



# X-eHealth

Exchanging Electronic Health Records  
in a common framework



## TODAY'S PRESENTATION

### X-eHealth (5')

PROJECT SCOPE, OBJECTIVES AND IMPACTS – **YASMIN FONSECA**

### X-eHealth a bridge towards evolution (7:30')

WHAT WILL BE FROM WAVE 7 ON – **MARCELLO MELGARA**

### X-eHealth outcomes for broader use (7:30')

INFORMATION MODELS

CDA AND FHIR– DRAFT OF FHIR SPECIFICATIONS ON LAB DOMAIN – **HYNEK KRUIK**

### Roundtable discussion (45')

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## X-EHEALTH

# SCOPE, OBJECTIVES & IMPACTS

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Yasmin Fonseca – Coordination Team





# PROJECT BACKGROUND

- X-eHealth intends to contribute to the Digital Single Market Strategy in the EU, in line with EEHRxF Recommendations

The **Digital Single Market strategy** seeks to ensure better access for consumers and business to online goods and services across Europe, for example by removing barriers to cross-border e-commerce and access to online content while increasing consumer protection.

The Digital Single Market **in Health** in Europe is based on three pillars:



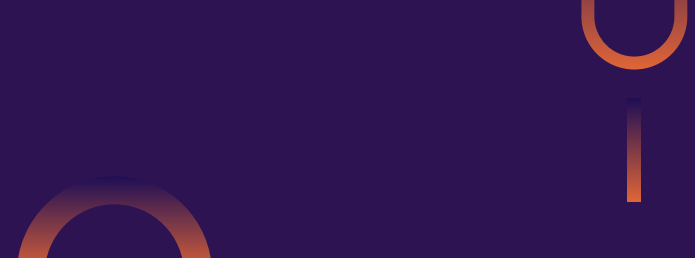
Citizens' secure access  
to their health data,  
also across borders



Personalised medicine  
through shared European  
data infrastructure



Citizen empowerment  
with digital tools for user feedback  
and person-centred care



# PROJECT SCOPE

X-eHealth's purpose is to develop the foundations for a common framework for **medical imaging**, **discharge reports**, **laboratory orders and results** and **rare diseases** to flow both alongside citizens care pathway and across health entities between EU Member States and neighbour countries.



**Medical Imaging**



**Hospital Discharge Reports**



**Laboratory Results**



**Rare Diseases**



# MYHEALTH@EU

- X-eHealth is developing specifications to improve and expand the services of MyHealth@EU

## X-eHealth aims to:



Define, specify and demonstrate the EEHRxF use cases



Elaborate on the **roadmap** for the **use cases for future** uptake on the eHDSI;



Submit the **outcomes** and recommendations of X-eHealth regarding EEHRxF and propose a sustainable **governance framework**



- MyHealth@EU specifications are adopted by eHMSEG, after going through the MyHealth@EU change proposal management
- Policy and strategic documents go through eHN
- Specifications and operational documents go through the MyHealth@EU change proposal management (eHOMB, eHMSEG)



Live now: CZ EE ES FI FR HR LU MT NL PT



Go - live planned 2022: CY GR HU IE IT LT PL SE SI SK



Go-live planned 2023



Application under review : AT DE DK IS NO RO



# EXPECTED IMPACTS

**Assure  
standardisation and  
harmonization of  
digital platforms and  
solutions**

Making data accessible in an actionable form for exchange and portability by citizens, researches, health services and health professionals

**Increase levels of  
digital literacy**

End users with the essential eSkills to enhance preventive approaches and advance the timeliness of intervention

