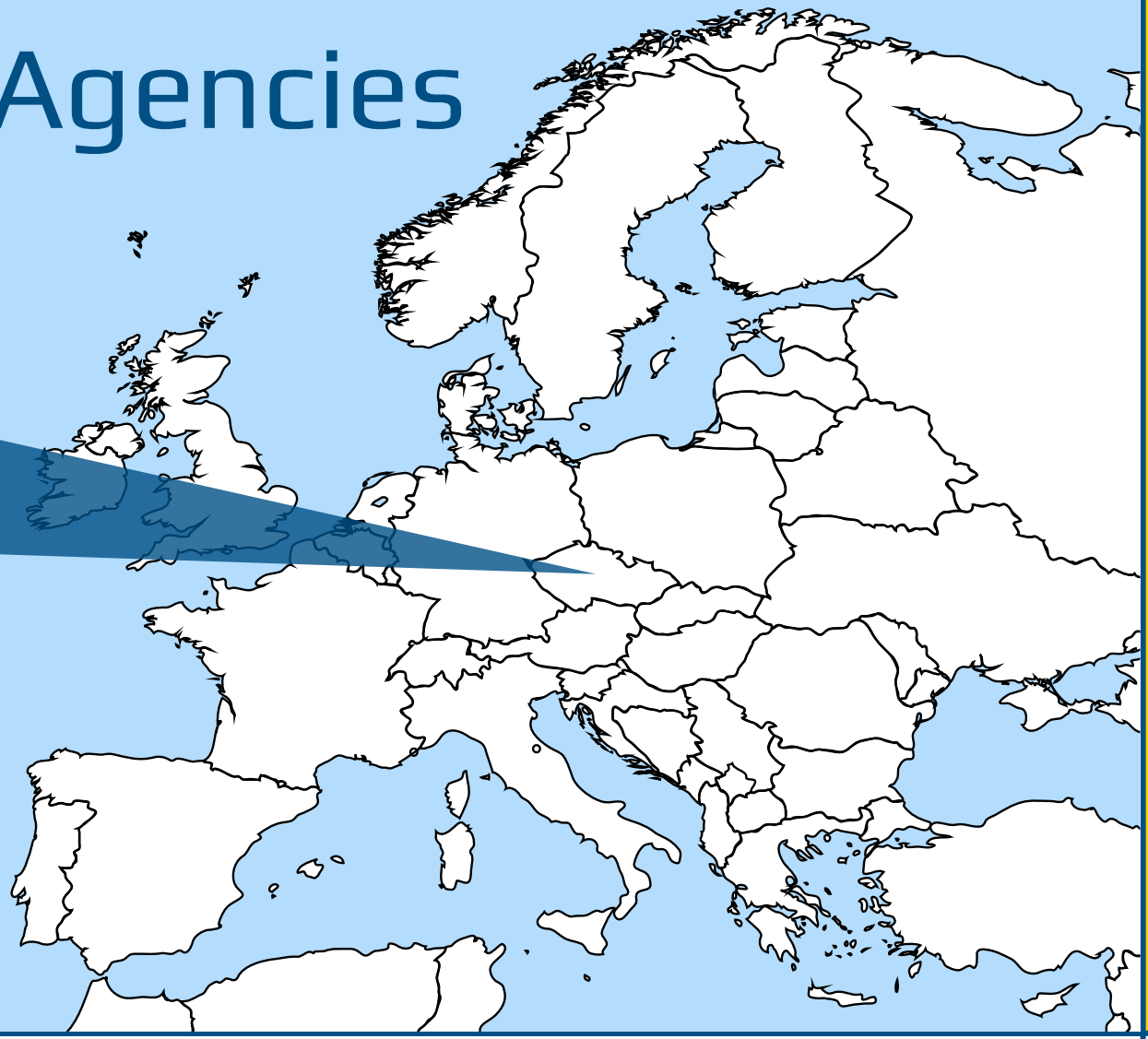
Involved Nacional Agencies



Czech Republic

- NCP implemented
- eP/eD at national level with proprietary specification
  - mapped to/from European ones for cross-border
- PS not used internally in Czech republic
  - only for cross-border

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Involved Nacional Agencies

Belgium

- NCP implemented
- Health data exchange achieved through the use of the Belgian "Care Sets“ approach
- HL7 FHIR profiles to support technically

Portugal

- NCP implemented
- Using FHIR standard at national level

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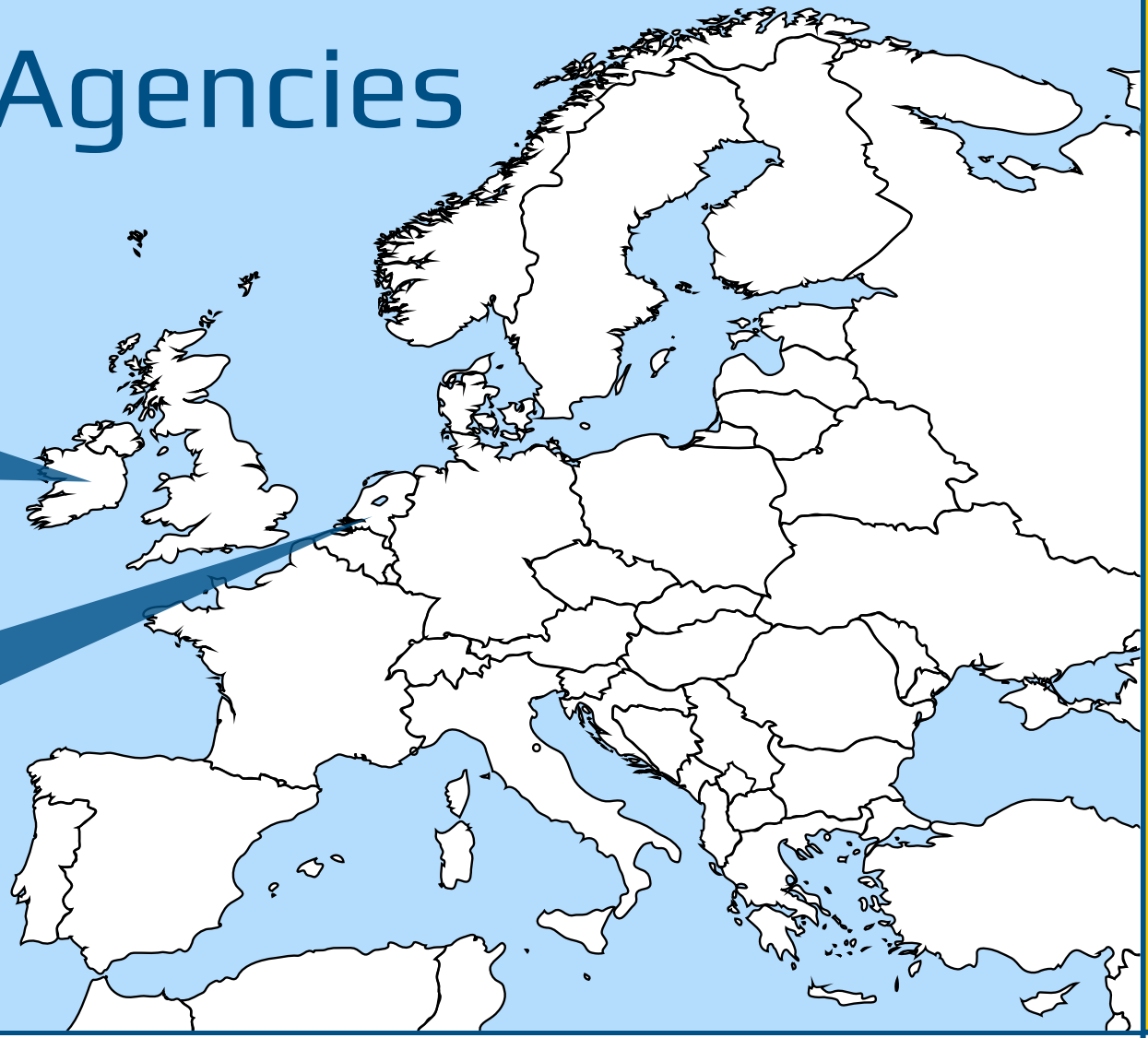
Involved Nacional Agencies

Ireland

- NCP being prepared
- Based on unstructured data and legacy systems
- Regional EHR systems being prepared

Netherlands

- NCP implemented
- Gap analysis between NL and EU



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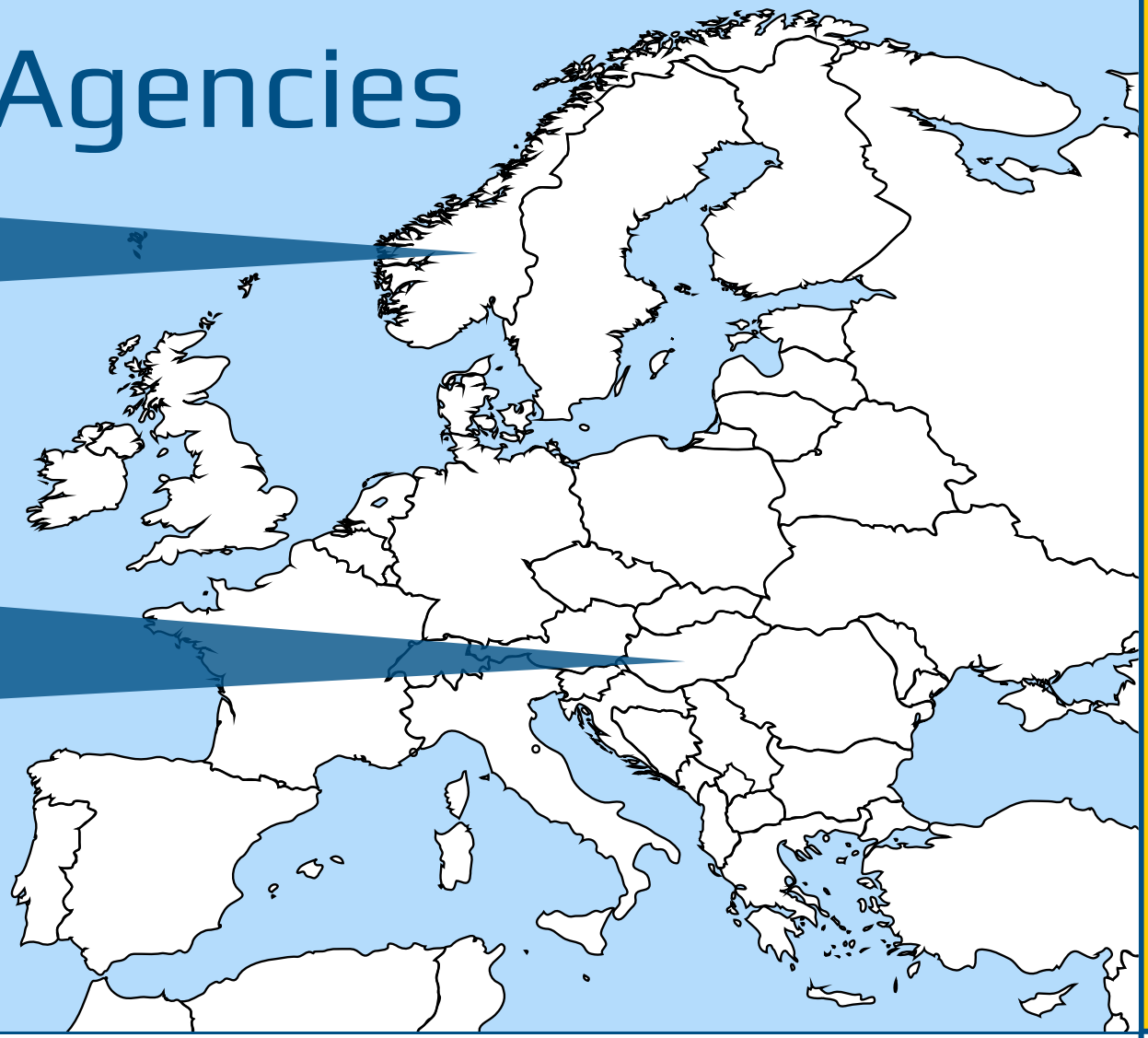
Involved Nacional Agencies

Norway

- NCP being prepared
- Gap analysis: EEHRxF vs. Norwegian eHealth solutions

Hungary

- NCP being prepared
- Use proprietary XML format and national codes
- PS compliant with the guidelines and uses common terminologies
- eP/eD can be converted from national to EU specifications



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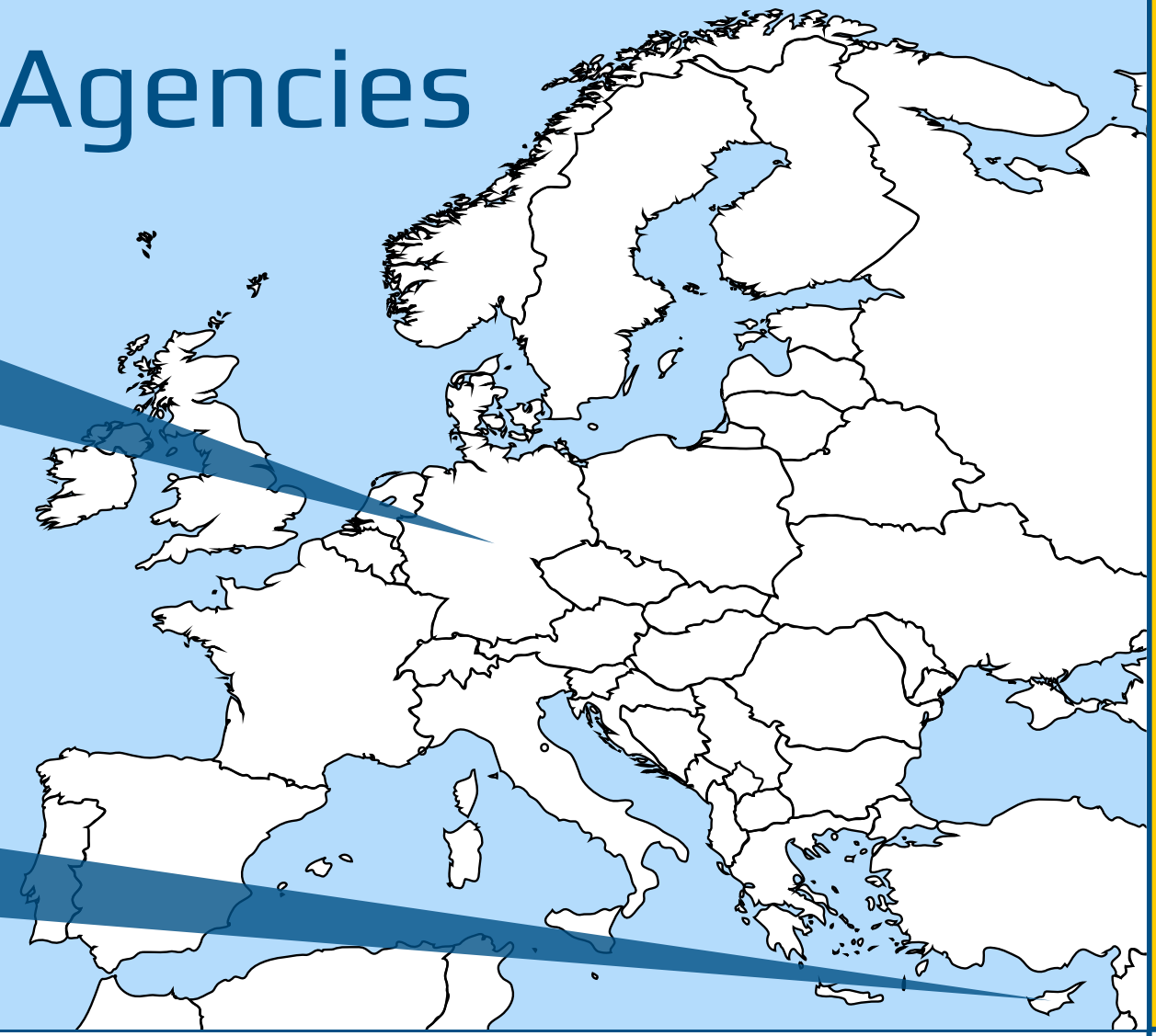
Involved Nacional Agencies



Germany

- NCP being prepared
- Centralized EHR national solution

Cyprus

- NCP being prepared
  - Considering priority categories
  - All healthcare providers will send information

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Online Surveys

Assessment of practice for production and exchange of health information aligned with EEHRxF

Priority Categories

- Patient Summary
- Laboratory Results
- Hospital Discharge Report

Primarily target audience

- Healthcare providers
- Healthcare professionals
- National/Regional agencies
- IT - EHR implementers, vendors

EUSurvey
https://ec.europa.eu/eusurvey/runner/xPanDHPS | https://ec.europa.eu/eusurvey/runner/XpanDHLabRep | https://ec.europa.eu/eusurvey/runner/xPanDHDR

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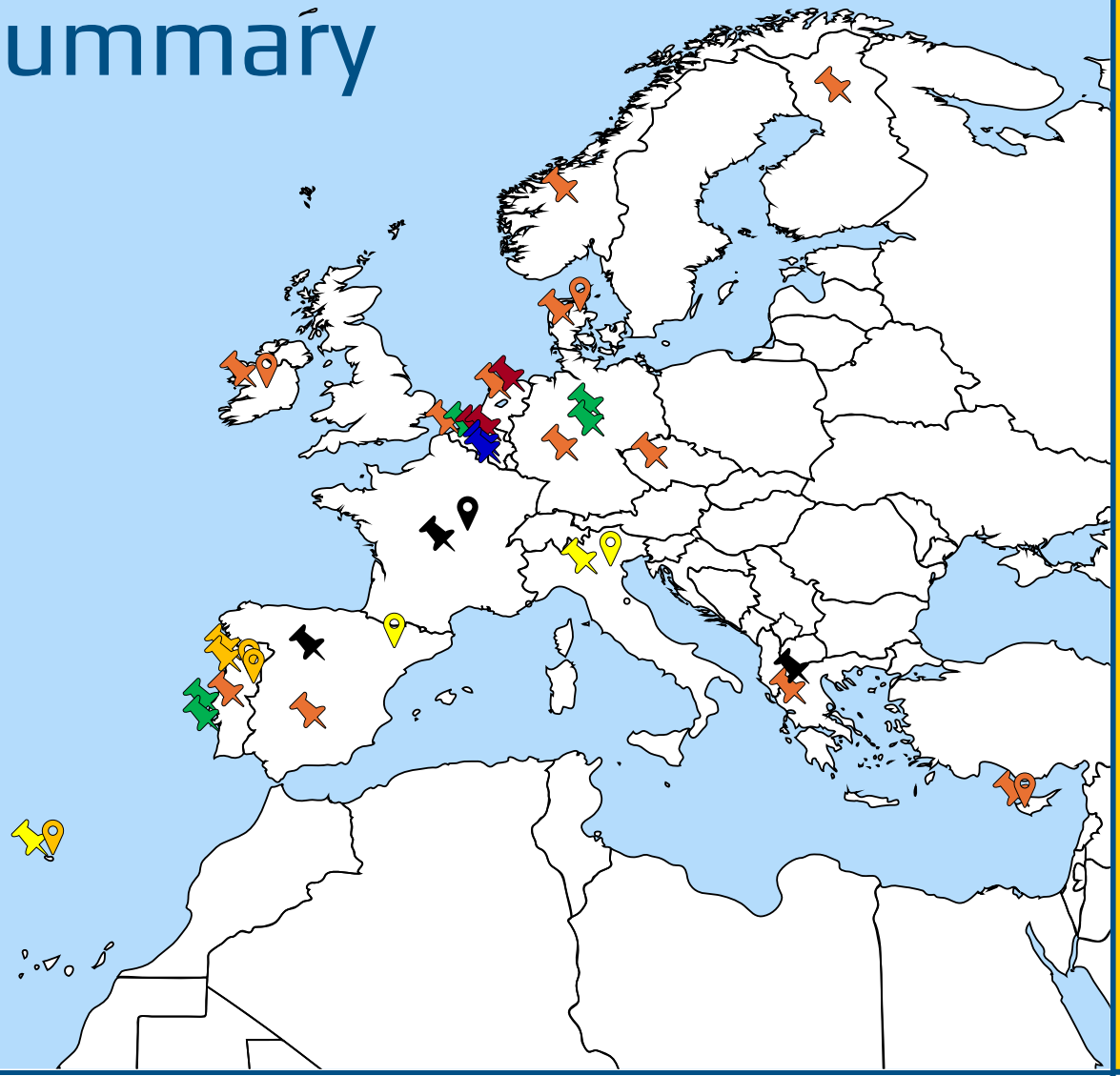
Patient Summary

Type of organisation	Workshops	Surveys
National agencies	12	3
Regional agencies	2	2
Academic and research	5	-
Healthcare providers	2	3
IT/EHR vendors	3	2
SDOs	3	-
Industry/Health associations	2	-



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Patient Summary

Level of Practice

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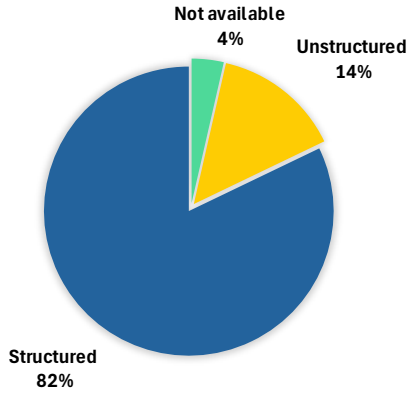
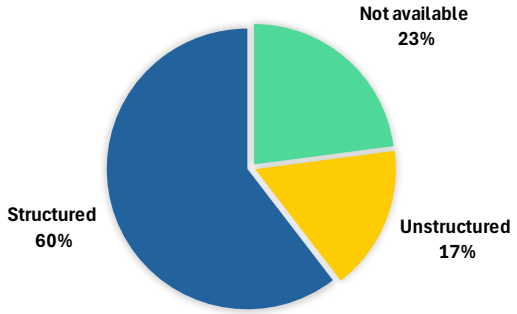
Patient Summary – Level of practice