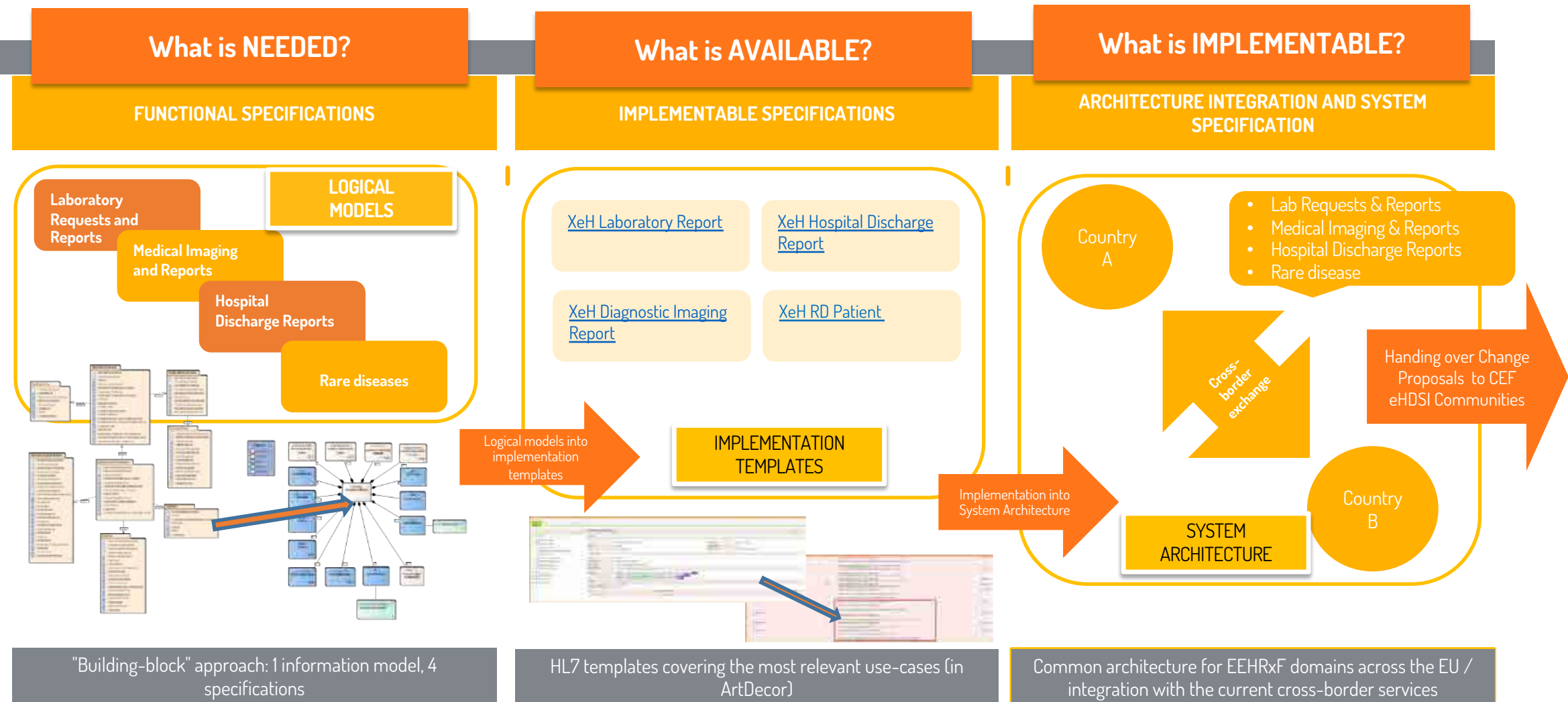
**Assure full system  
integration and  
architecture**

Development of a citizen-centred health record solution that enhance citizens self-management whilst adding supplementary data for a tailored Digital Service Infrastructure

**Greater confidence  
and safety for  
citizens/patients**

Better and easier online access to citizens' health record information to ensure greater confidence and safety when traveling across Europe

# CONCERTED ACTION: WP5/6/7



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## X-EHEALTH

# A BRIDGE TOWARDS EVOLUTION

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Marcello Melgara – WP7 Leader





# The Basic Pillars of European eHealth

- **Patient Safety (and Privacy) FIRST**
    - Provide **Updated, Reliable, Understandable** clinical information, where and when needed, to provide health care to the patient
  - **Common Trust among Member States on their Healthcare systems**
    - Adopt “common” policies & procedures
    - Adopt “common” International Standards
    - Adopt “common” validation processes
      - Testing Strategy & Conformance approval
  - **Do not interfere into the National processes**
    - Guidance not imposition
- *The eHN political role in these decades in MSs eHealth growth*

# The roadmap



1) PS; eP/eD 2) Patient Access; Health Care Encounter Report (HCER);  
Medication Related Overview, Emergency 112, EHIC



PS; eP/eD; Patient Access; Health Care Encounter Report

## Expansion



### CEF eHDSI

eHealth Digital Service Infrastructure  
A service provided by the European Union

(EU)PS; eP/eD; Original Clinical Document

## Extension



### My health @ EU

eHealth Digital Service Infrastructure  
A service provided by the European Union



eP/eD ISO IDMP

(I)PS; OrCD, Lab Report;