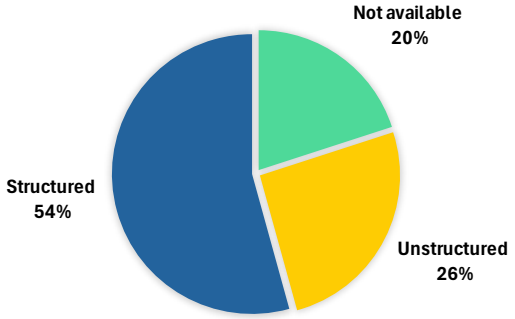
Identification of the patient



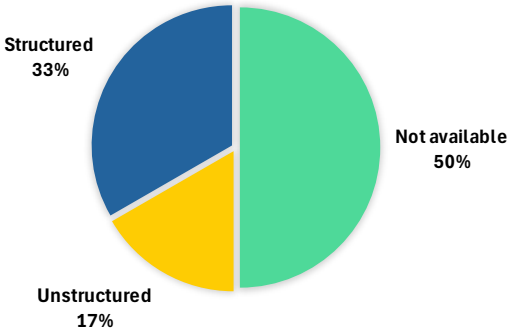
Preferred HP to contact



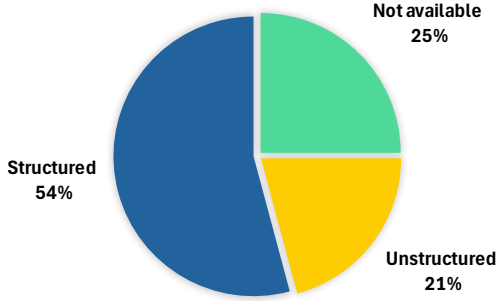
Contact person/ legal guardian



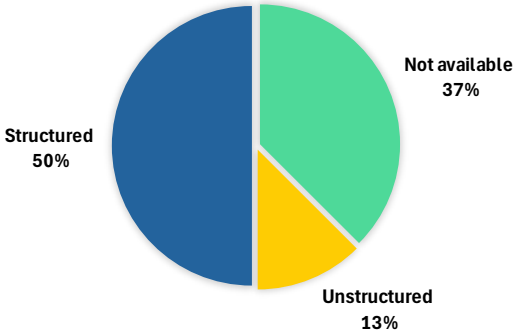
Insurance Information



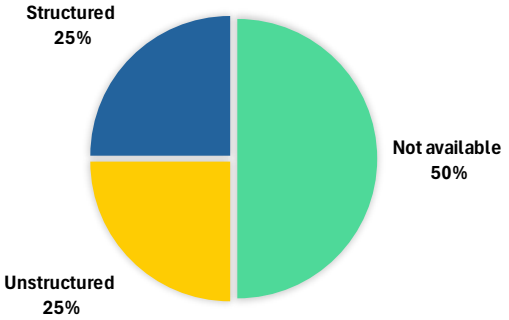
Document data



Author and Organisation



Additional information



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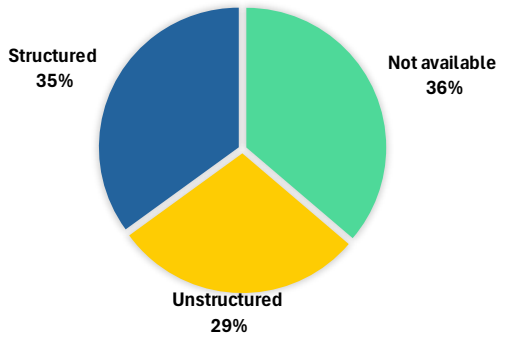
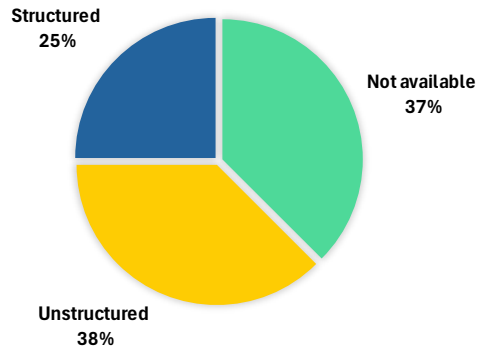
Patient Summary – Level of practice

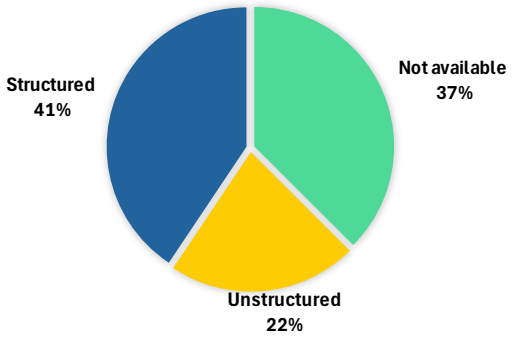
Alerts - Allergy



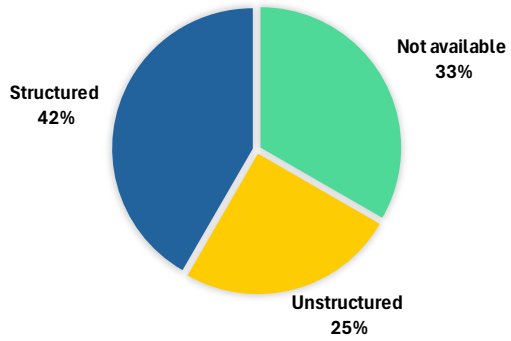
Alerts - Medical alert information



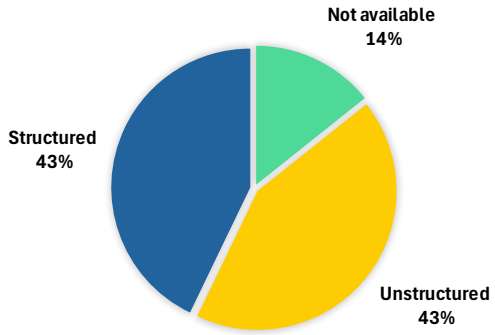
Medical history - Vaccination/ prophylaxis information



Medical history - Resolved, closed or inactive problems



Medical history - Medical history



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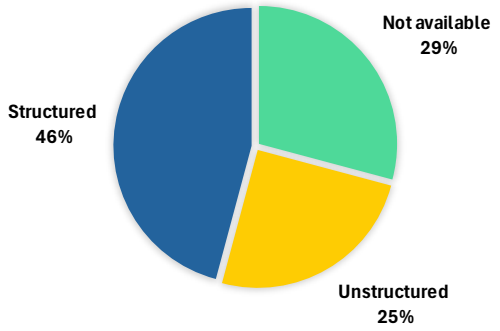
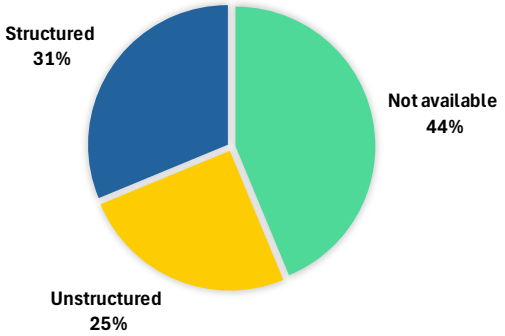
Patient Summary – Level of practice

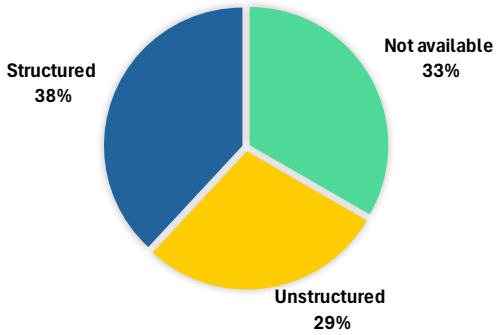
Medical problems - Current problems



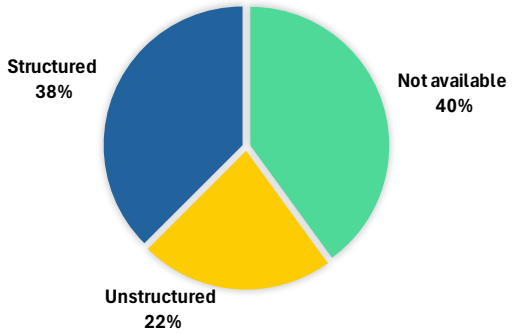
Medical problems - Medical devices and implants



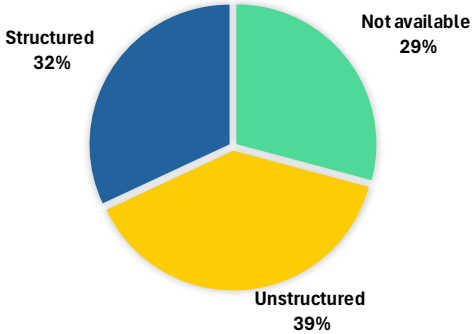
Medical problems - Procedures



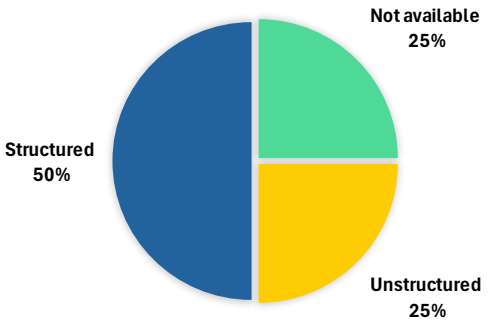
Medical problems - Functional status



Medication summary - Current and relevant past medicines



Social history



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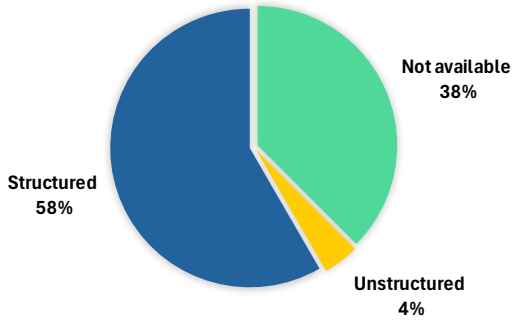
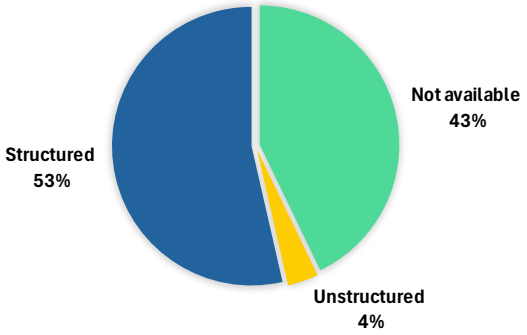
Patient Summary – Level of practice

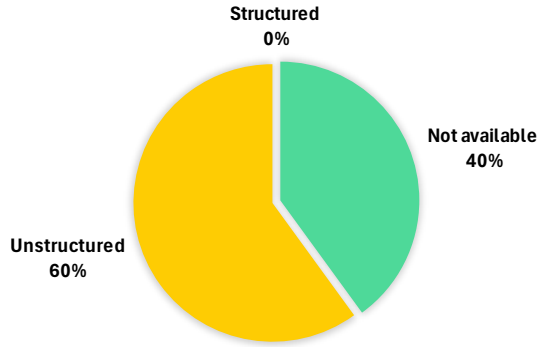
Pregnancy history - Current pregnancy



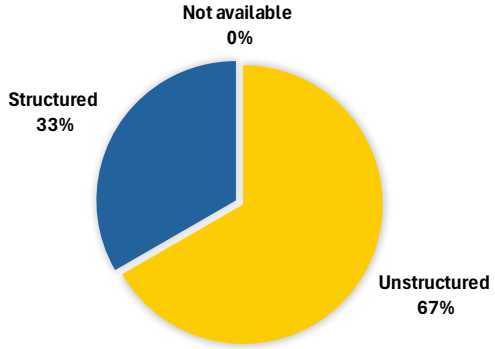
Pregnancy history - Previous pregnancies



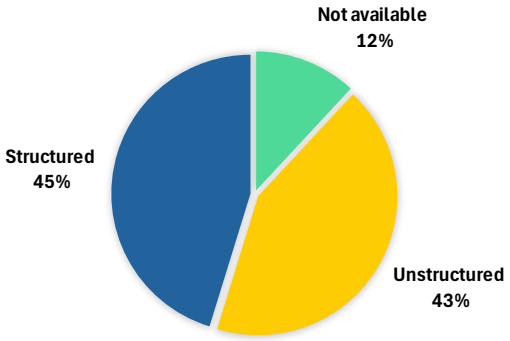
Patient provided data - Travel history



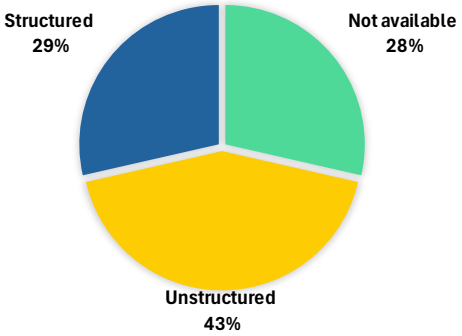
Patient provided data - Advance Directive



Results - Result observations



Plan of Care



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XpanDH
Expanding Digital Health through a pan-European EHRxF-based Ecosystem

EHR @dataspace

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EHR Xchange Format

European Commission

Patient Summary

Level of Alignment

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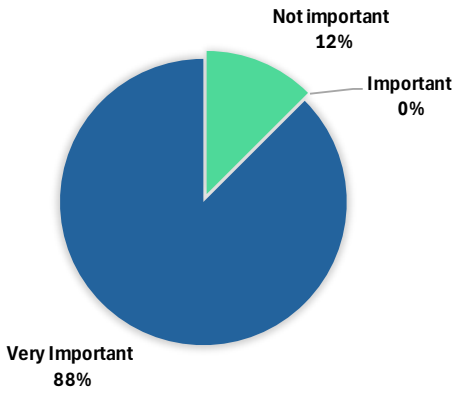
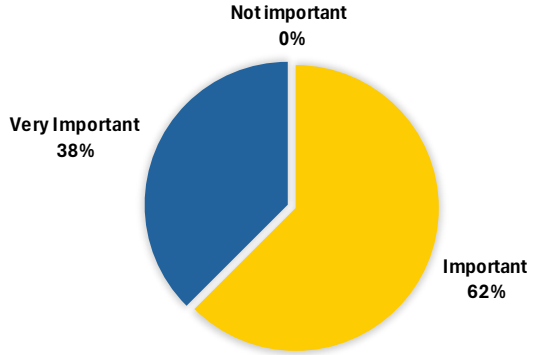
Patient Summary – Level of alignment

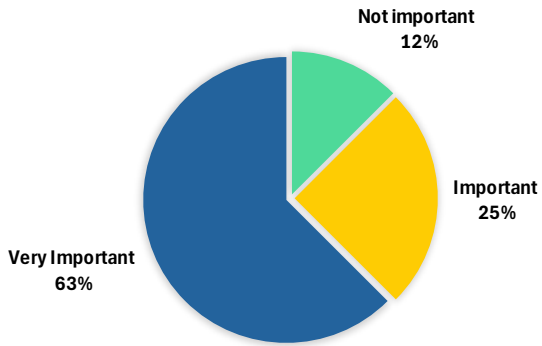
Identification of the patient



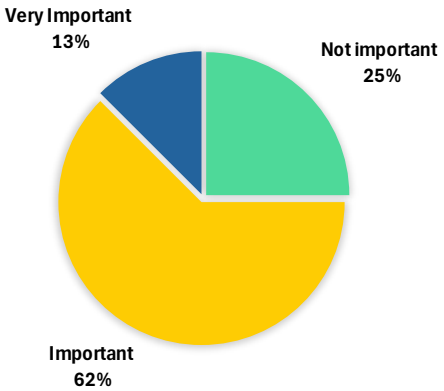
Preferred HP to contact



Contact person/ legal guardian



Insurance Information



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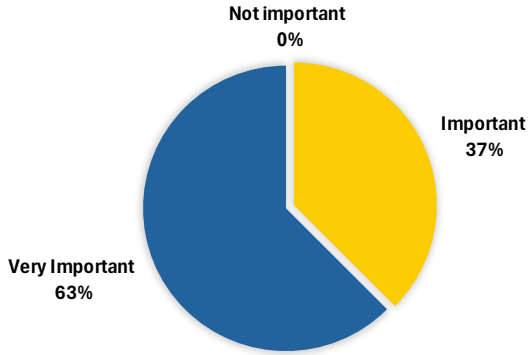
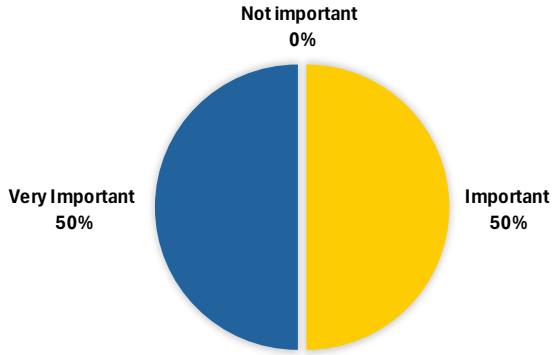
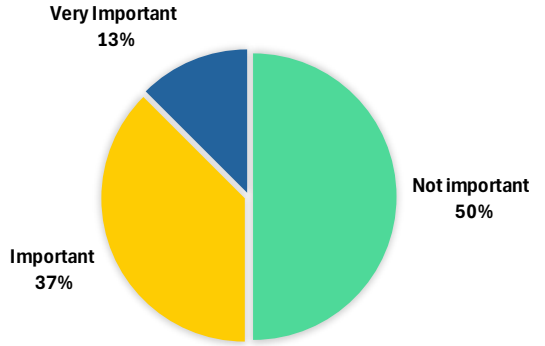


Author and Organisation



Additional information



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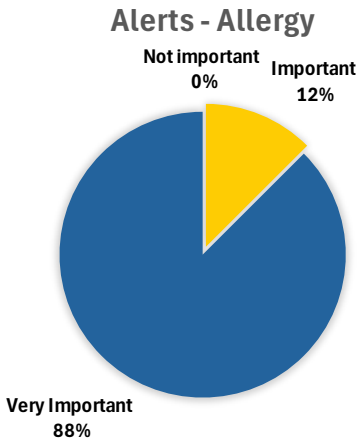
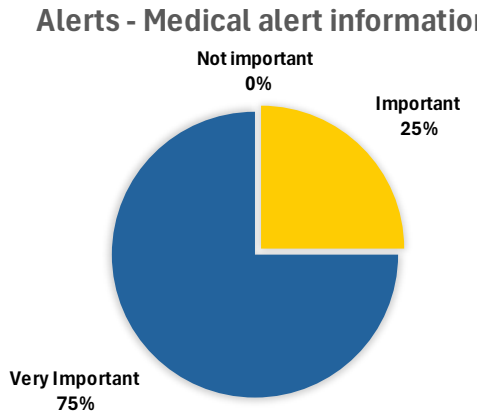
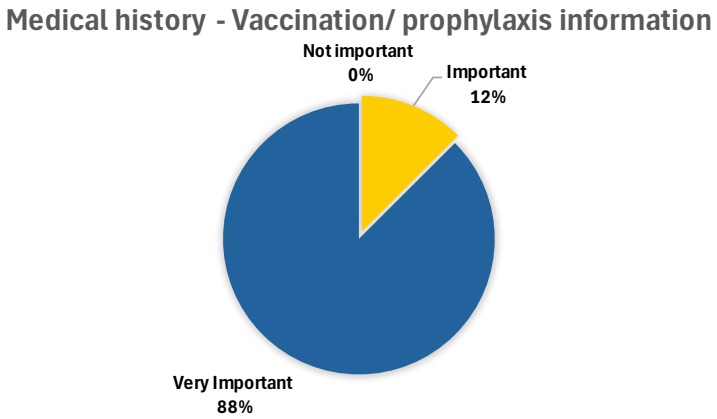
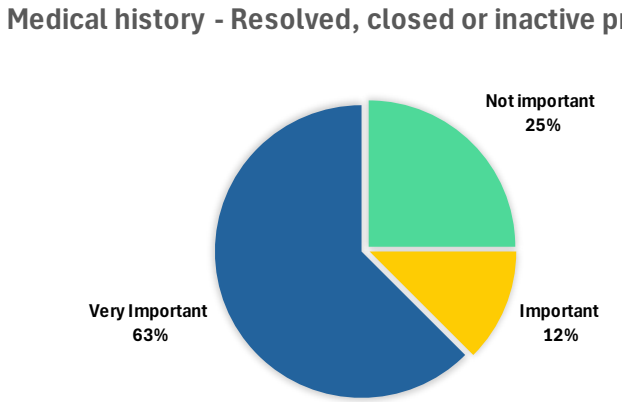
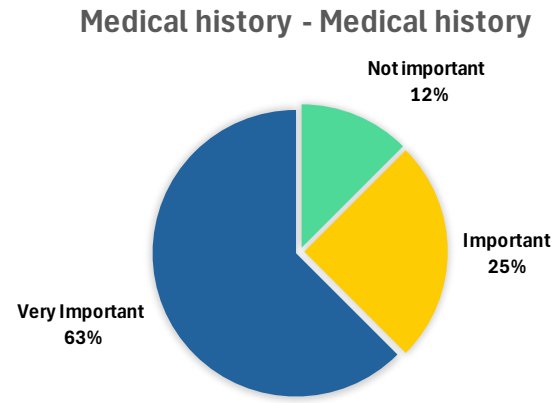
Patient Summary – Level of alignment











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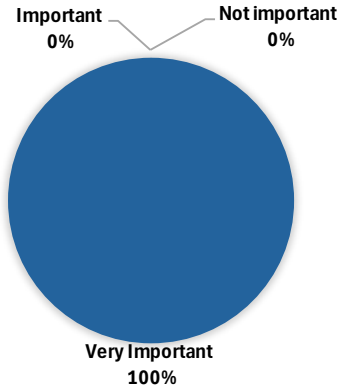
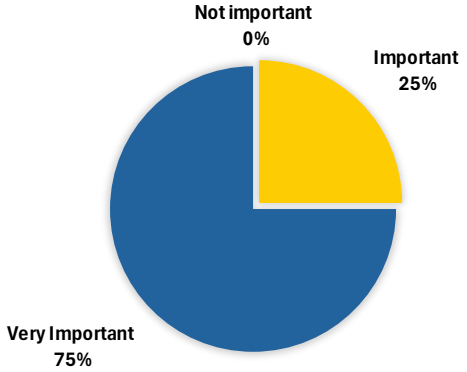
Patient Summary – Level of alignment

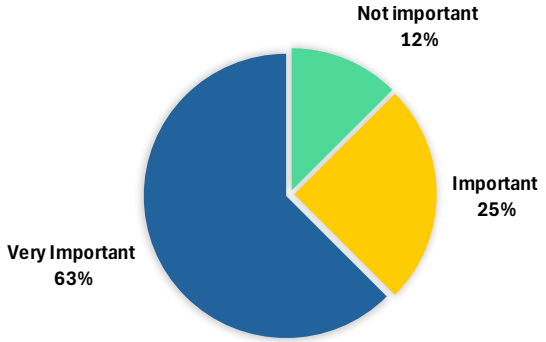
Medical problems - Current problems



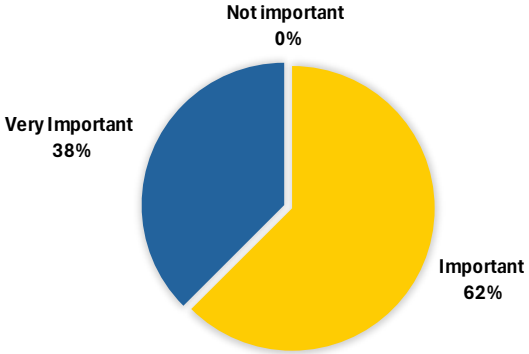
Medical problems - Medical devices and implants



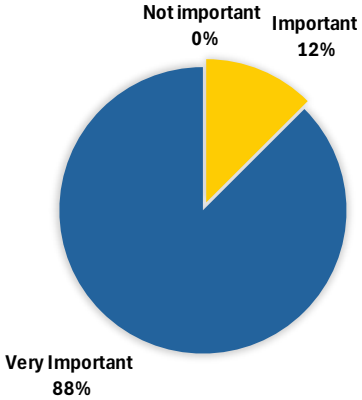
Medical problems - Procedures



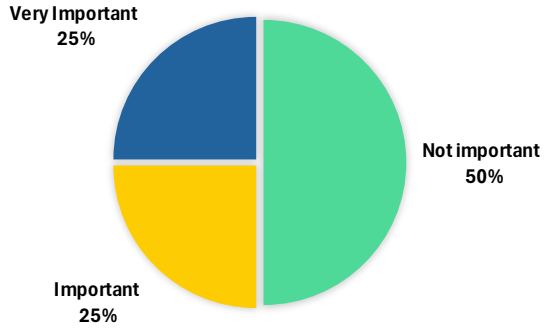
Medical problems - Functional status



Medication summary - Current and relevant past medicines



Social history



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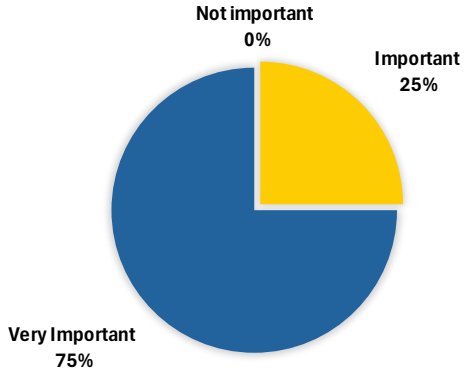
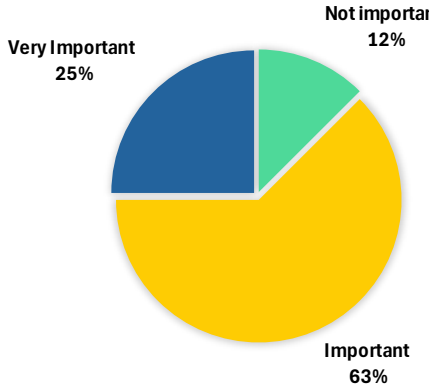
Patient Summary – Level of alignment

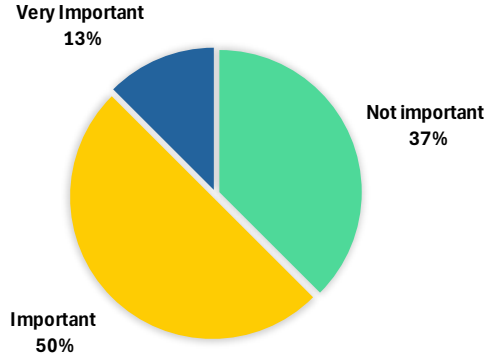
Pregnancy history - Current pregnancy



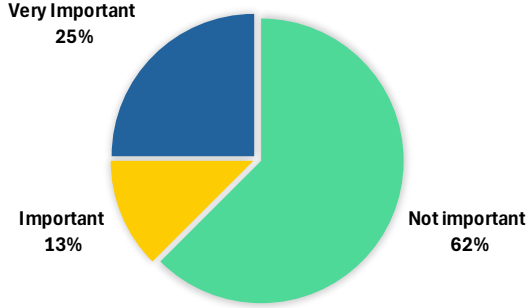
Pregnancy history - Previous pregnancies



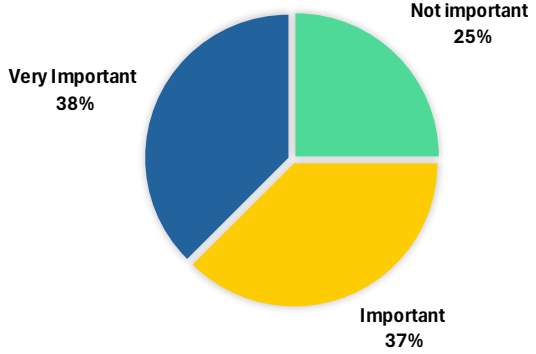
Patient provided data - Travel history



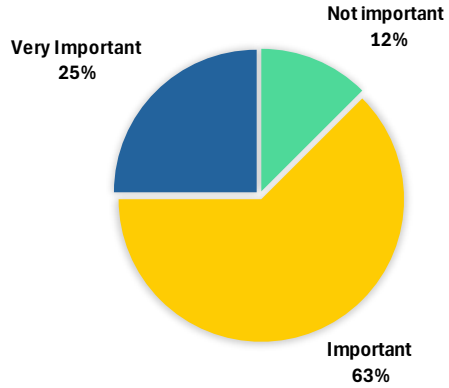
Patient provided data - Advance Directive



Results - Result observations



Plan of Care



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XpanDH
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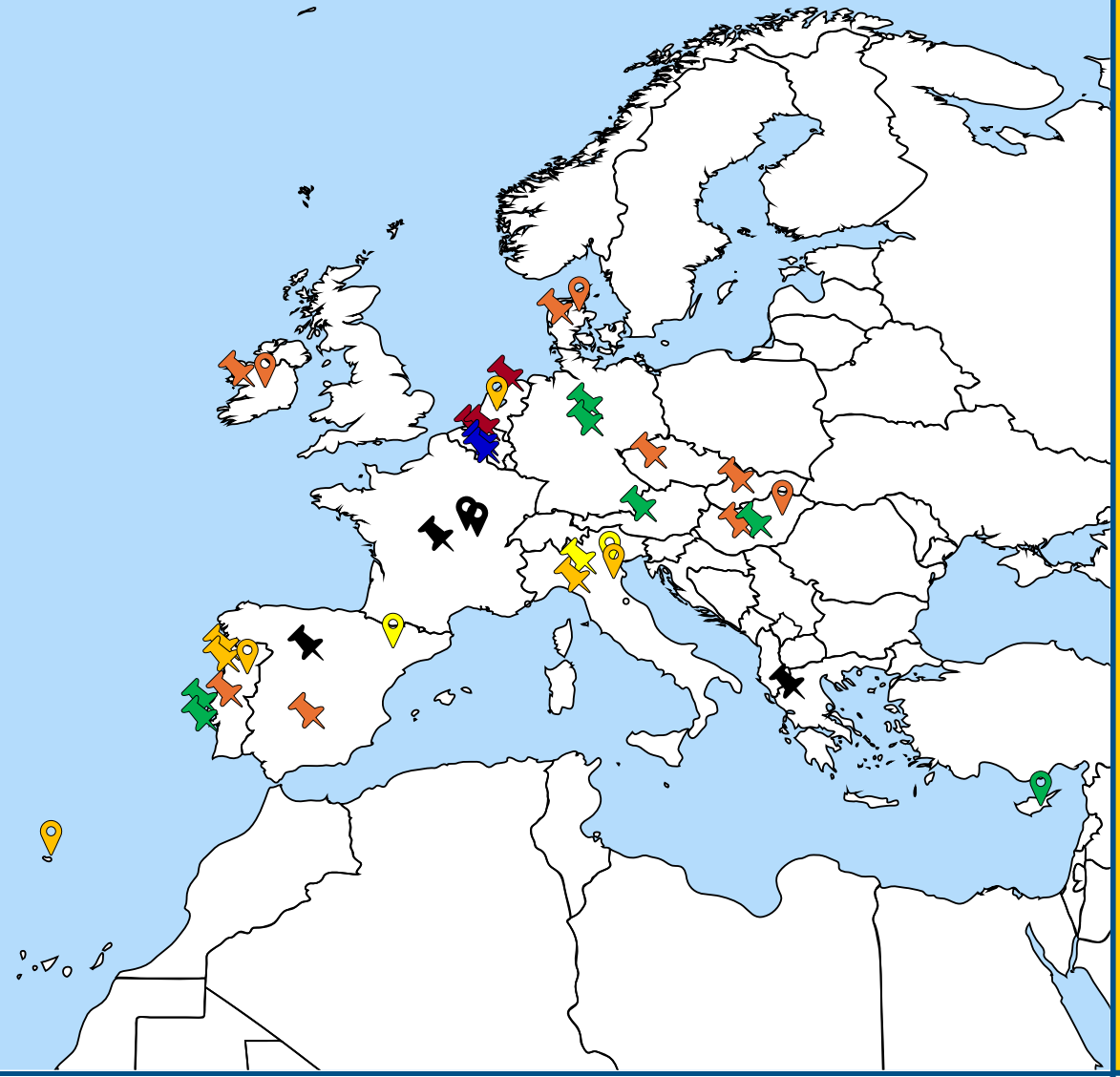
EHR @dataspace

Share
EHR Xchange Format

European Commission

Laboratory Results

Type of organisation	Workshops	Surveys
National agencies	7	3
Regional agencies	1	2
Academic and research	6	1
Healthcare providers	3	4
IT/EHR vendors	3	2
SDOs	3	-
Industry/Health associations	2	-



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Laboratory Results

Level of Practice

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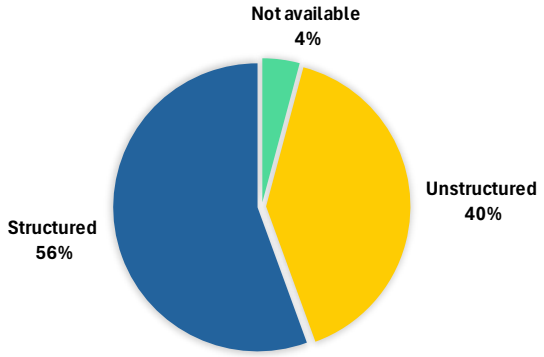
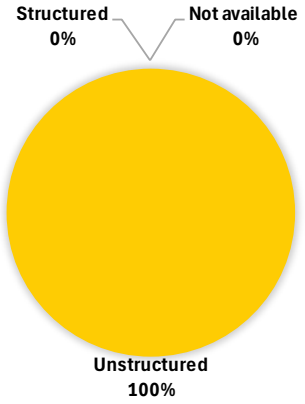
Laboratory Results – Level of practice

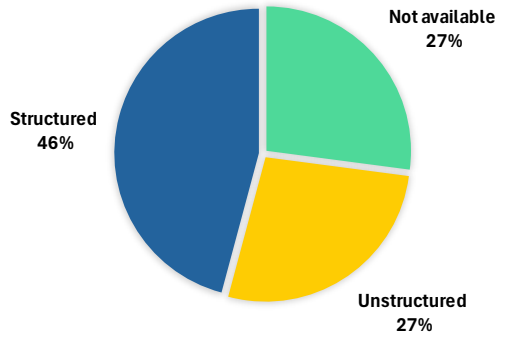
Identification of the patient



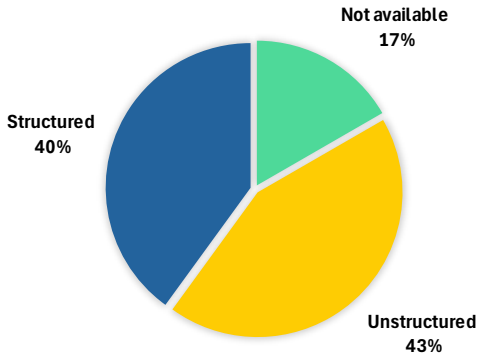
Health insurance and payment information



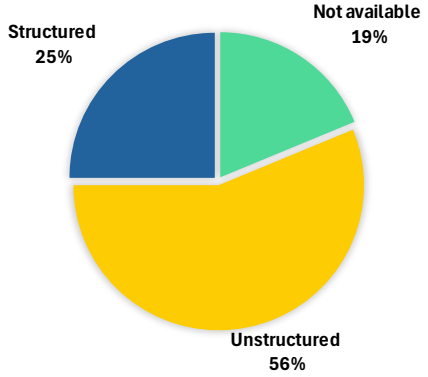
Information recipient



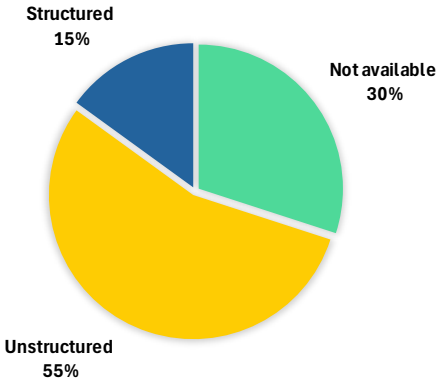
Author



Legal authenticator



Result validator



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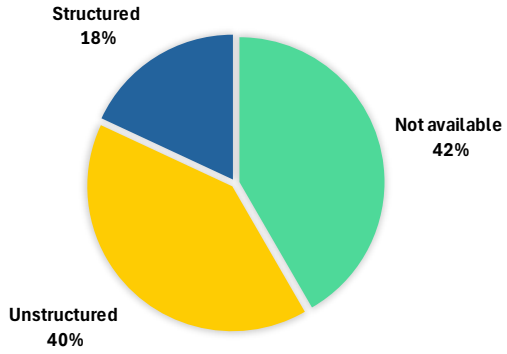
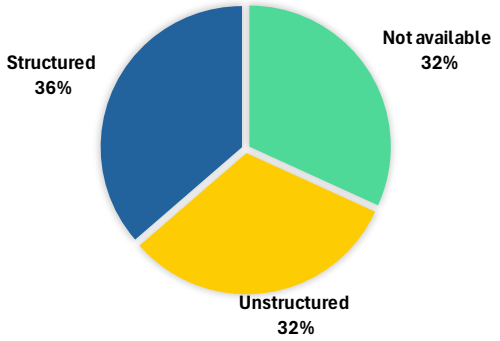
Laboratory Results – Level of practice

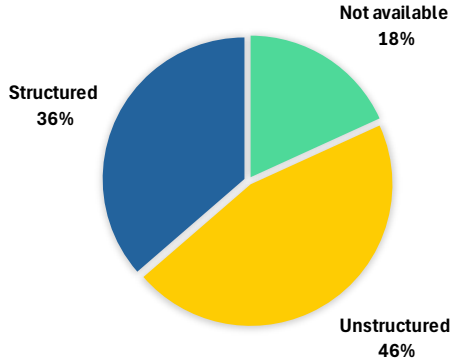
Laboratory report metadata



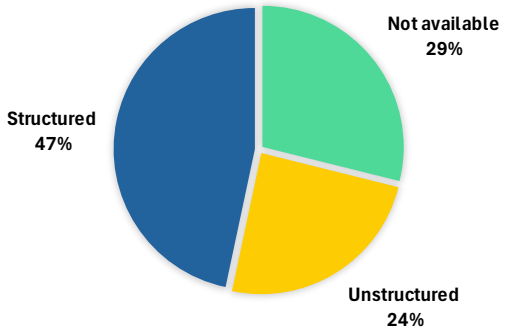
Order information



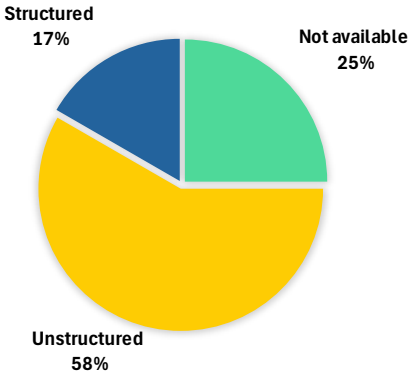
Order reason



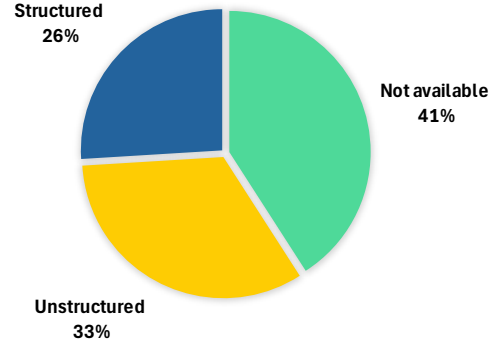
Specimen information



Laboratory report narrative



Observation details



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Laboratory Results

Level of Alignment

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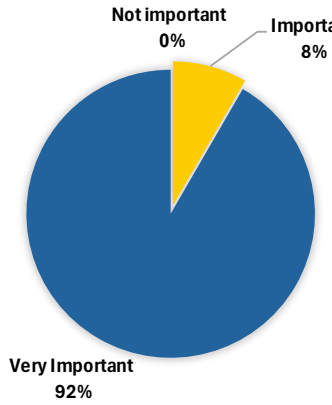
Laboratory Results – Level of alignment

Identification of the patient



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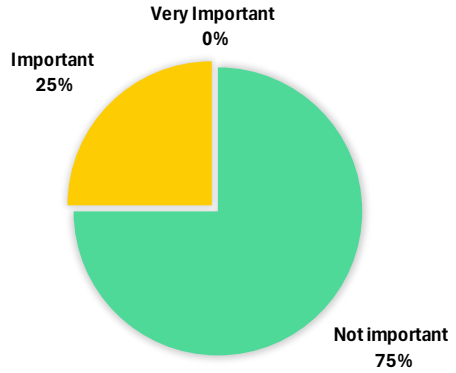

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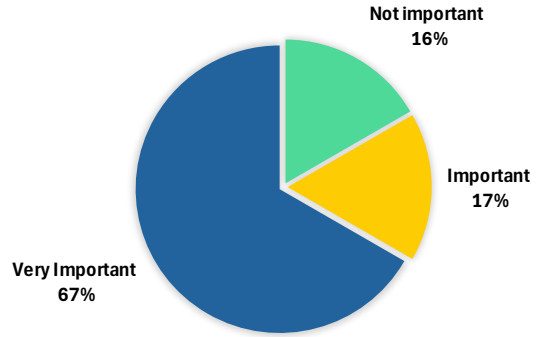

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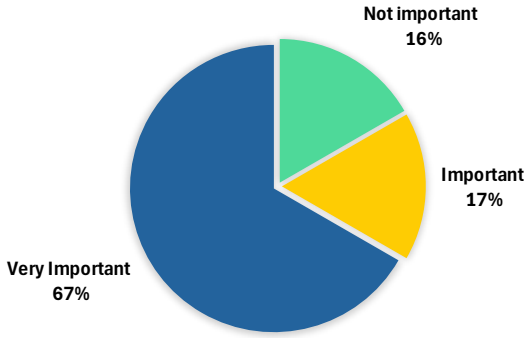

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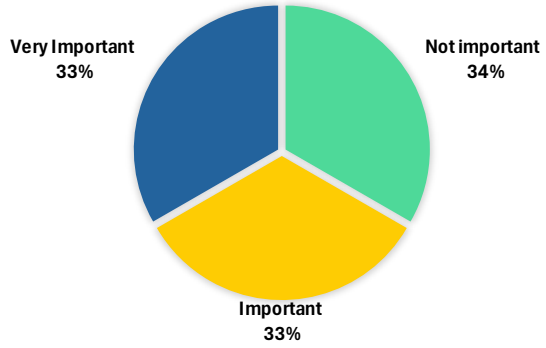