+ Lab Results, Hospital Discharge Letters  
(HCER), Images and reports, Rare Diseases

## Evolution

### MyHealth@EU new Calls:

PATHED: Patient Access,  
POTENTIAL: eP in the eWallet  
New Use Cases/scenarios,  
SNOMED CT License  
Joint Action on European Health Data  
Space preparation

### Horizon Europe:

Setting up a EEHRxF Ecosystem  
eX-panDH Proposal (Hospital on FHIR)  
Large Scale Pilot on eWallet & eP/eD

IHE-Europe EXPERIENCE DAY 2022

2025



# MyHealth@EU

Next to ePrescription and Patient Summary, more services will be added.



# How X-eHealth started:

## COMMISSION RECOMMENDATION

of 6.2.2019

on a European Electronic Health Record exchange format

(Text with EEA relevance)

### THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

- (1) Citizens have the right to access their personal data, including their health data as provided for by Regulation (EU) 2016/679 of the European Parliament and of the Council<sup>1</sup>, which lays down the conditions for lawful processing of personal data, including data concerning health, as defined therein<sup>2</sup> (health data). However most citizens cannot yet access (nor securely share) their health data across borders.
- (2) The ability of citizens and healthcare providers to securely access and share electronic health records ('EHR's), that is to say collections of longitudinal medical records or similar documentation of an individual, in digital form, within and across borders has a number of benefits: an improvement in the quality of care for citizens, reduction in

- Support Member States in their efforts to build **interoperable** electronic health records, ensuring adequate **protection and security** of health data
- Propose an **EEHRxF** – i.e. a common set of logical and technical specifications to be used across the EU for different kinds of health data that do or will form part of the EHR