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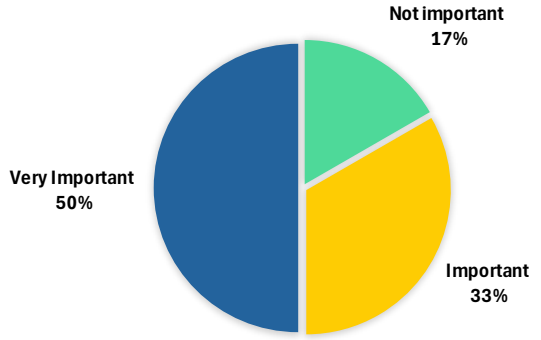

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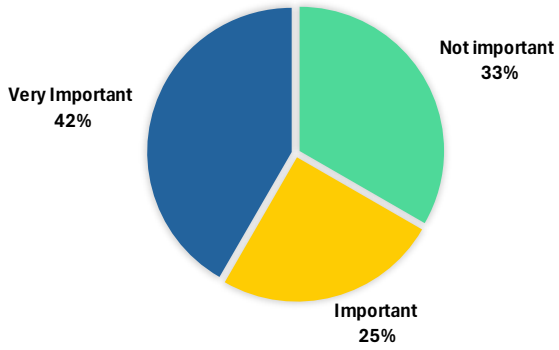
Laboratory Results – Level of alignment

Laboratory report metadata



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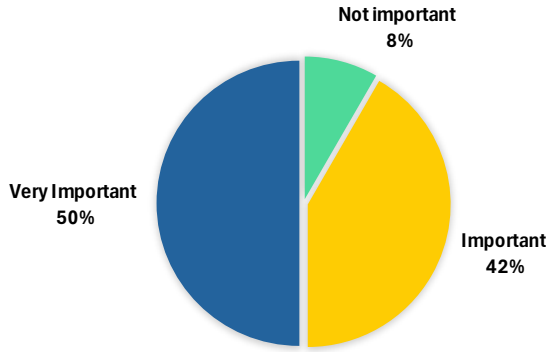

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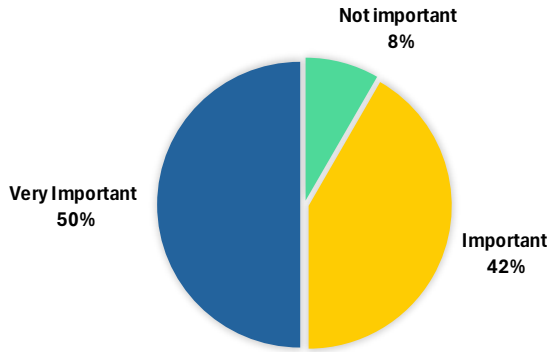

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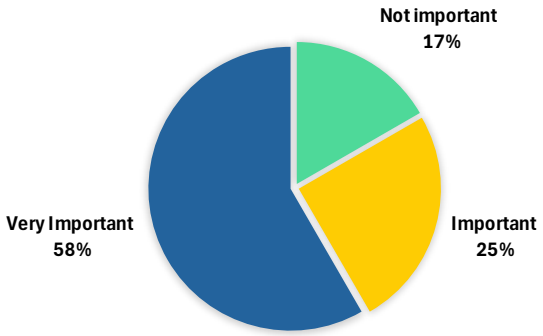
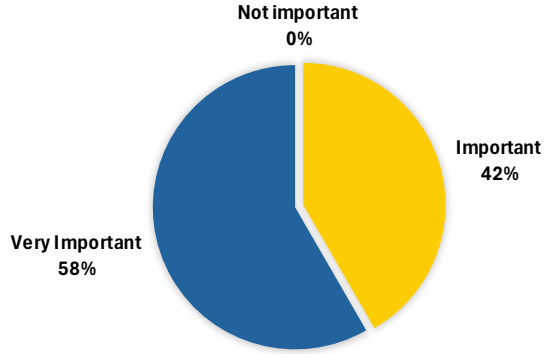


Laboratory report narrative



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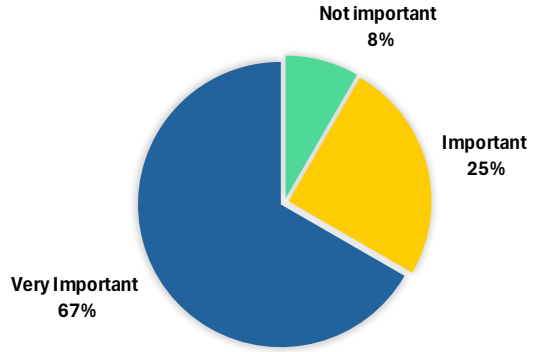

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Laboratory Results

Level of Practice and Alignment
Follow-up diabetic patients

Technical workshops and One-on-one

Hungary and Portugal

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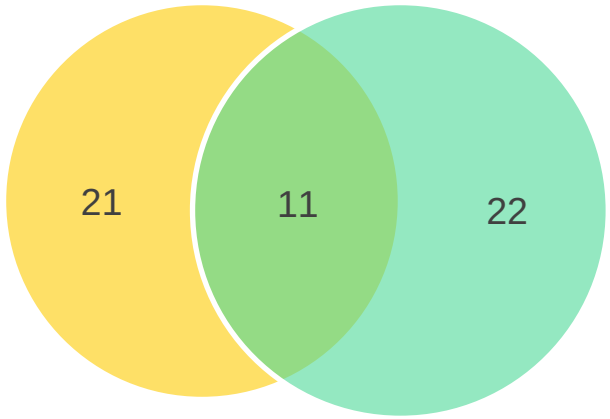
Laboratory Report – Level of practice

Structured



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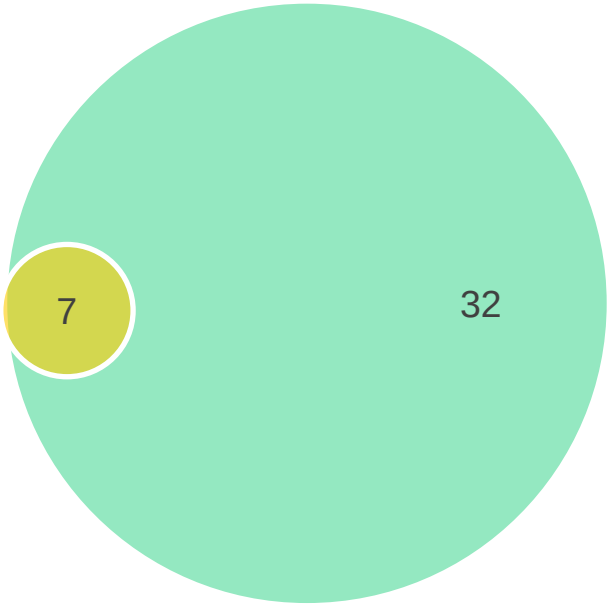

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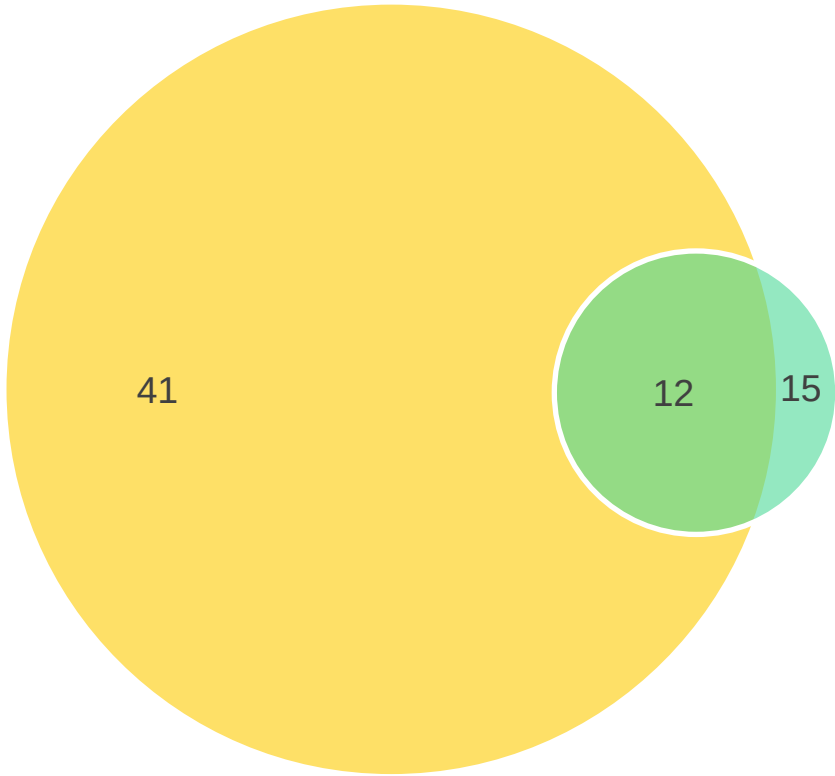

Hungary

Portugal

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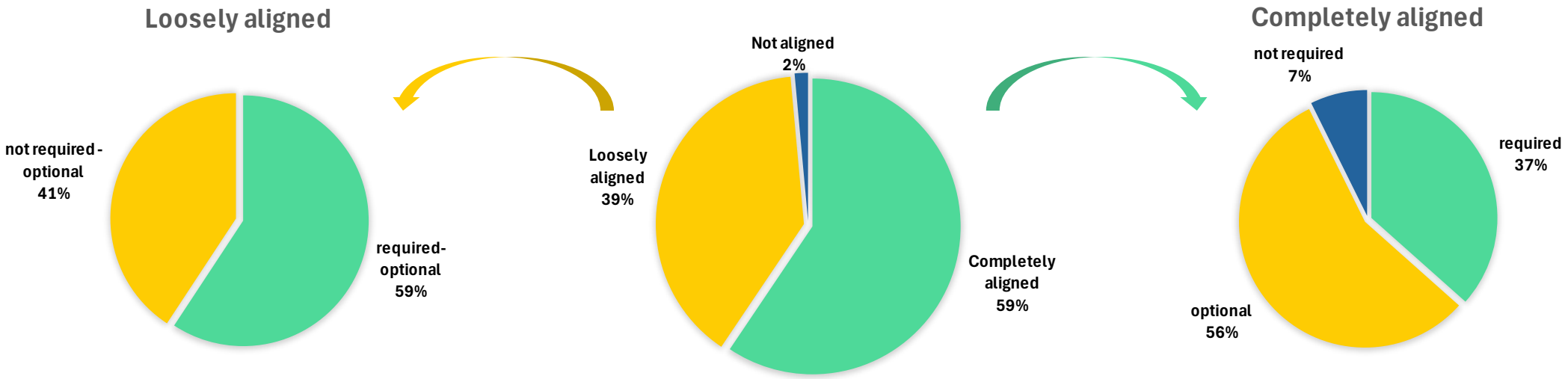
Laboratory Report – Level of alignment

- Between Hungary and Portugal



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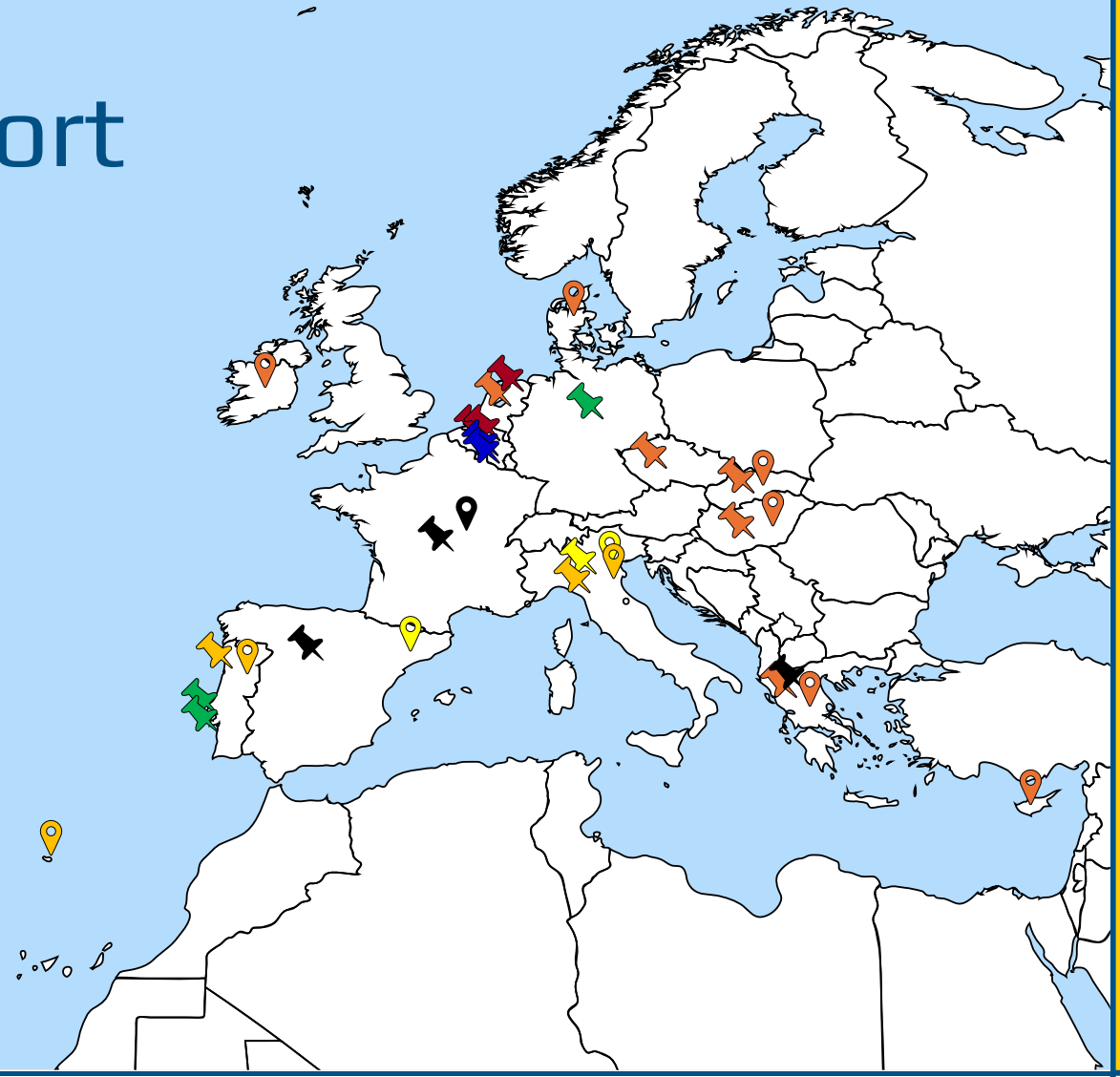
Hospital Discharge Report

Type of organisation	Workshops	Surveys
National agencies	5	6
Regional agencies	1	2
Academic and research	3	-
Healthcare providers	2	3
IT/EHR vendors	3	1
SDOs	3	-
Industry/Health associations	2	-



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Hospital Discharge Report

Level of Practice

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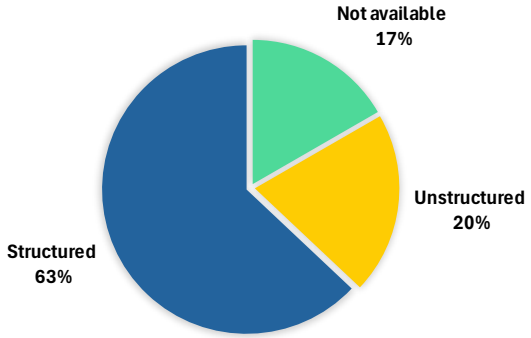
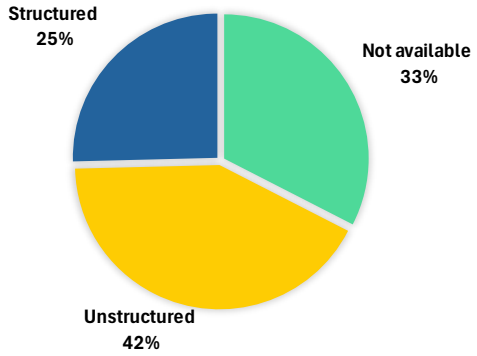
Hospital Discharge Report – Level of practice

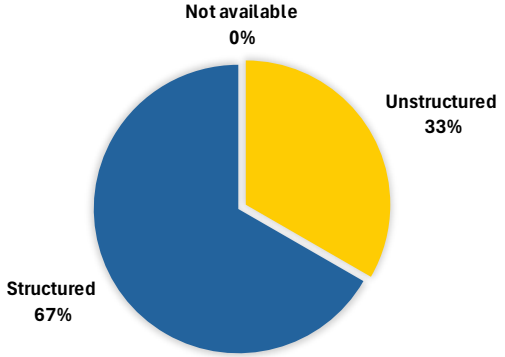
Identification of the patient



Patient related contact information



Health insurance and payment information



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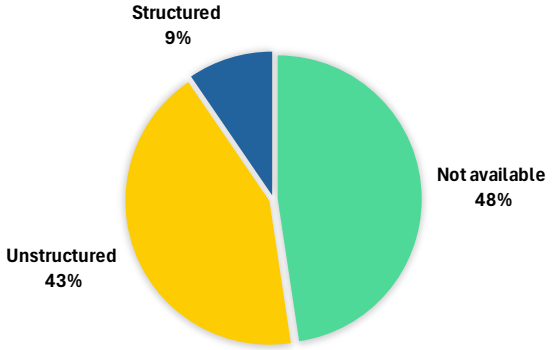

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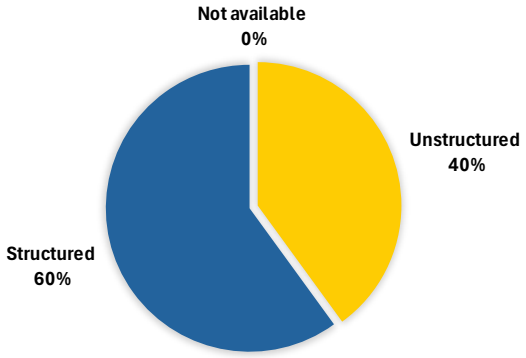

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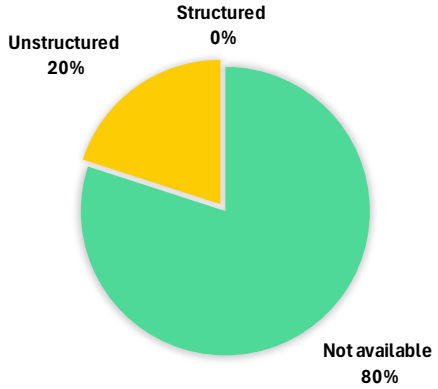

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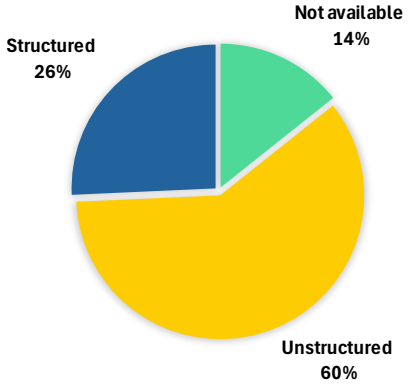

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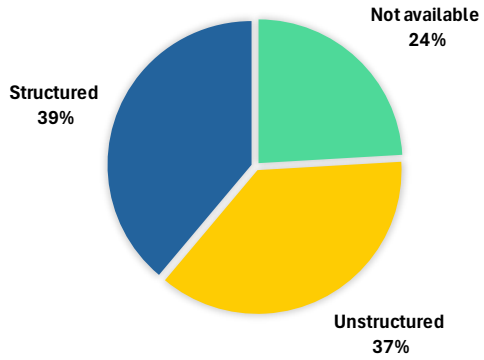

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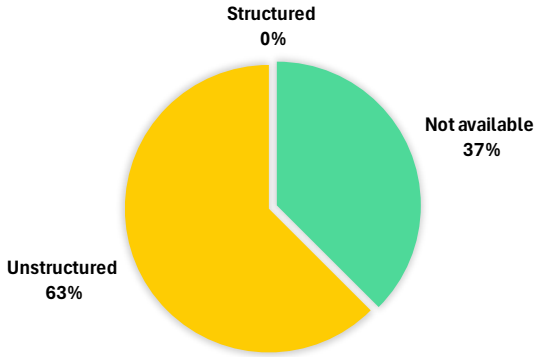
Hospital Discharge Report – Level of practice

Hospital Discharge Report narrative form



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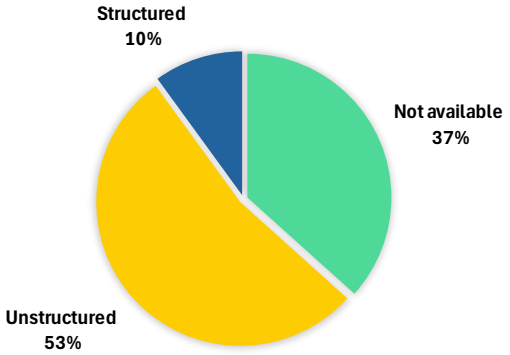
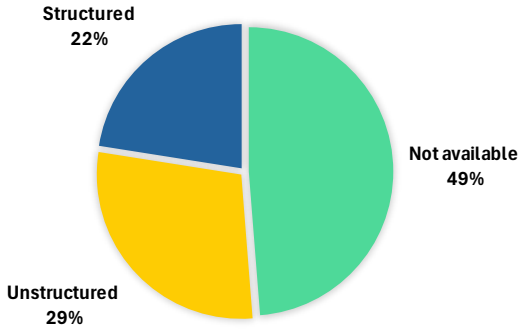
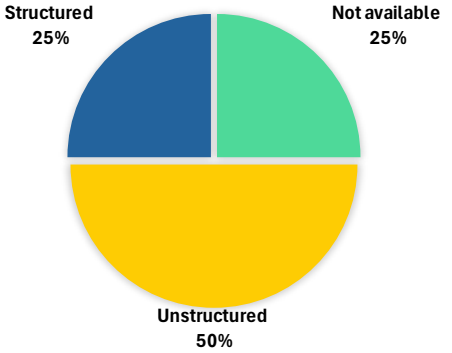