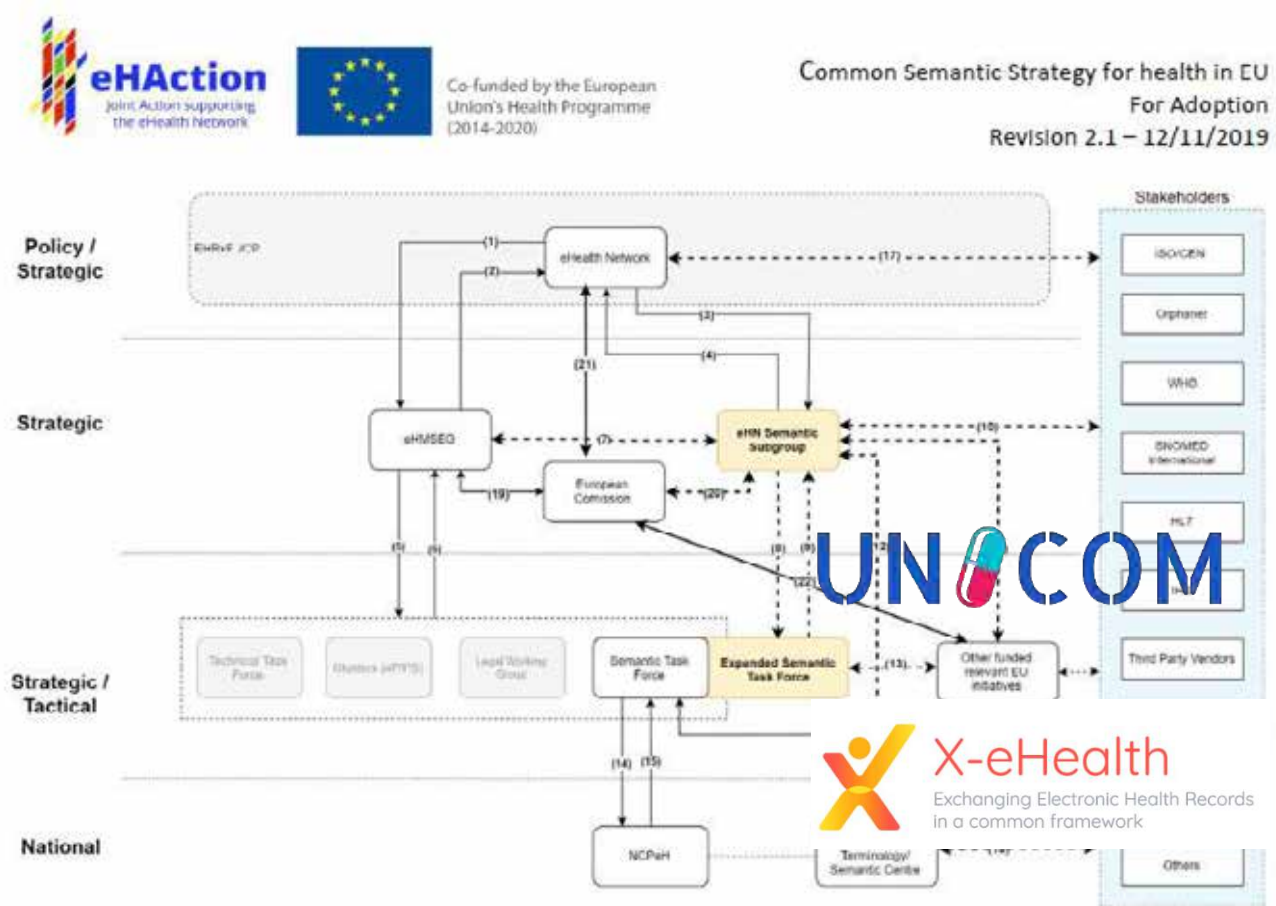


Figure 2 - Proposed revised governance framework for semantics in the eHN structure

### Coordination and Support Action (CSA) – Horizon 2020 proposal to adopt EHRx (X-eHealth Project)

A project to adopt the EHRx EC recommendation will be proposed under the call "SC1-HCC-07-2020: Support for European eHealth Interoperability roadmap for deployment". The information domains that have not yet been discussed will be the focus of this call (Laboratory Results; Medical Imaging and Reports; Hospital Discharge Reports). It is natural that there is a need to assemble new semantic assets for the three new domains, and that some of that work should be aligned with eHMSEG work, as well as under guidance of the eHN Semantic Subgroup.

## How X-eHealth started:

Lab Requests & Results



Rare Diseases



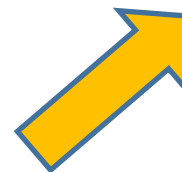
Medical Imaging



Discharge Letters



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

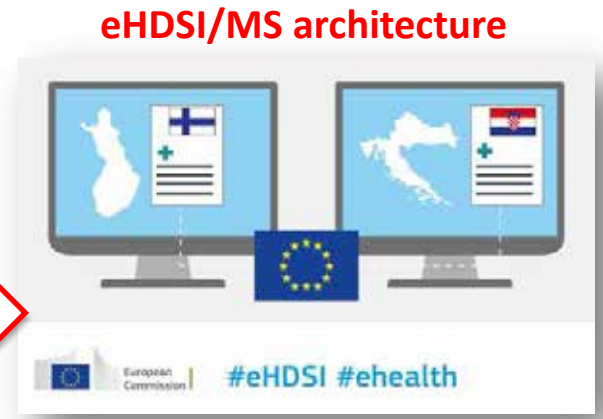
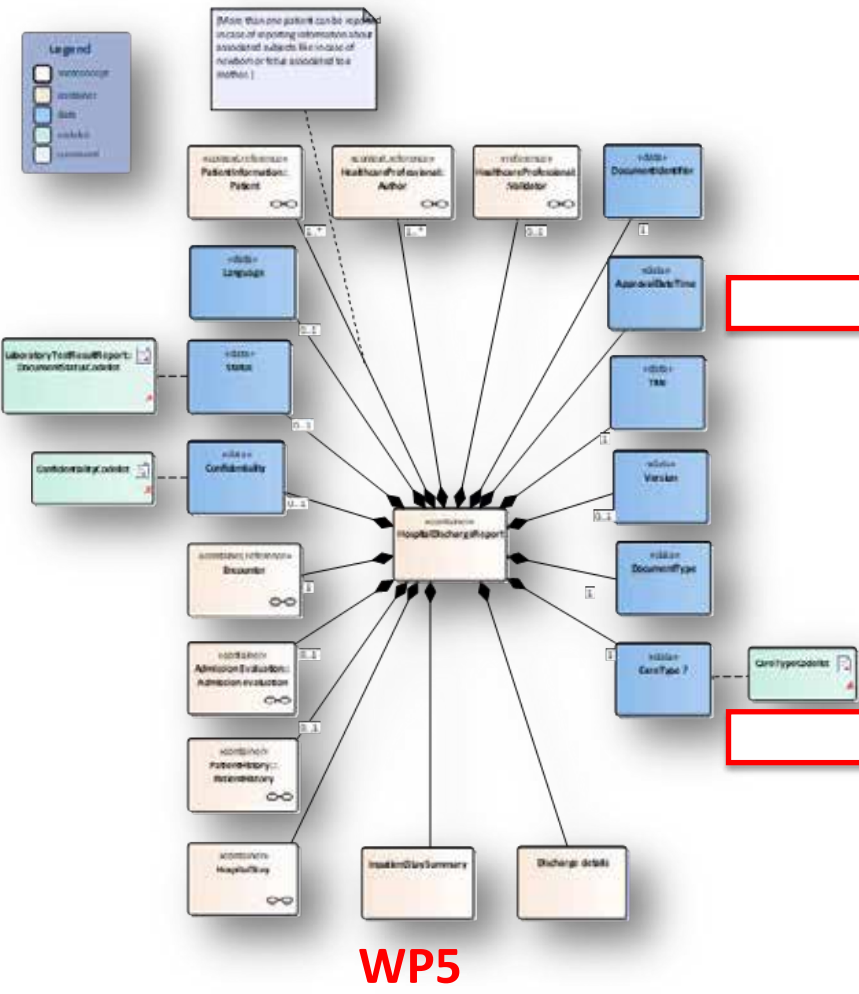