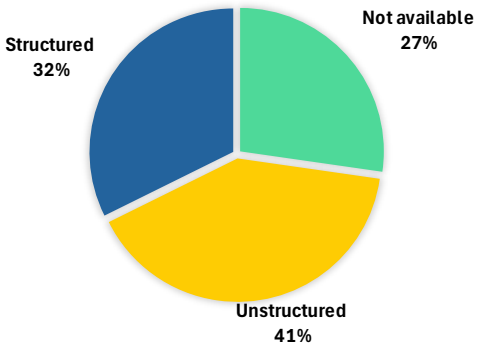
Alerts - Allergy and Intolerance



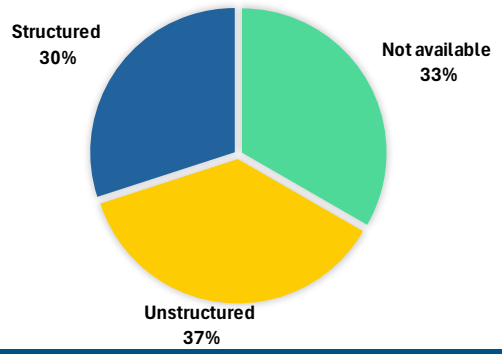
Alerts - Medical alerts



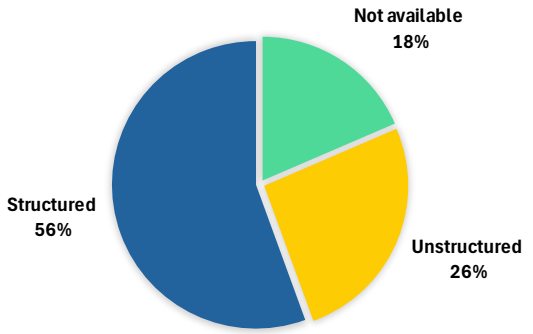
Encounter - Admission



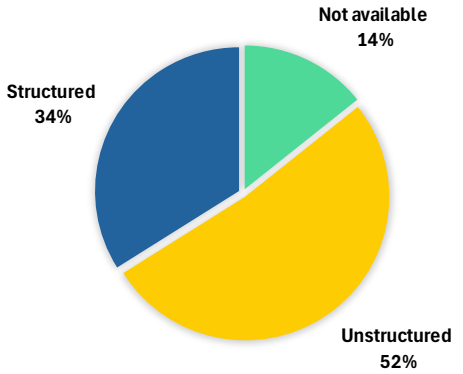
Encounter - Admission reason



Encounter - Discharge



Admission evaluation - Objective findings



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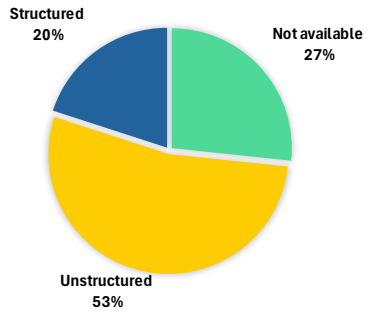
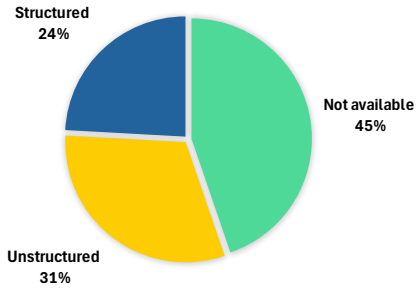
Hospital Discharge Report – Level of practice

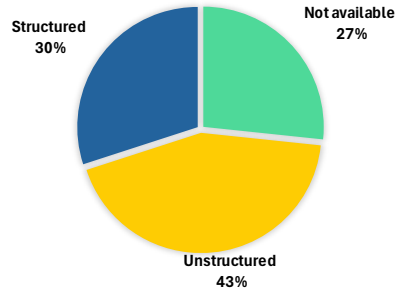
Admission evaluation - Functional status



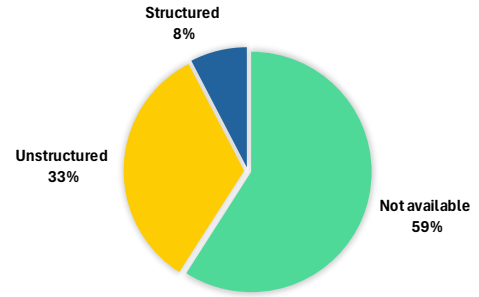
Patient history - Medical history



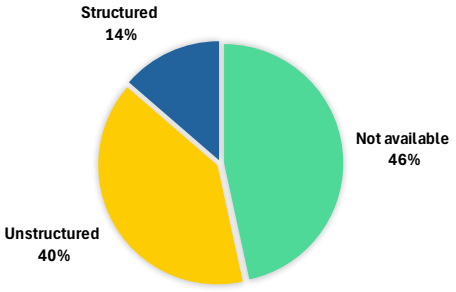
Patient history - Family history



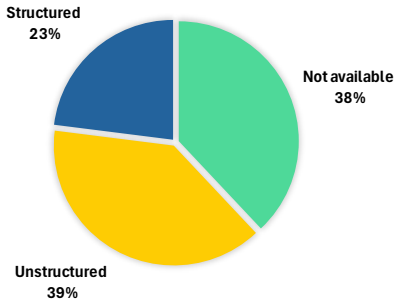
Patient history - Social determinants of health



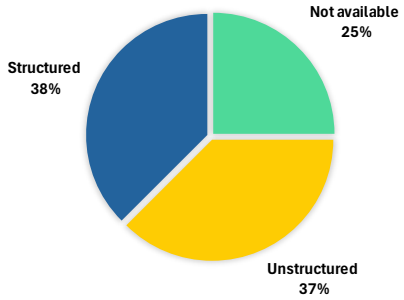
Patient history - Use of substances



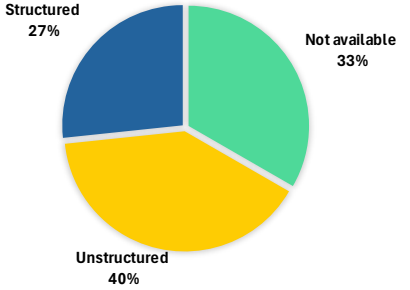
Course of hospitalisation - Diagnostic summary



Course of hospitalisation - Significant procedures



Course of hospitalisation - Medical devices and implants



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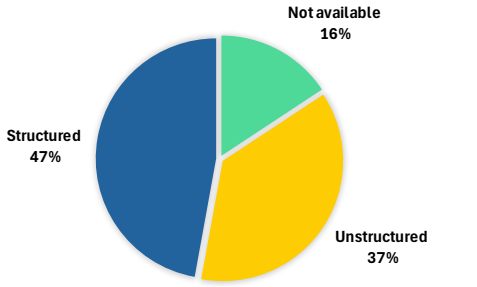
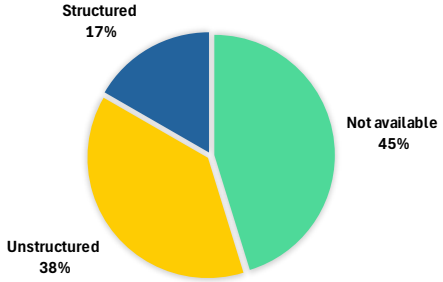
Hospital Discharge Report – Level of practice

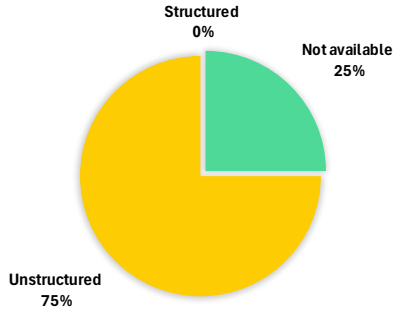
Course of hospitalisation - Pharmacotherapy



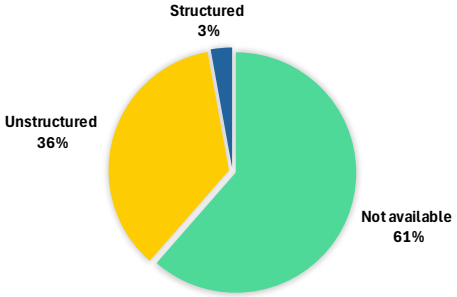
Course of hospitalisation - Significant Observation Results



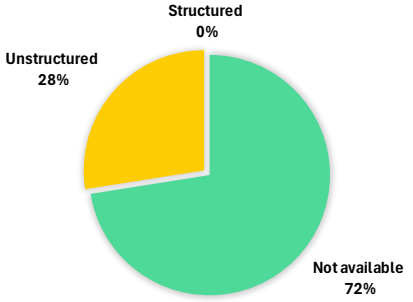
Course of hospitalisation - Synthesis



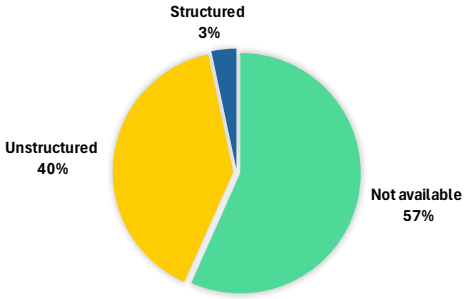
Discharge details - Objective findings



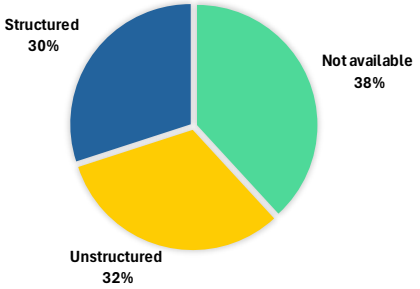
Discharge details - Functional status



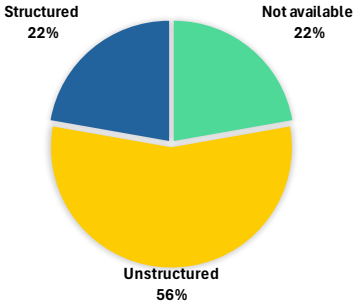
Care plan - Care plan



Care plan - Medication summary



Other recommendations



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Hospital Discharge Report

Level of Alignment

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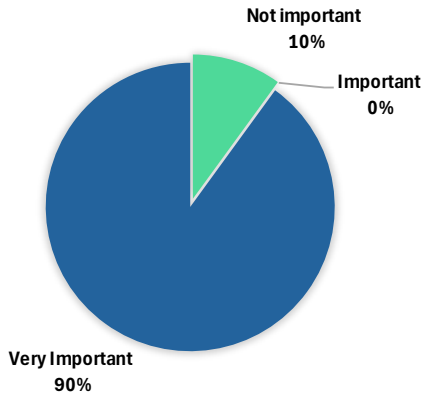
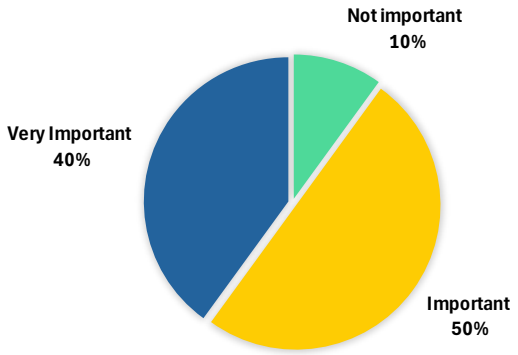
Hospital Discharge Report – Level of alignment

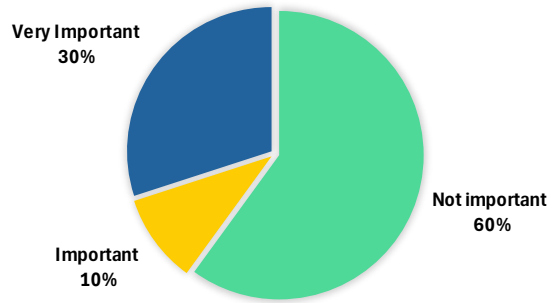
Identification of the patient



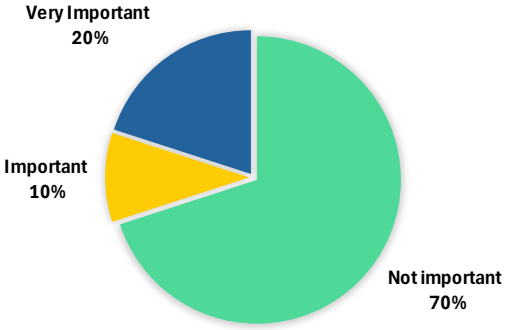
Patient related contact information



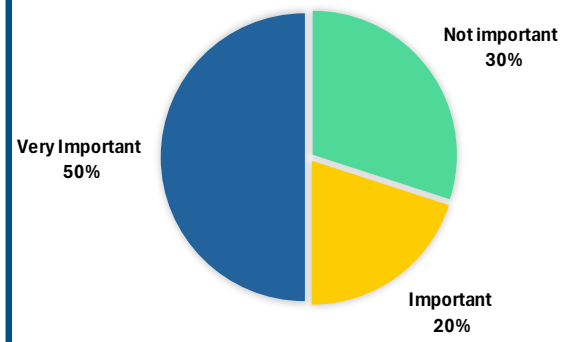
Health insurance and payment information



Information recipient



Author



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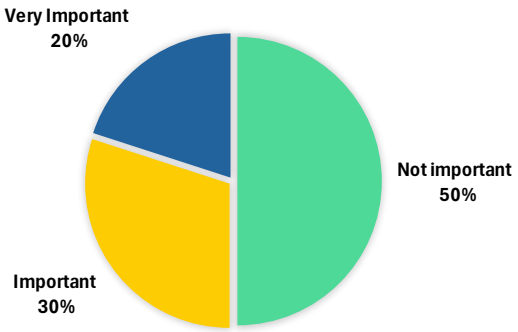

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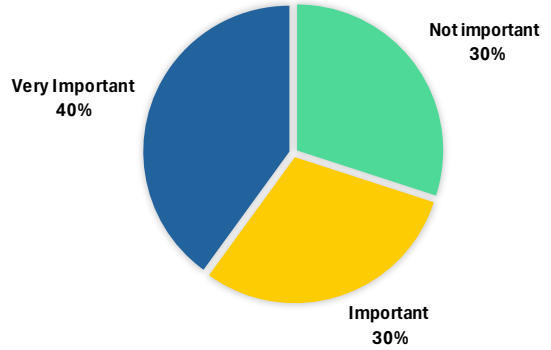

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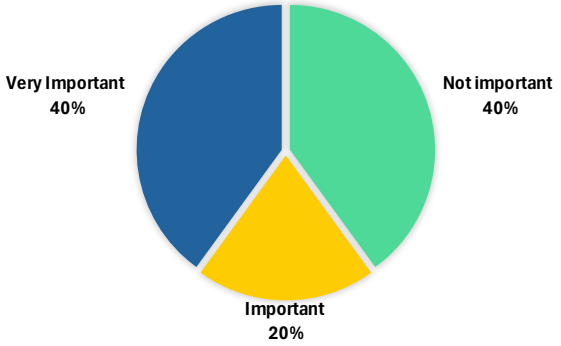

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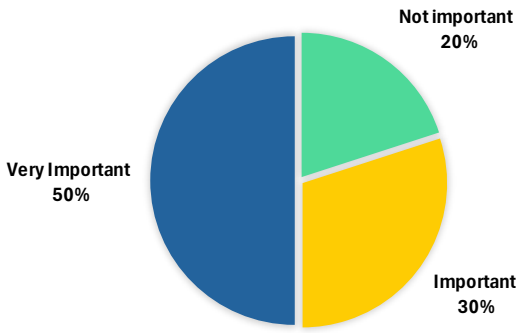
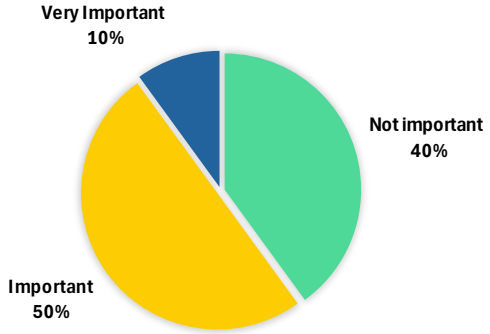
Hospital Discharge Report – Level of alignment

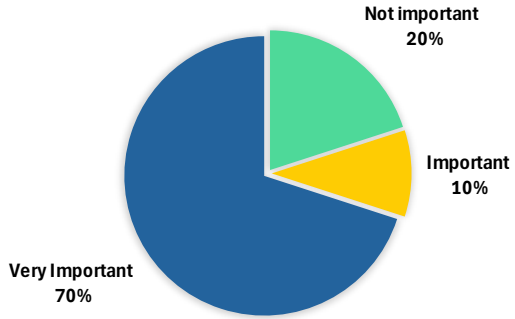
Hospital Discharge Report narrative form



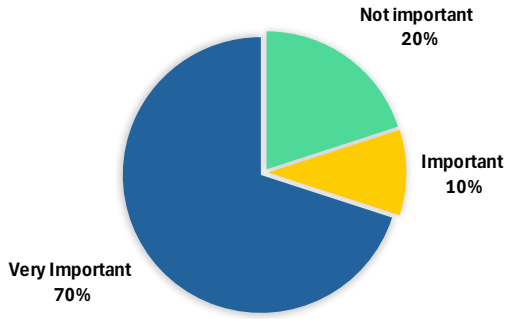
Advance directives - Living will



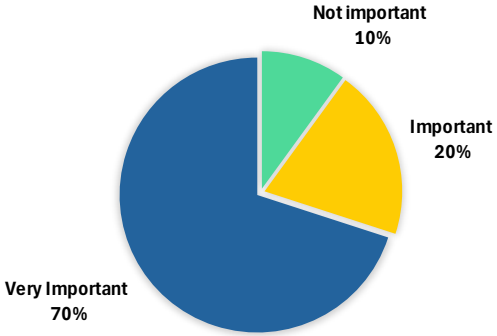
Alerts - Allergy and Intolerance



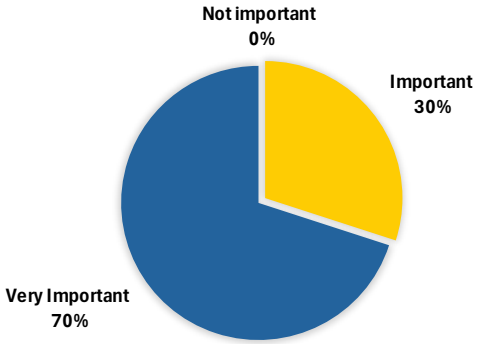
Alerts - Medical alerts



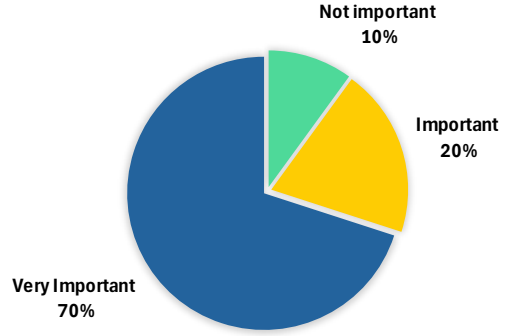
Encounter - Admission



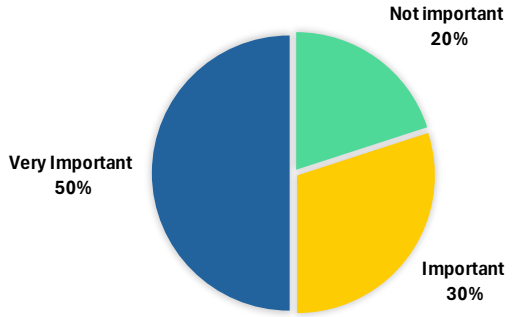
Encounter - Admission reason



Encounter - Discharge



Admission evaluation - Objective findings



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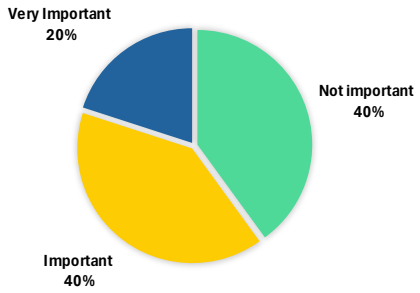
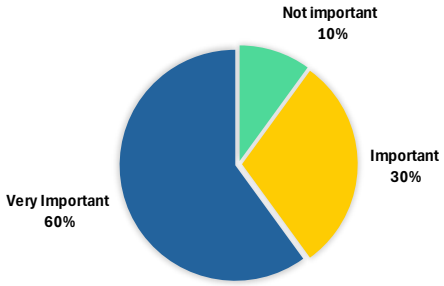
Hospital Discharge Report – Level of alignment

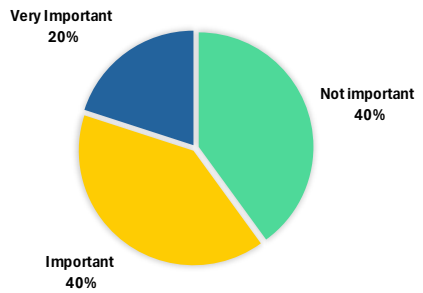
Admission evaluation - Functional status