Member States  
& Communities

Logical model = Implementation independent

# X-eHealth specification flow

HL7 CDA/FHIR Implementation Templates



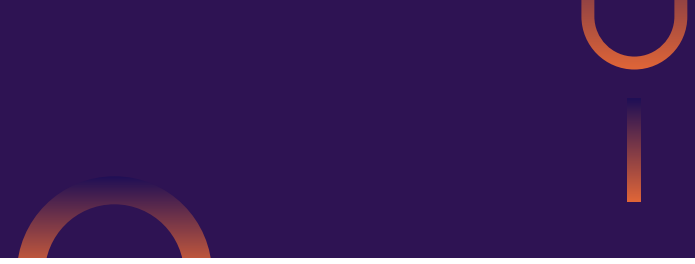
Re-use of current infrastructure  
Extension: eHDSI Change Proposals



# Extension & Evolution

- **Extension in eHDSI (1)**

- Extend / enforce the adoption of ISO IDMP attributes in eP & PS, already now!
- Add new services to exchange new documents
- Exploiting as much as possible current Legal, Organisational, Technical and Semantic Assets
  - List of Lab Reports and retrieval of one, [Lab Requests & Lab Report](#),
  - List of Hospital Discharge Letters and retrieval of one
  - List of Image Reports and retrieval on one, [Image Manifest \(KOS\)](#), [DICOM Images](#)
  - Patient Summary for Rare Diseases (eHN Guidelines on PS Ver.3), [Patient Summary for Rare Cancer](#)



# Extension & Evolution



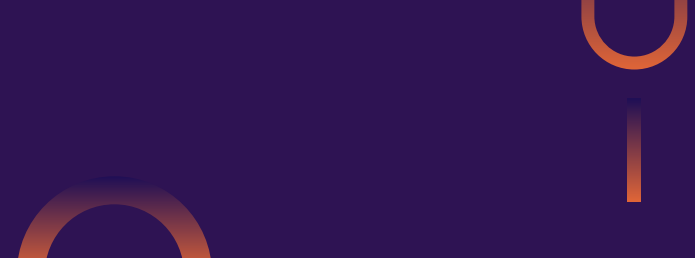
- **Extension in eHDSI (2)**
  - New eHDSI eHMSEG WG to select Use Cases and jointly co-create Change Proposal for Wave 7 (Sep. 2022) and Wave 8 (Sep. 2023)
    - New eHDSI Specifications
    - New assets for 2022 (Wave 6), 2023 (Wave 7) and 2024 (Wave 8)
    - New IHE Gazelle testing tools for conformance check



# Extension & Evolution

- **Evolutions (1)**

- Adoption of ISO IDMP Identifiers (PhPID, MPID, PCID), when available
- eHDSI / MyHealth@EU Paradigm changes
  - From “My data travel **WITH** me”, also to “My data travel **FOR** me”
  - E.g. request second opinion, send request to foreign labs, push documents to further Healthcare Professional or Providers, ...
  - From patient manual identification to eID (despite national restrictions: HEALTHeID)
- Patient Mediated Access
  - Patient Access / eWallet
- Evolution of the “Four Corner Architecture” (Non forgetting ERN CPMS & EHDS-2)
- From Documents to Data: new technologies