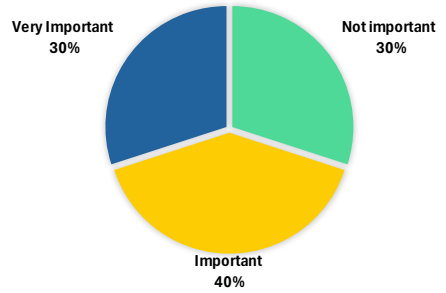
Patient history - Medical history



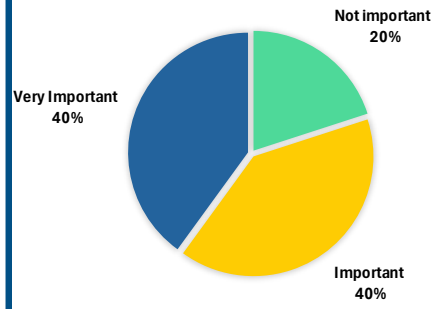
Patient history - Family history



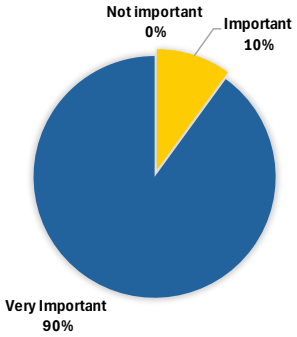
Patient history - Social determinants of health



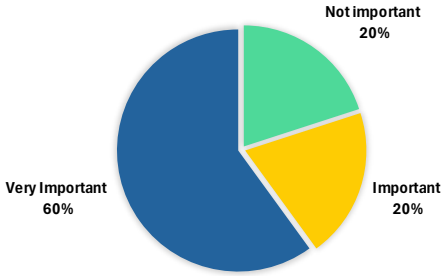
Patient history - Use of substances



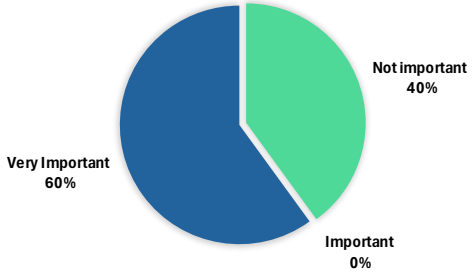
Course of hospitalisation - Diagnostic summary



Course of hospitalisation - Significant procedures



Course of hospitalisation - Medical devices and implants



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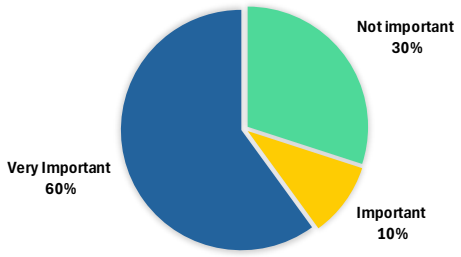
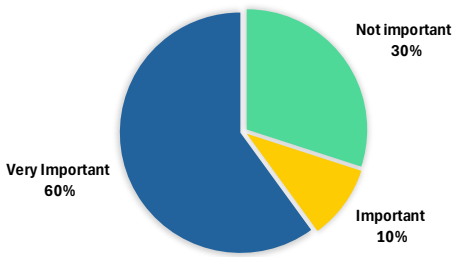
Hospital Discharge Report – Level of alignment

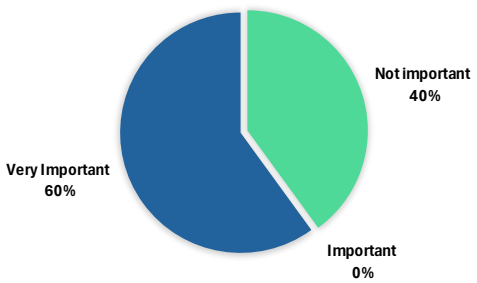
Course of hospitalisation - Pharmacotherapy



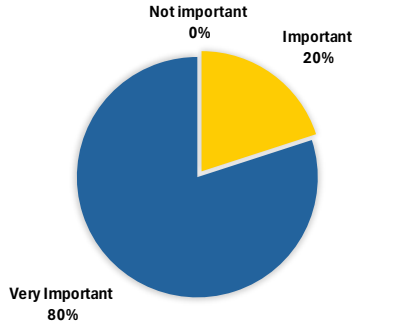
Course of hospitalisation - Significant Observation Results



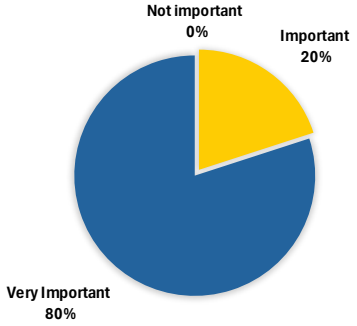
Course of hospitalisation - Synthesis



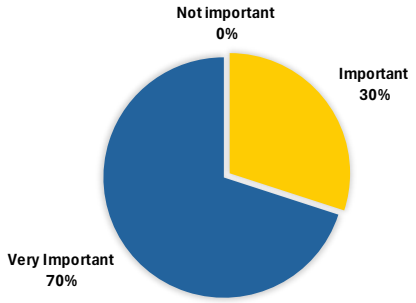
Discharge details - Objective findings



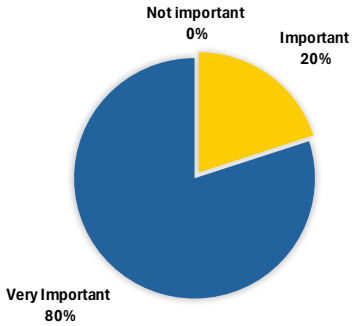
Discharge details - Functional status



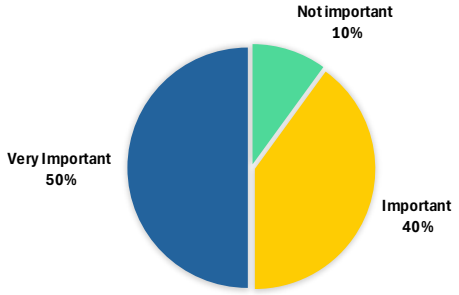
Care plan - Care plan



Care plan - Medication summary



Other recommendations



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Hospital Discharge Report

Level of Alignment

Technical workshops and One-on-one

Portugal, Greece and Slovakia

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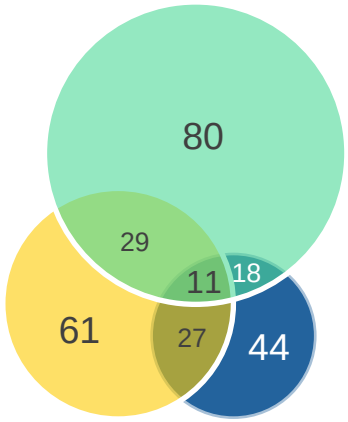
Hospital Discharge Report – Level of practice

Structured



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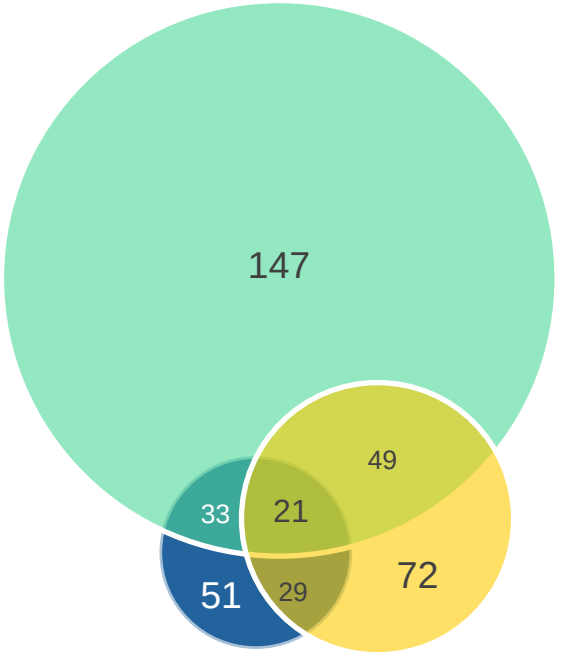

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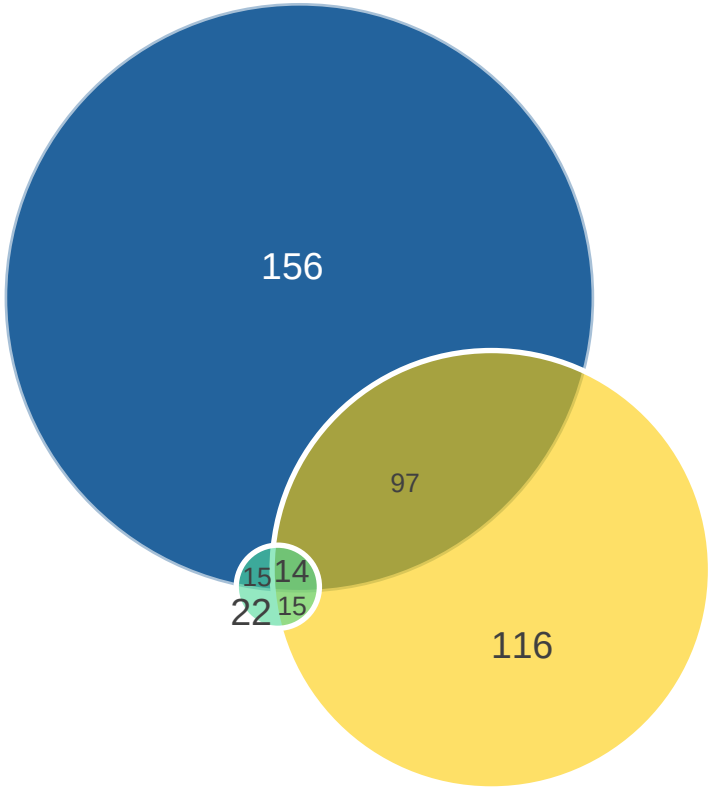

Slovakia

Greece

Portugal

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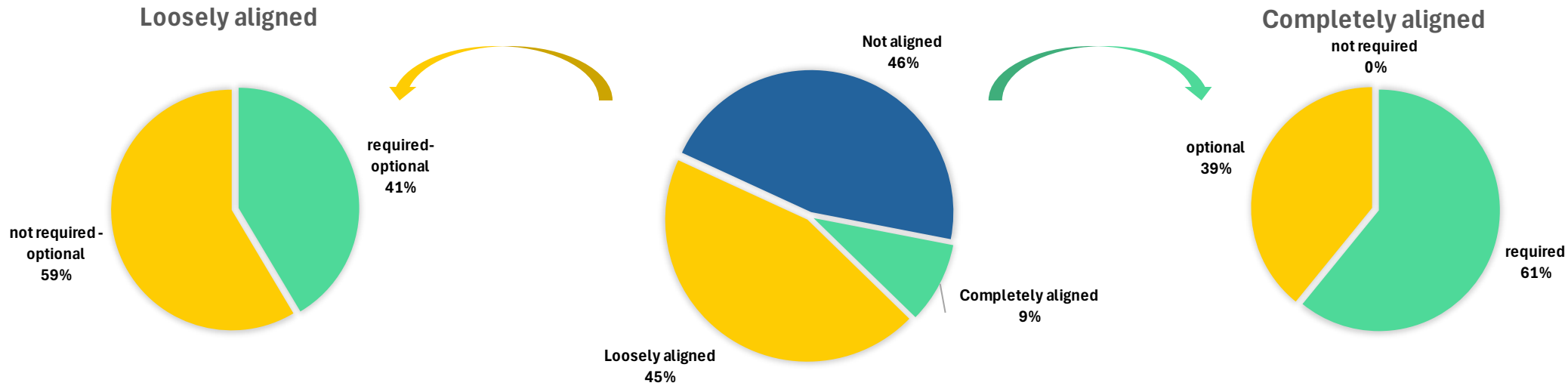
Hospital Discharge Report – Level of alignment

- Between Portugal, Greece and Slovakia



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Future Directions

Patient Summary

Laboratory Results

Hospital Discharge Report

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Additional information for the 3 Priority Domains

Additional information	
Security and Compliance – include directly in the report or as metadata?	
Digital Signature	Digital signature verifying the authenticity of the document.
Encryption Status	Status of data encryption for security.
Compliance Status	Status of GDPR compliance.
Access Permissions	Roles authorized to access the document.
Patient education and resources	
Patient Education Materials	Educational resources provided to the patient.
Support Services Information	Contact details for available support services.
Feedback mechanism	
Patient Satisfaction Feedback	Mechanism for patients to provide feedback.

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Future Directions – Patient Summary

- **Difficulties / Challenges**
  - Build and update
    - Who has responsibility for creating and updating (how frequently?) the patient summary is not clear in all countries. Responsible doctor (e.g. family doctor) vs automated systems that collect the information.
    - Different strategies for deciding what information should be included in the patient summary in fields such as results, past medicines, history of problems - E.g. the most recent ones (e.g. the last six months), decision by the doctor responsible for the PS, all information available.
  - Merge and harmonization
    - For the patient, it is important to have an aggregated patient summary, instead of what exists currently: information scattered across different institutions (e.g. public and private).

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Future Directions – Patient Summary

Additional Field	Description	Code System
Patient Summary header – Identification of the patient		
Preferred Language	The language the patient prefers for communication	
Report header – Contact / legal guardian → + Emergency contact		
Medical history – Previous hospitalizations		
Previous Hospitalizations	Record of past hospital stays, including reasons and outcomes. (Date, Reason for Admission, Outcome)	ICD-10, SNOMED CT GPS, ISO 8601
Medical history – Medical history		
Family medical history	Health conditions that are prevalent in the patient's family.	SNOMED CT GPS
Patient provided data – Observations / Measures		
Personal Measures	Measures provided by patient such as average daily steps, average daily heart rate, etc).	LOINC
Patient provided data - Advance Directive		
Proxy Information	Contact information for the person authorized to make decisions.	Not typically coded
Cultural Considerations	Any specific cultural considerations relevant to care.	Not typically coded
Preferred Care Providers	Preferred healthcare providers for the patient.	hl7:Practioner
Plan of care		
Follow-Up Appointment	Suggested future appointments for ongoing care (Date, Purpose of visit).	ICD-10, SNOMED CT GPS

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Future Directions – Laboratory Results

- **Difficulties / Challenges**
  - Dealing with national code systems
    - Countries with national strategy and their code systems catalogues with mapping for international ones
    - Countries with national data exchange based on unstructured data, with each laboratory using its own coding system.
  - The list of LOINC and SNOMED CT code systems is very extensive.

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Future Directions – Laboratory Results

Additional Field	Description
Report header – Provider information	
Laboratory Name	Name of the laboratory conducting the test.
Report header – Data protection flag	
Data Protection Flag	Indicates if the report contains potentially disturbing results.
Access Control	Determines who can access the report based on the Data Protection Flag.
Patient Notification	Details on how patients are informed about access restrictions.
Patient instructions and follow-up	
Patient instructions	Instructions given to the patient regarding the test.
Follow-Up Appointment	Details of any necessary follow-up appointment related to the test.

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Future Directions – Hospital Discharge Report

- Difficulties / challenges
  - Deal with plain text
    - In many organizations, much of the information in a hospital discharge report is provided in a block in plain text and not in a structured way.
  - List of data fields very large
    - An agreement on appropriate subset (depending on specialty) can reduce the list of data fields.
  - Dealing with national code systems
    - Countries with alignment with the international code systems, considered their usage or mapping table between the national ones and the international.
    - Countries with proprietary codes that need discussion and strategies for mapping.
  - Usage of national implementations of ICD-10 is quite common.
    - The transition to ICD-11 is not expected in the short term.

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Future Directions – Hospital Discharge Report

Additional Field	Description	Code System
Patient related contact information – Preferred HP		
ID organisation	code of HP organization	
ID department	code of department in the HP organization	
Encounter - Discharge		
Hospitalisation outcome	Patient' discharge condition.	A. Satisfactory C. Critical P. Poor S. Stable O. Other U. Unknown D. Death
Encounter - Admission		
Admitting weight	Weight on admission. To be completed for patients age less than 1 year.	

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Thanks!

Maria Marques

UNINOVA

XpanDH WP4 leader | xShare WP3 co-leader

Email: mcm@uninova.pt

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XpanDH
Expanding Digital Health through a pan-European EHRxF-based Ecosystem

Xt EHR @dataspace

Share EHR Xchange Format

European Commission

2nd European EHR Exchange Format Expert Summit

Industry transformation preparing for the format

Verena Thaler & Andreas Klingler

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Industry Preparation: inside the „black box“

Dr. Andreas Klingler, Siemens Healthineers, COCIR

COCIR Cybersecurity & Interoperabilty WG Co-Chair
MTE Interoperability WG Member
IHE International Board Member
IHE-Europe Deputy Vendor Co-Chair
DICOM Executive Commitee Member
Joint Initiative Council Past Chair

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Art. 2(n) 'EHR system':

any system where the appliance/software allows to store, intermediate, export, import, convert, edit or view personal electronic health data that belongs to the **priority categories** of personal electronic health data (referred to in Art.5) and is intended by the manufacturer to be used by healthcare providers **in providing patient care** or **by a patient to access their health data.**

Art. 5 'Priority categories'

patient summaries, electronic prescriptions, electronic dispensations, medical imaging studies and related imaging reports, **medical test results** including laboratory and other diagnostic results and related reports, discharge reports.

MS may require additional categories.

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MDs, IVDs, high risk AIs:

Manufacturers of MDs and IVDs that **claim interoperability** of those devices with the harmonized components shall prove compliance with the essential requirements on the harmonized components laid down in Section 2 of Annex II. (Art.14(3))

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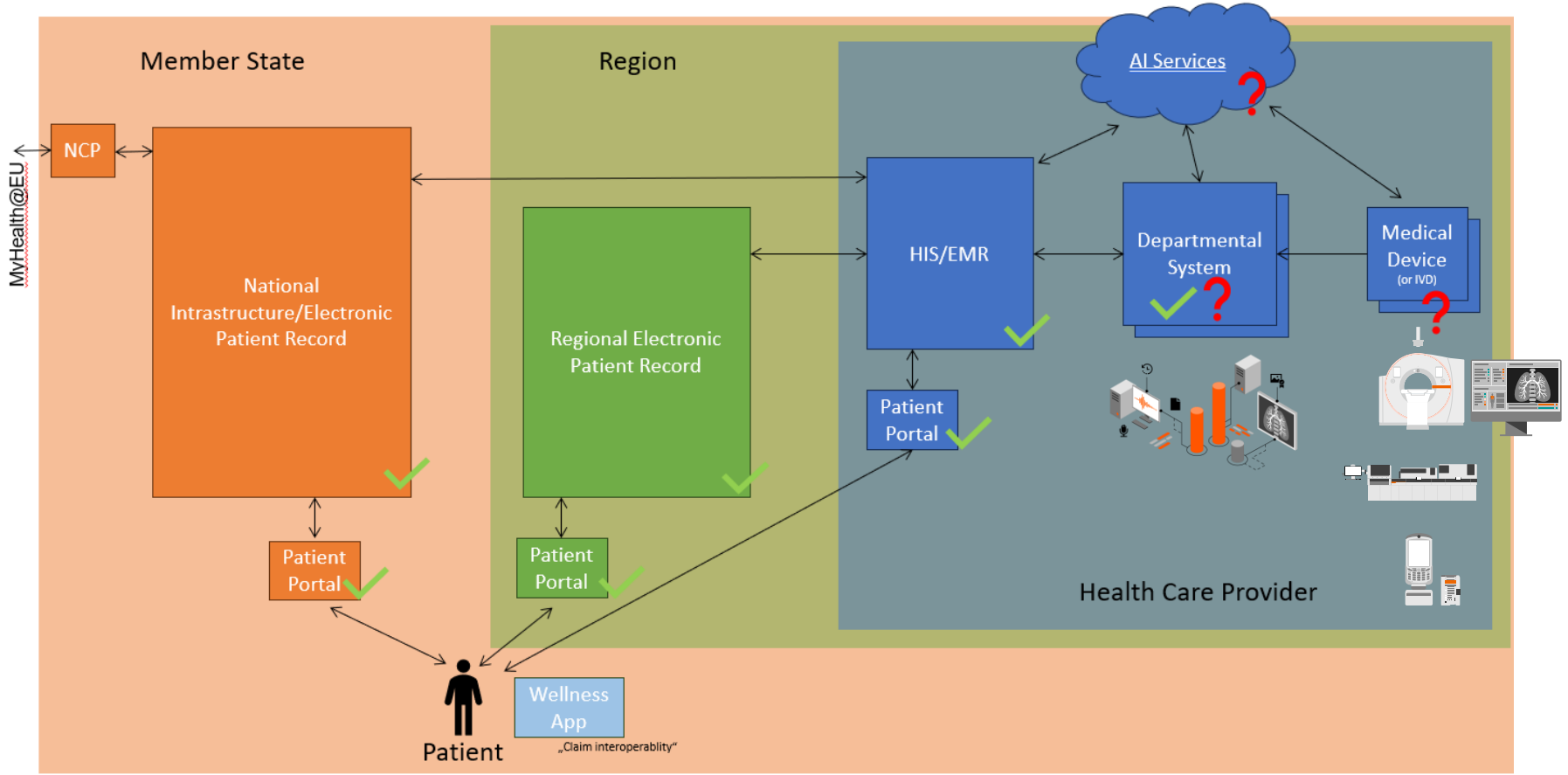
„EHR System“ Scope?