# Extension & Evolution



- Evolutions (2)

- Deep evaluation of impacts on
  - Legal aspects / national laws
  - Organisational / workflow / Patient – Health Professional Identification aspects
  - Technical aspects
  - Semantic aspects (Implementation Guides; Preferred Code Systems / ValueSets)
- ✓ Sustainability & Affordability through Standards & standardized (conformance check) procedures
  - ❖ EU Regulation on European Health Data Space
    - © “Certified EHR”
  - ✓ The key role of eHN Work Groups, MyHealth@EU Work Groups, Member States and SDOs

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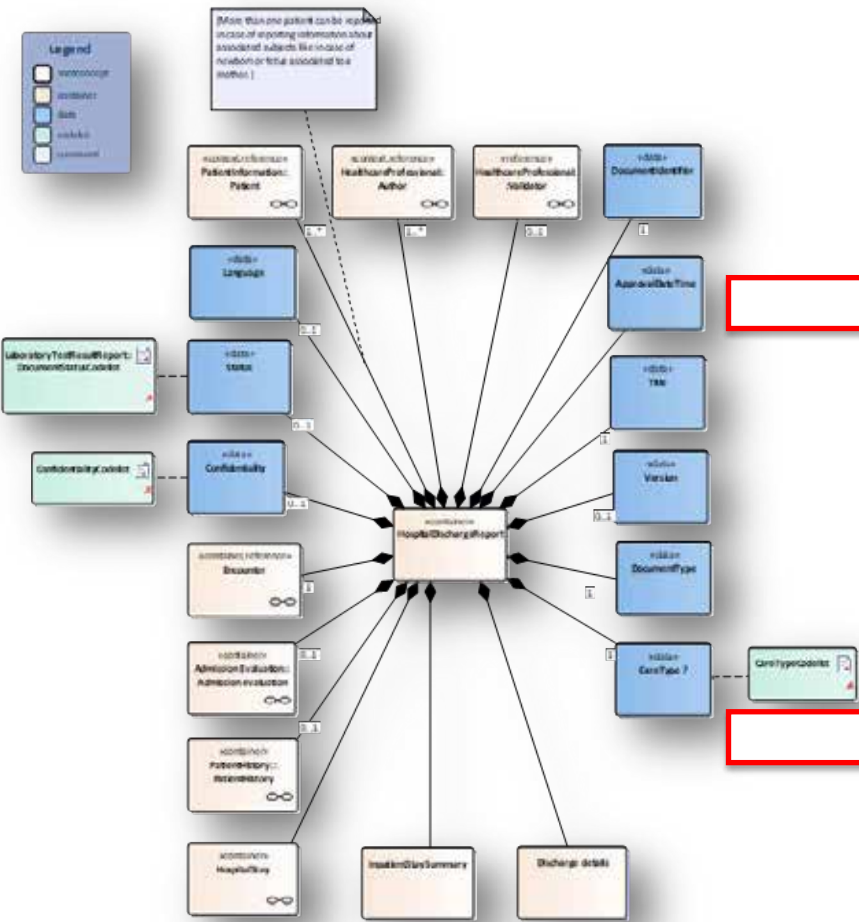
## X-EHEALTH OUTCOMES FOR BROADER USE