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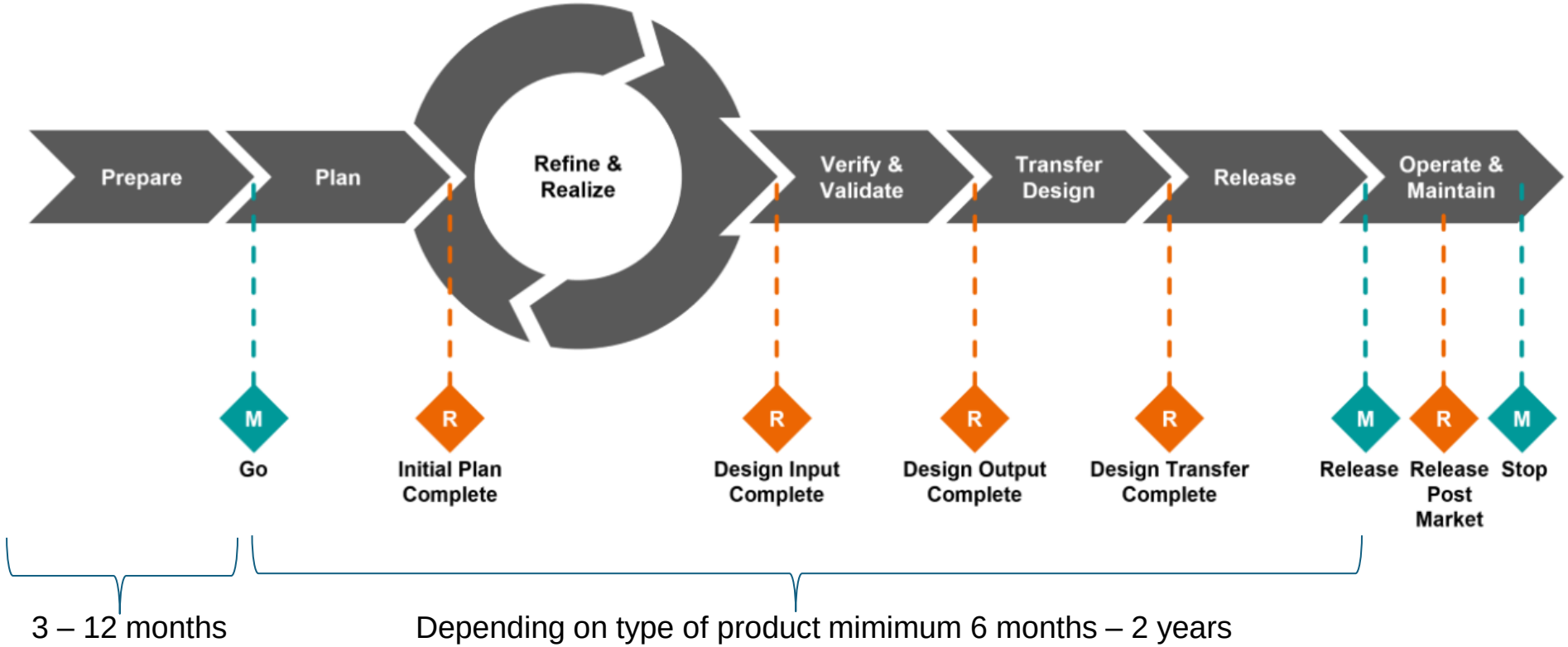
Understanding Product Livecycle Timelines



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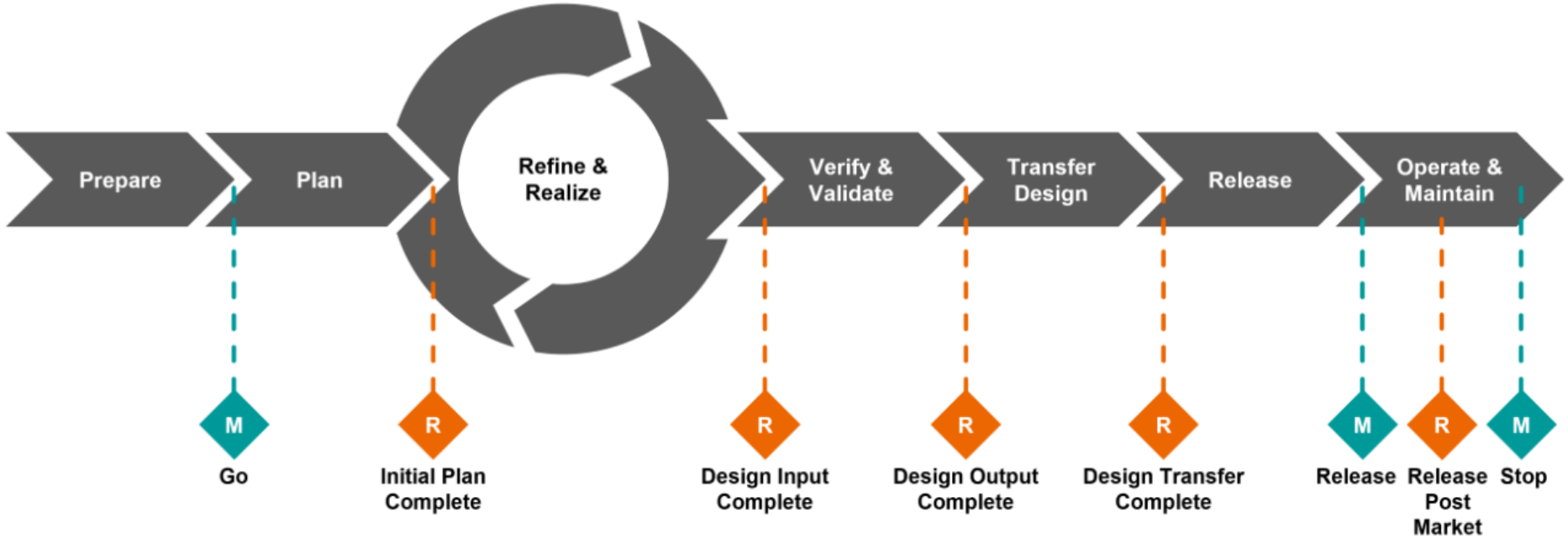
Understanding Product Livecycle Timelines



Need Plugathons here
Access to draft specifications

Need test cases/tools plus Connectathons/Projectathons here
Preferably IHE-based

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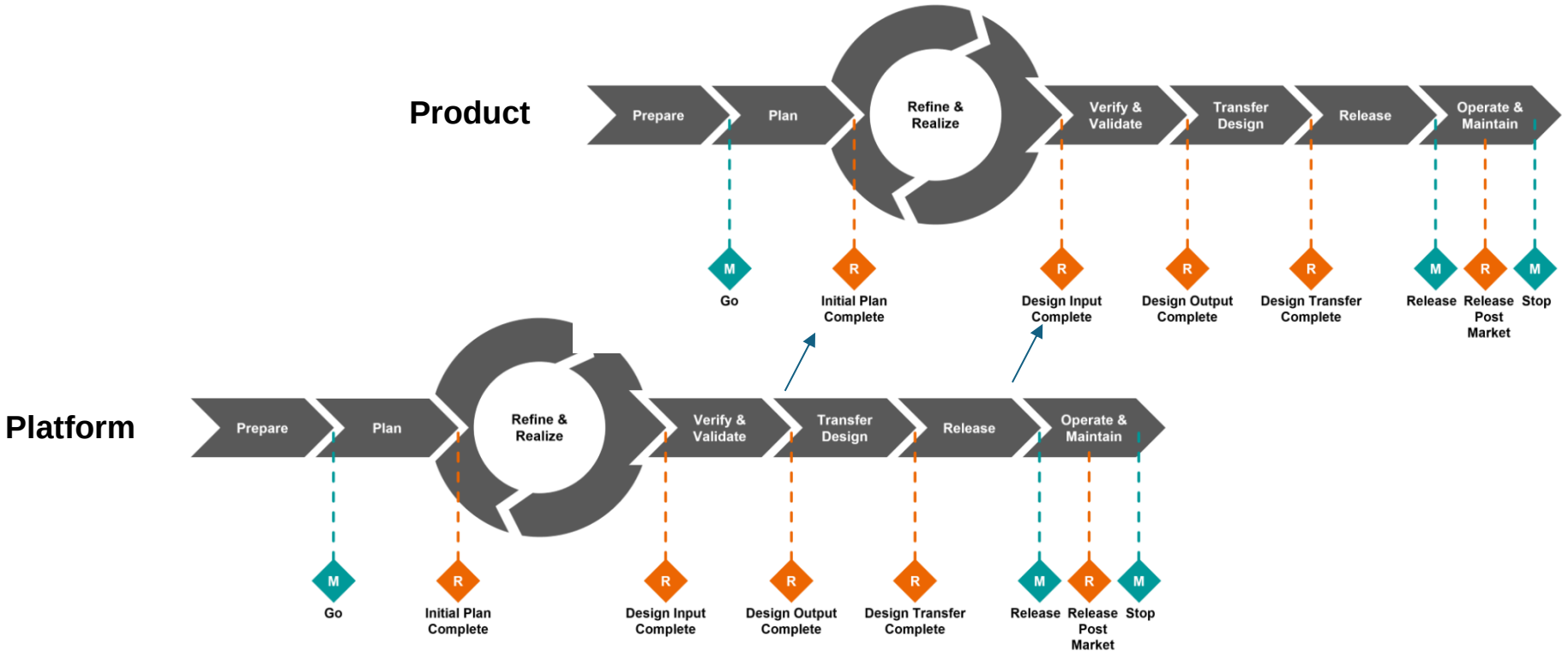
Understanding Product Livecycle Timelines



Overall for platform based <u>medical devices</u> ~ 3 years

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eHMSEG Support of the EEHRxF Format Uptake

Klara Jirakova
Chair – eHealth Member State Expert Group (eHMSEG)
Czech Republic – National Contact Point for eHealth

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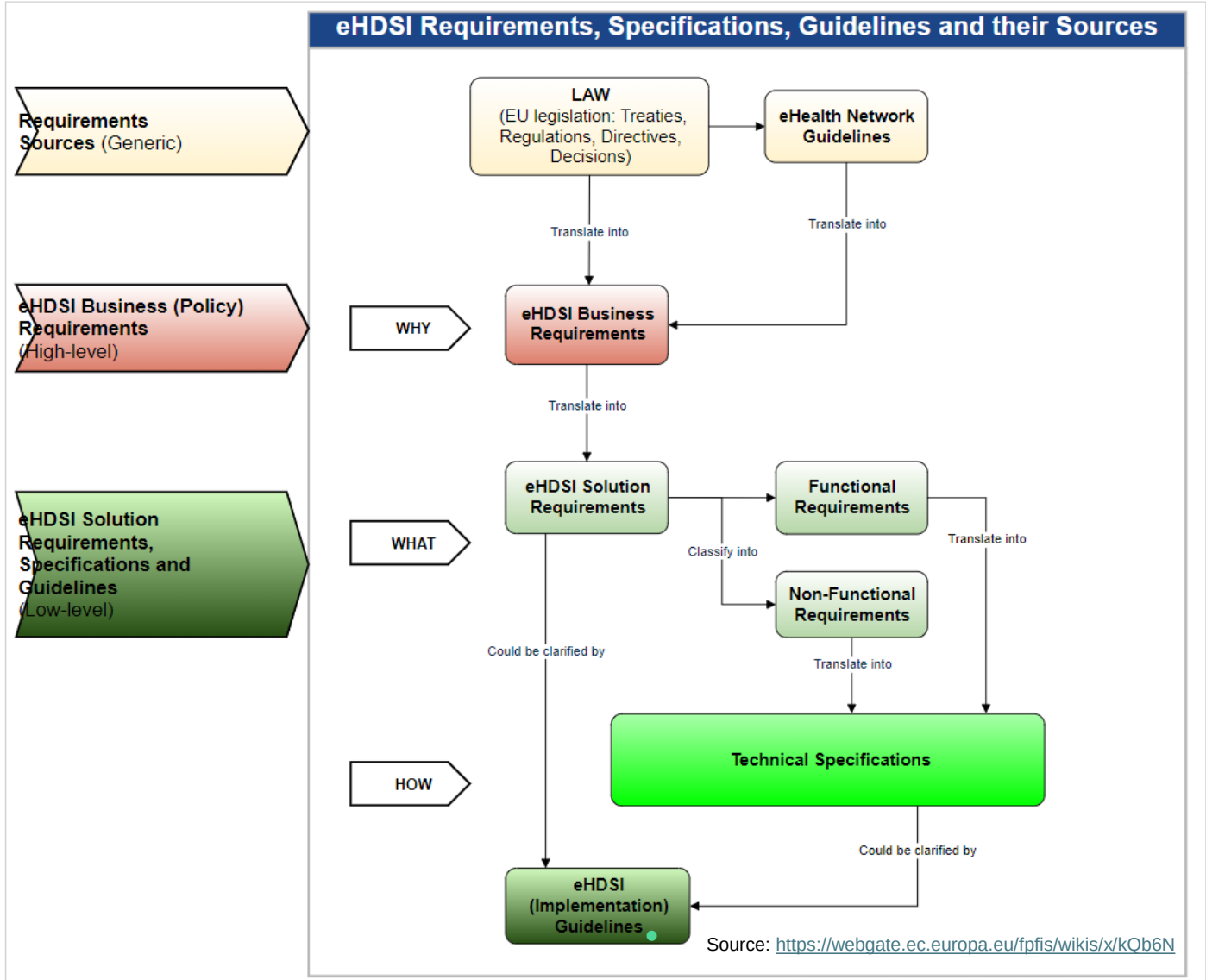
The Why, What and How

From Law to

eHealth Network Guidelines to

MyHealth@EU (eHealth Digital Services Infrastructure)

My Health @ EU
eHealth Digital Service Infrastructure
A service provided by the European Union



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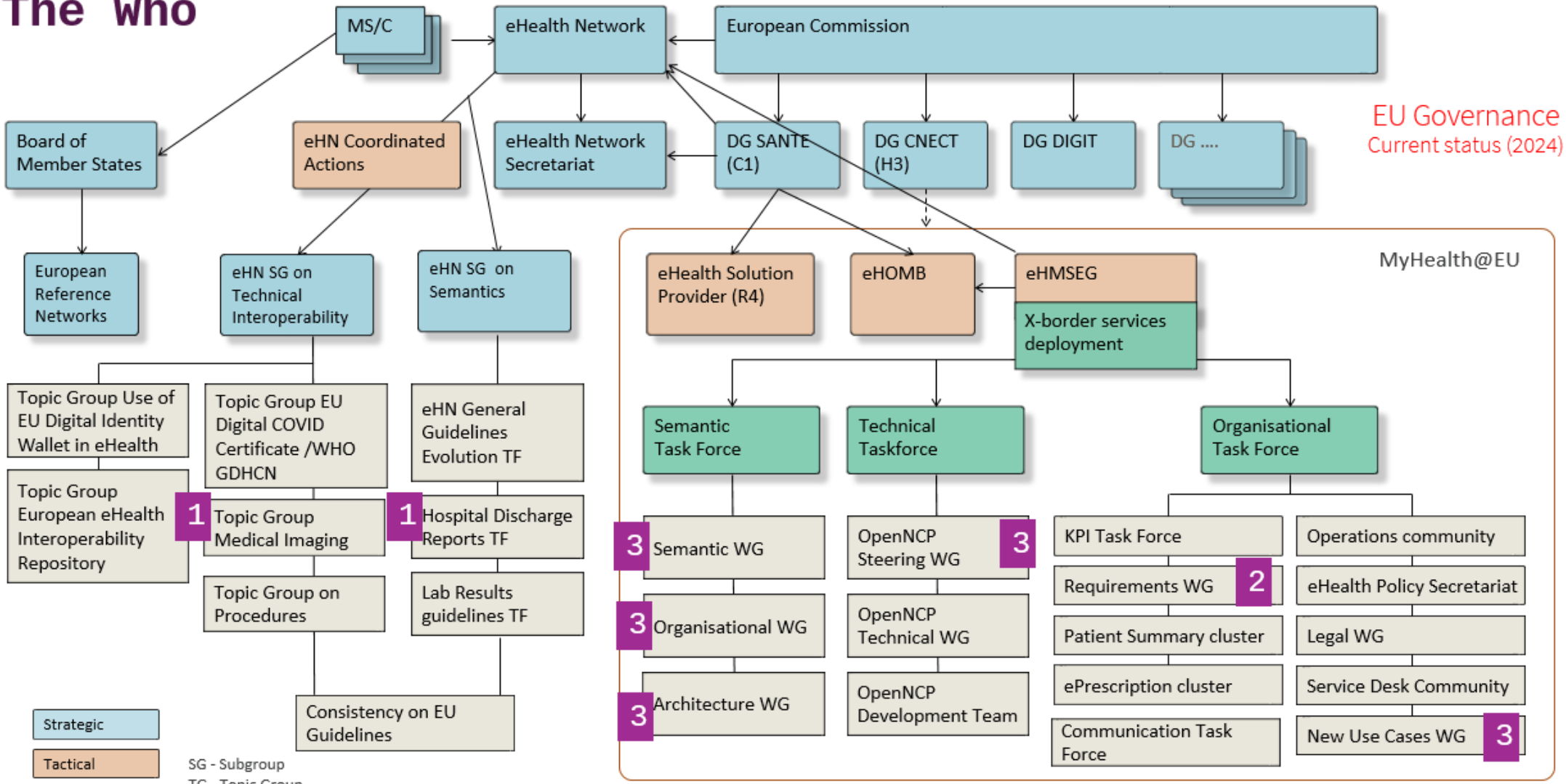
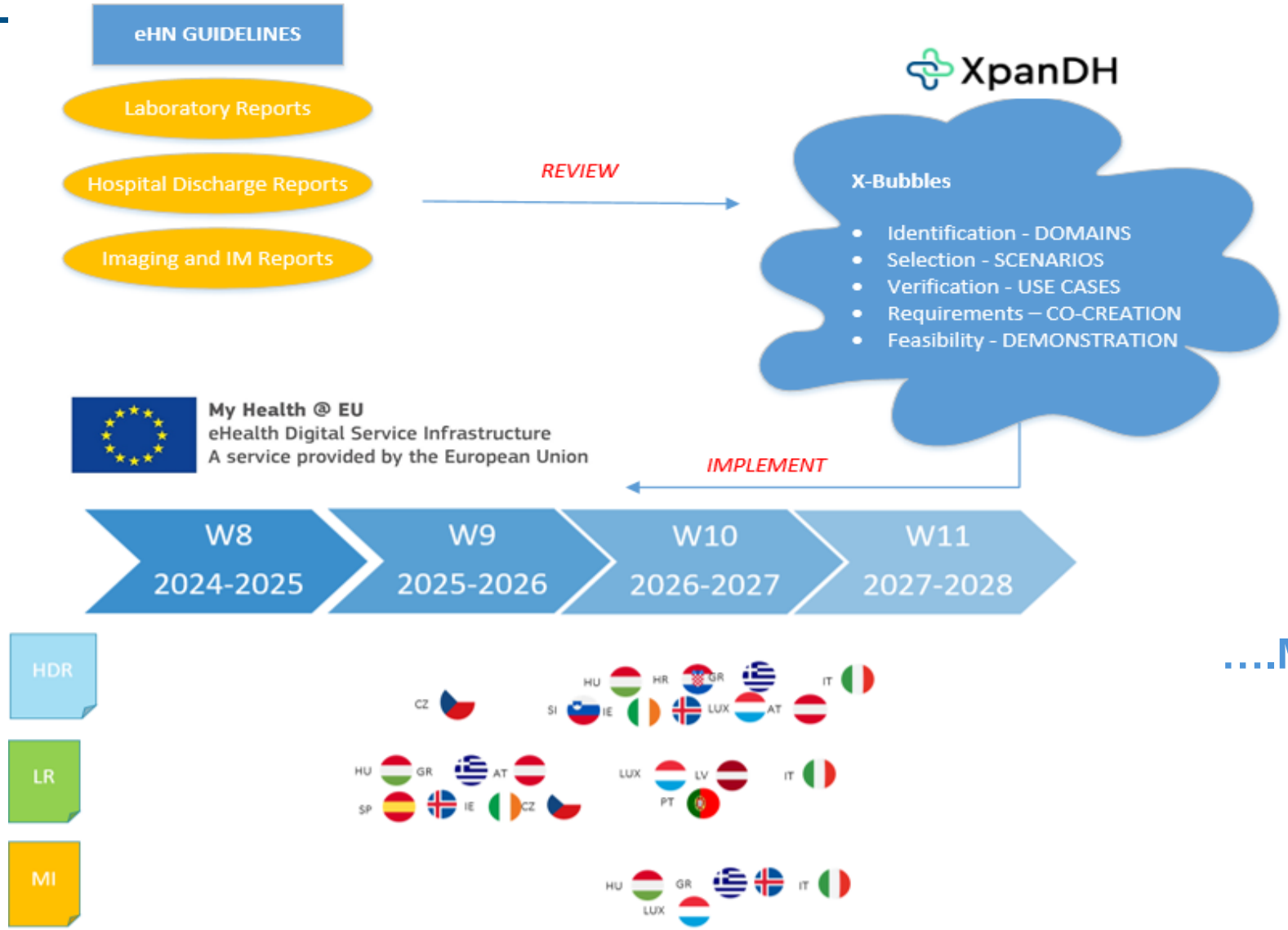
The Who



Source: Vincent van Pelt, Eamonn Coyne



….MyHealth@EU „2.0“

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Thank you for your support and cooperation!

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Share
EHR Xchange Format

European Commission

2nd European EHR Exchange Format Expert Summit

eHN support the uptake of the format

Daniel Karlsson & Panayiotis Savva

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eHealth Network Support of EEHRxF

- Guidelines Consistency
- EHDS Impact Assessment
- Support of Xt-EHR
  - Education and Training
  - Xt-EHR Consultation Hour
- EHDS Transition

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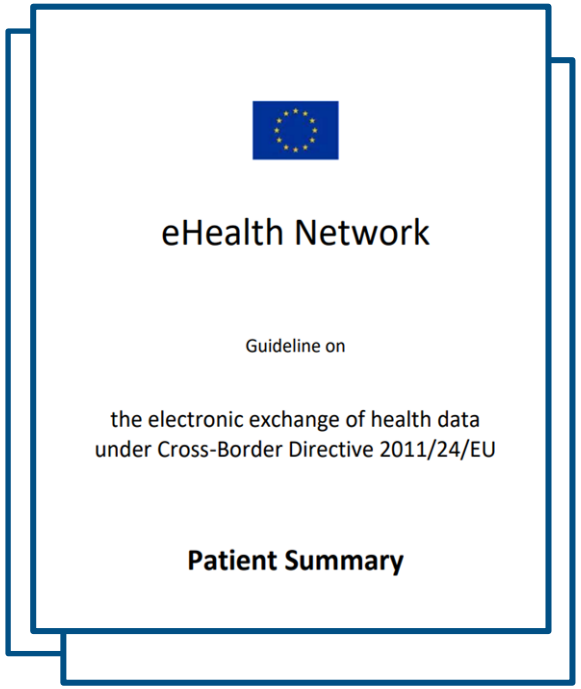
Guidelines Consistency

- eHealth Network guidelines have been developed for over a decade now
- Each new version has brought improvements, but also deviation

- The work done by the subgroups have resulted in
  - New versions of guidelines with alignment in textual parts
  - A comparison of all data sets in all guidelines, handed over to the Xt-EHR Joint Action



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EHDS Impact Assessment

- Assess and communicate the impacts of EEHRxF adoption on Member States
- Survey for Member States to assess readiness, identify technical and semantic challenges, and gather insights for alignment with the EEHRxF with national needs
- Provide technical and semantic support through the eHN Subgroups.
- National Architecture Adaptation
- Ensure compatibility with EEHRxF.

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Support of the Xt-EHR

- eHN Organization: Overview of eHN, MyHealth@EU, Semantic & Tech IOP Subgroups.
- eHN Guidelines: Importance, reading and interpretation, implementation needs.
- Includes representatives from several EU countries and Xt-EHR stakeholders.
- **Xt-EHR Consultation Hour**
- Monthly sessions to address specific questions from Xt-EHR Joint Action work packages, with participation from Member States, DG SANTE, and eHN Subgroups. The first session took place on October 4, 2024, bringing together 17 Member States to focus on semantic and technical interoperability solutions.

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EHDS transition 1

Article 71
Amendment to Directive 2011/24/EU

Article 14 of Directive 2011/24/EU is deleted with effect from 6 years of entry into force of this Regulation.

Article 6
European electronic health record exchange format

…
The format sha… elements:
(a) **harmo…** electronic health data and defining str… d data groups for the representation… parts of the electronic health data;
(b) **coding systems and values** …ontaining electronic health data;
(c) **technical interoperability specificatio…** exchange of electronic health data, including its conte… epresentation, **standards and profiles**.

EEHRxF

eHAction
Joint Action supporting the eHealth Network

Member States/Countries document about a
Common Semantic Strategy for Health in the European Union

Information paper for the eHealth Network

16-08-2019
Version 1.5

Grant Agreement nº 801558

Co-funded by the European Union's Health Programme (2014-2020)

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EHDS transition 2

2011/24/EU
+
Common Semantic Strategy
+
eHN guidelines
+
Xt-EHR results

EHDS
+
Implementing acts
with requirements and specifications

eHealth Network
+
eHN subgroups

EHDS Board
+
EHDS Board subgroups
+
MyHealth@EU Steering Group

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Xt EHR @dataspace

Share EHR Xchange Format

European Commission

Xt-EHR developments and perspectives on EHR requirements

Haralampos Karanikas
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Shared Services of the Ministry of Health, E.P.E.

Zoltan Lantos
Project Manager of National Contact Point for eHealth
ESZFK Health Informatics Service and Development Center

ΗΔΙΚΑ
ΗΛΕΚΤΡΟΝΙΚΗ ΔΙΑΚΥΒΕΡΝΗΣΗ ΚΟΙΝΩΝΙΚΗΣ ΑΣΦΑΛΙΣΗΣ Α.Ε.

eHälsomyndigheten
Swedish eHealth Agency

SPMS EPE
Serviços Partilhados do Ministério da Saúde

ESZFK
Egészséginformatikai Szolgáltató és Fejlesztési Központ

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Universal across WPs / domain / services

- Support development of EEHRxF implementing acts:
  - ***Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems***
- eHN Guidelines and MyHealth@EU Requirements as basis
- Inter-WPs alignment across Xt-EHR
- Data sets, Data elements, Common Elements across Domains
- HL7 CDA → HL7 FHIR
- Collaboration SDOs, ISO standards
- Logical model
- Conformity / Maturity model for EHR systems

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HTA; ROI

VALUE

DATAFLOW

Gateway API

Set of Data Points with Metadata

Fit for Purpose

Contexts

Data points

Identity

WP4/WP5

EHDS

Policy

eHN

eHMSEG

MyHealth@EU

https://interoperable-europe.ec.europa.eu/collection/nifo-national-interoperability-framework-observatory/solution/european-interoperability-framework-eif-toolbox/levels-interoperability

Health Data Space

Mathematics

Nature and Society

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WP6 Electronic prescriptions and patient summary towards EHDS

T6.1 Patient Summary: EEHRxF, requirements and specifications for EHR systems

- Task leader: ARIA (Co-lead NBHW)
- Final Deliverable Jan 2026
- Milestone 17 (draft deliverable)
  - Survey: PS vs. IPS, PS national vs. cross-border, Low conformance, Standards
  - Basic elements of PS
  - Universal aspects (see separate slide)

Implemented in MyHealth@EU

T6.2 ePrescriptions/eDispensation: EEHRxF, requirements and specifications for EHR systems

- Task leader: SeHA
- Final Deliverable Jan 2026
- Milestone 19 (draft deliverable)
  - Requirements analysis performed
  - Standardised representation of medication in all domains (PS etc)
  - Universal aspects (see separate slide)

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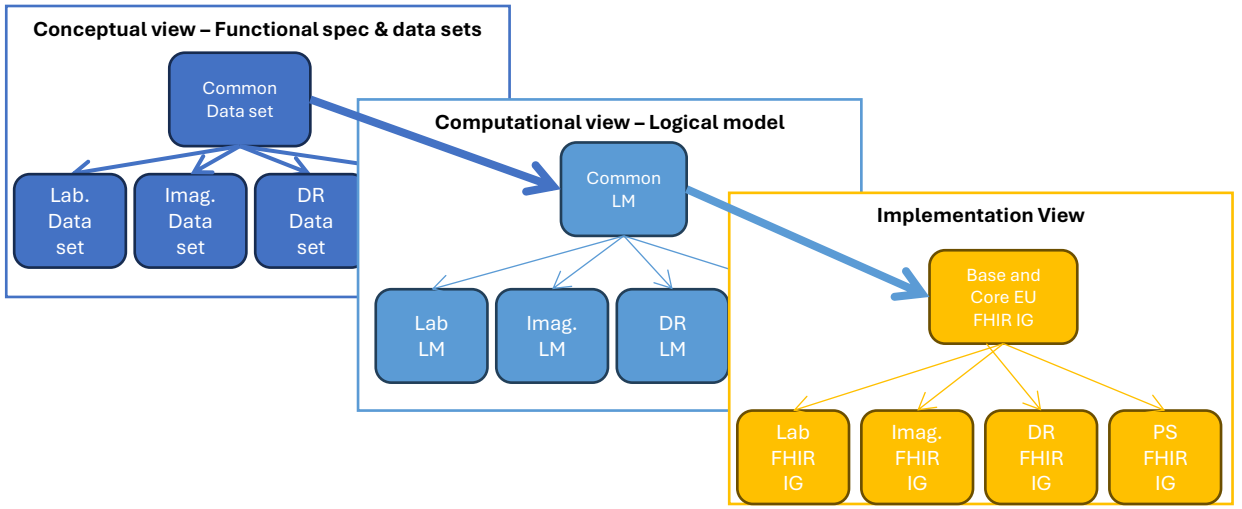
WP7 New services for EHR systems towards EHDS (SPMS)

- **EEHRxF, requirements and specifications for EHR systems**:
  - Medical test results, including laboratory and other diagnostic results and related reports (**Task 7.1, VR**)
  - Medical imaging studies and related imaging reports (**Task 7.2, NICTIZ**)
  - Discharge reports (**Task 7.3, VR**)

X-eHealth
eHN Guidelines



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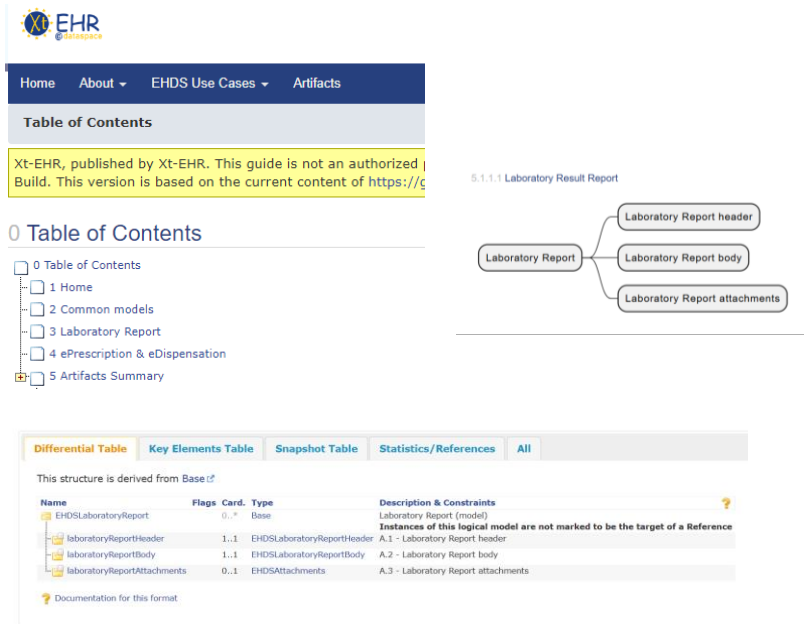
Logical Model WG

Code	Cardinality	Data element	Description	Data type	Preferred Code System
C.2	1..1	Health professional	Health professional (HP)	Backbone Element	
C.2.1	0..*	Identifier of the HP	An identifier of the health professional that is unique within a defined scope. Example: National health professional ID. Multiple identifiers could be provided.	Identifier	At least the name or id should be provi
C.2.2	0..1	Name of the HP	Name of the health professional that has been treating or taking responsibility for the patient. [the structure of the name will be the same as for the patient (given name, family name / surname)]	Human Name	At least the name or id should be provi
C.2.3	0..1	Address	Mailing and home or office addresses. The addresses are always sequences of address parts (e.g. street address line, country, postcode, city) even if postal address formats may vary depending on the country. An address may or may not include a specific use code; if this attribute is not present it is assumed to be the default address useful for any purpose. Telecommunication contact information (addresses) associated with a person, such as	Address	



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  - Discharge reports (**Task 7.3, VR**)

3 Milestones achieved in October 2024, which will undergo revision. It includes:

- Initial **business requirements**, as well as preliminary **functional, technical and semantics** specifications
- **FHIR** as the preferred standard for the new domains in line with eHN guidelines
- **Ongoing data modeling** efforts to complement these developments

Next steps:

- Map deliverable's sections to relevant EHDS articles and align scope
- Refine Data Model within WP7 & with WP6
- Align with T5.4 concerning specific metadata elements
- Define requirements for data entry, display, and transmission (EHDS API)
- Support WP8 functional profiles based on data operations
- Finalize draft for stakeholder consultation

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WP8 Certification and labelling framework (IDIKA SA)

WP8, in collaboration with WPs 4-7, is carrying out the necessary tasks to provide guidance in support of the forthcoming EHDS Regulation and in particular in support of Chapter 3, EHR Systems and Wellness Applications, Section 3 on conformity of EHR systems:

- **Assess the results of previous and ongoing initiatives** in the field of Conformity Assessment, evaluation and labelling across Europe (e.g. Label2Enable, EuroCAS, XpanDH, IHE International, national approaches to conformance and profiling in Member States, etc.).
- Development of an assessment framework and Conformity Assertions based on the **XT-EHR technical specifications for the implementation of interoperability of electronic health records (EEHRxF)** and **Logging,** taking into account functional and conformity assessment schemes for functional models and profiles of electronic health records.
  - Collaboration between stakeholders and WPs is needed on required maturity of EHR systems, both on detailed level (data elements) and higher level of abstraction (functions and data segments for data exchange and visible to users).
  - Existing models of binding between regulations and detailed requirements from member states and related projects are an important basis for the work.
- Development of guidelines to support the industry for an assessment framework for the **evaluation of interoperability and security of wellness applications**, taking into account in particular CEN-ISO/TS 82304-2:2021 Health software - Part 2: Health and wellness applications - Quality and reliability standard.
- Collaborate with relative projects and stakeholders in the domain based on “Stakeholders Engagement Processes” lead by the XT-EHR coordination team.

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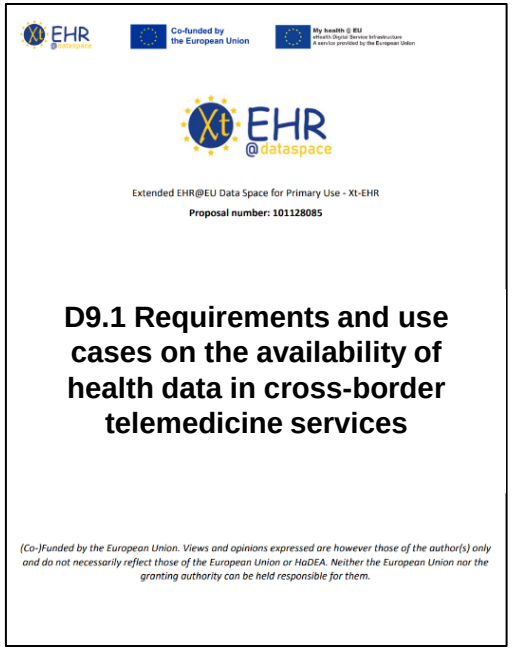
WP9 – Telemedicine under MyHealth@EU in alignment with EHDS proposal (SPMS)



Submitted Oct 31, 2024

Using MyHealth@EU services to support:

- Teleconsultation between a **Patient** in their country of affiliation (Country A) and a **Health Professional (HP)** in a different country (Country B).
- Teleconsultation between **two HPs**, one in Country A and the other in Country B, discussing the **case of the patient from Country** A.
- **Sharing a report** based on the main outcomes generated during the teleconsultation from country B **to country A** – discharge report.

13 proposals generated to support this new capacity, with special focus on:

1. Patient identification and authentication
2. Data access
3. Reusing existing MyHealth@EU assets to minimize overall impact

MyHealth@EU requirements catalogue revised: 6 requirements need amendment + 1 new requirement

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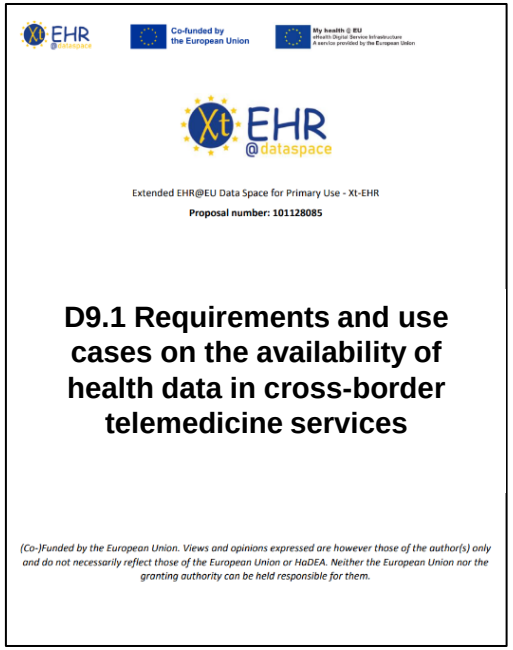

EHR @dataspace

Extended EHR@EU Data Space for Primary Use - Xt-EHR

Proposal number: 101128085

D9.1 Requirements and use cases on the availability of health data in cross-border telemedicine services

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Submitted Oct 31, 2024

Patient Identification & authentication

- Reuse of the International Search Mask (ISM) attributes from Country-A, which are already implemented in MyHealth@EU.
- **Two-factor**, **interoperable identification mechanisms** must be implemented for cross-border telemedicine services.
- **Proposed solutions** were based on recommendations from eIDAS experts, consortium expertise and findings from the HEALTHeID project:
  - Preferred approach involves **reconciling** patient identification and authentication information within **Country A's infrastructure**.
  - **EUDI Wallet** could provide a standardized, interoperable solution for cross-border remote patient authentication. eHealth use case under testing in the POTENTIAL project.

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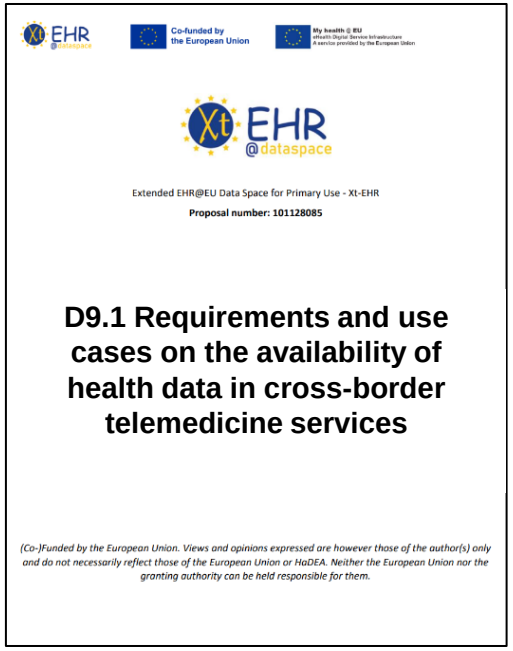

Submitted Oct 31, 2024

Patient validation for sharing data

- Enable **asynchronous access** to patient data, a capability not currently supported MyHealth@EU.
- **Patient Information Notice** (PIN) to be sent to the patient by email or other secure online transmission mechanism, prior to the teleconsultation.
- **Proposed solutions**:
  1. **Coordinated Identification & Authentication**: Requires active participation from the patient. Aligns with current identification and authentication services.
  2. **Consent form approach**: Patient electronically signs a consent form using the current eIDAS framework, to authorize data access without real-time authentication. This consent should be revocable and in compliance with GDPR.
  3. **Country A's Managed Consent Process**: Country A to manage a specific consent process, where citizens can authorize the use of MyHealth@EU services for cross-border telemedicine services.
  4. **Additional considerations**: **notification mechanism** to alert the patient whenever their data is accessed, ensuring transparency and trust.

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WP9 – Telemedicine under MyHealth@EU in alignment with EHDS proposal (SPMS)

Next steps

D9.2 – *Technical specifications on the availability of health data in cross-border telemedicine services*:

- Advance initial proposals of D9.1, especially patient identification and authentication requirements.
- Develop / update MyHealth@EU artefacts / requirements catalogue including functional and non-functional workflows and key technical specifications.
- Analyze existing authentication mechanisms used by MS that could be leveraged for this context.

D9.3 – *Requirements for Large-Scale Uptake of Telemedicine Service*

- Ongoing survey “Cross-Border Telemedicine in the EU: Information Gathering for Policy Harmonization” (link)

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Xt-EHR deliverables of WP5-9 for stakeholder consultation

WP/ Number of Deliverable	Deliverable Name	**Stakeholder consultation phase -> tentative date** for when deliverable is shared for comments - deadline to provide comments	
WP5/ D5.1	Technical Requirements for EHRs, logging component and key system interfaces	3	30.04.2025 - 11.06.2025
WP5/ D5.2	Technical requirements for EEHRxF metadata	3	30.04.2025 - 11.06.2025
WP6/ D6.1	Patient Summary: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems	5	15.06.2025 - 15.09.2025
WP6/ D6.2	Electronic prescription and electronic dispensation: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems	5	15.06.2025 - 15.09.2025
WP7/ D7.1	Medical test results, including laboratory and other diagnostic results and related reports: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems	8	31.08.2025 - 12.10.2025
WP7/ D7.2	Medical imaging studies and related imaging reports: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems	9	30.09.2025 - 11.11.2025
WP7/ D7.3	Discharge reports: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems	6	31.07.2025 - 11.09.2025
WP8/ D8.1	Classification and functional profiles of EHR systems guidelines	7	04.08.2025 - 14.09.2025
WP8/ D8.2	EHR Conformity Assessment Scheme assertion document and checklists	7	04.08.2025 - 14.09.2025
WP8/ D8.3	Wellness application labelling guidelines	2	30.03.2025 - 11.05.2025
WP9/ D9.1	Requirements and use cases on the availability of health data in cross- border telemedicine services under MyHealth@EU	1	03.02.2025 - 17.03.2025
WP9/ D9.2	Technical specifications on the availability of health data in cross-border telemedicine services under MyHealth@EU	4	29.05.2025 - 11.07.2025
WP9/ D9.3	Requirements for Large-Scale Uptake of Telemedicine Service	3	30.04.2025 - 11.06.2025

Over summer vacation period -> longer consultation phase

Xt EHR @dataspace

2nd European EHR Exchange Format Expert Summit

COFFEE BREAK

Starts again at 11:50

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