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Kružík Hynek – WP5 Leader



Logical model = Implementation independent



WP5

HL7 CDA/FHIR Implementation Templates



WP6

eHDSI/MS architecture

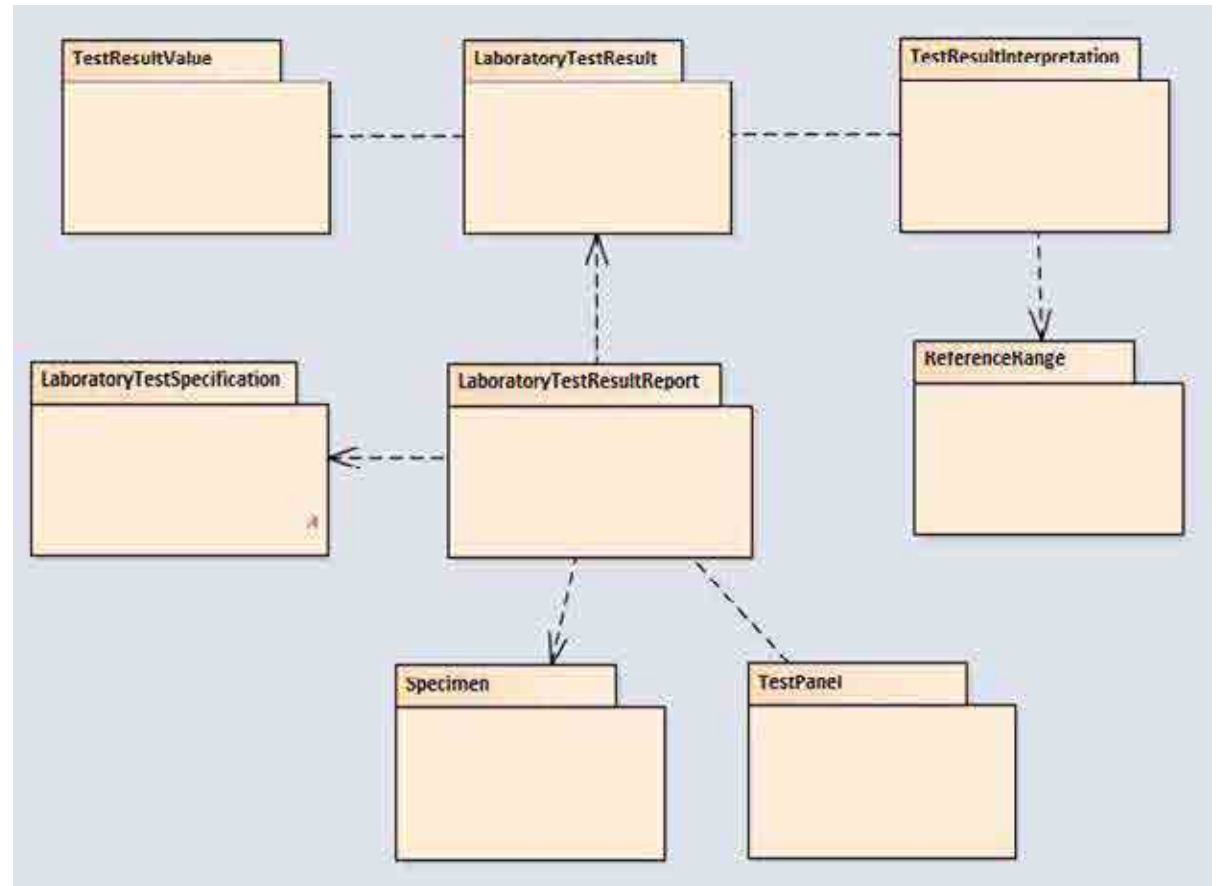


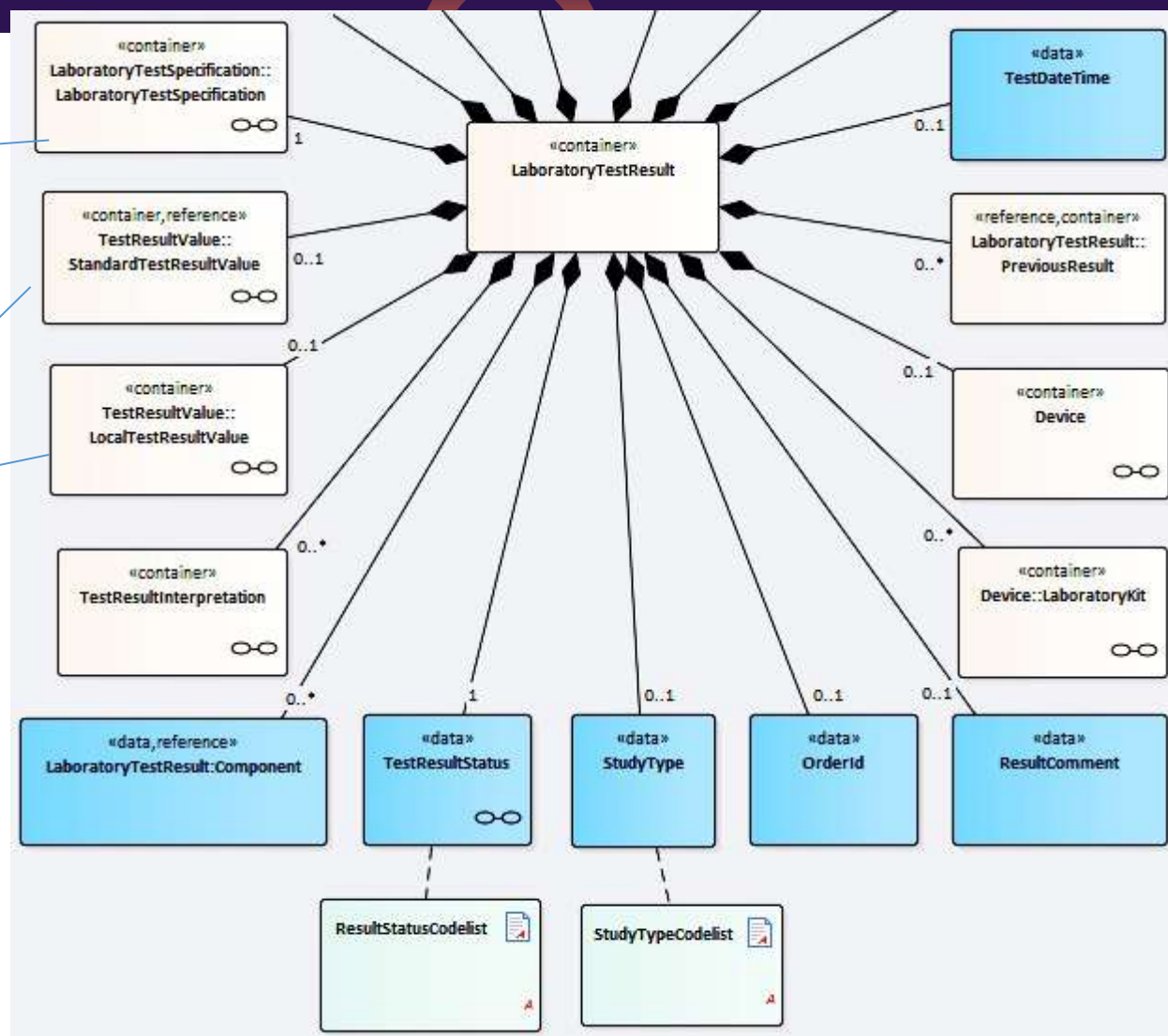
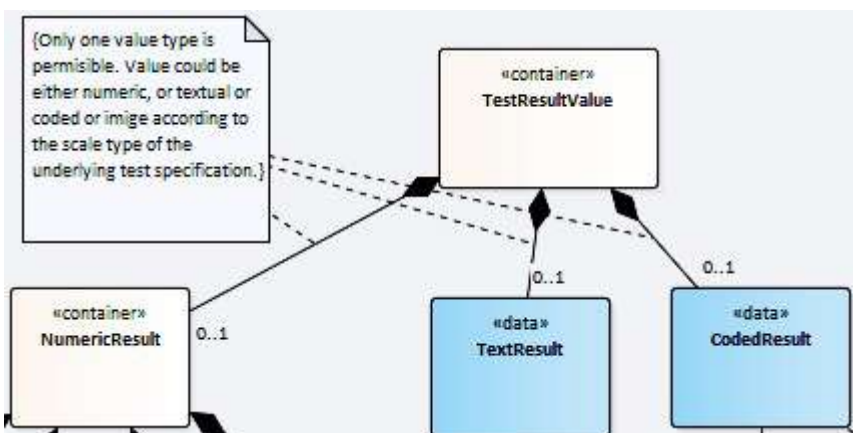
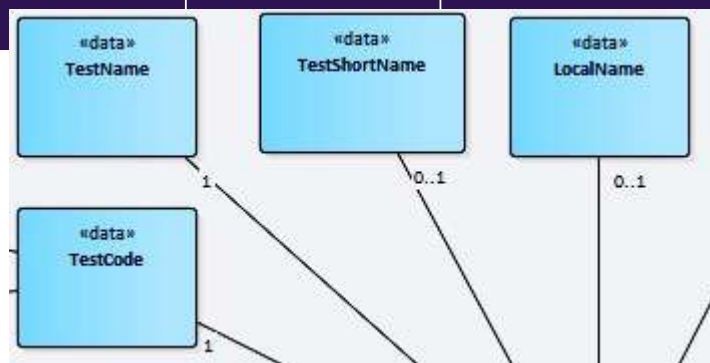
Re-use of current infrastructure  
Extension: eHDSI Change Proposals

WP7

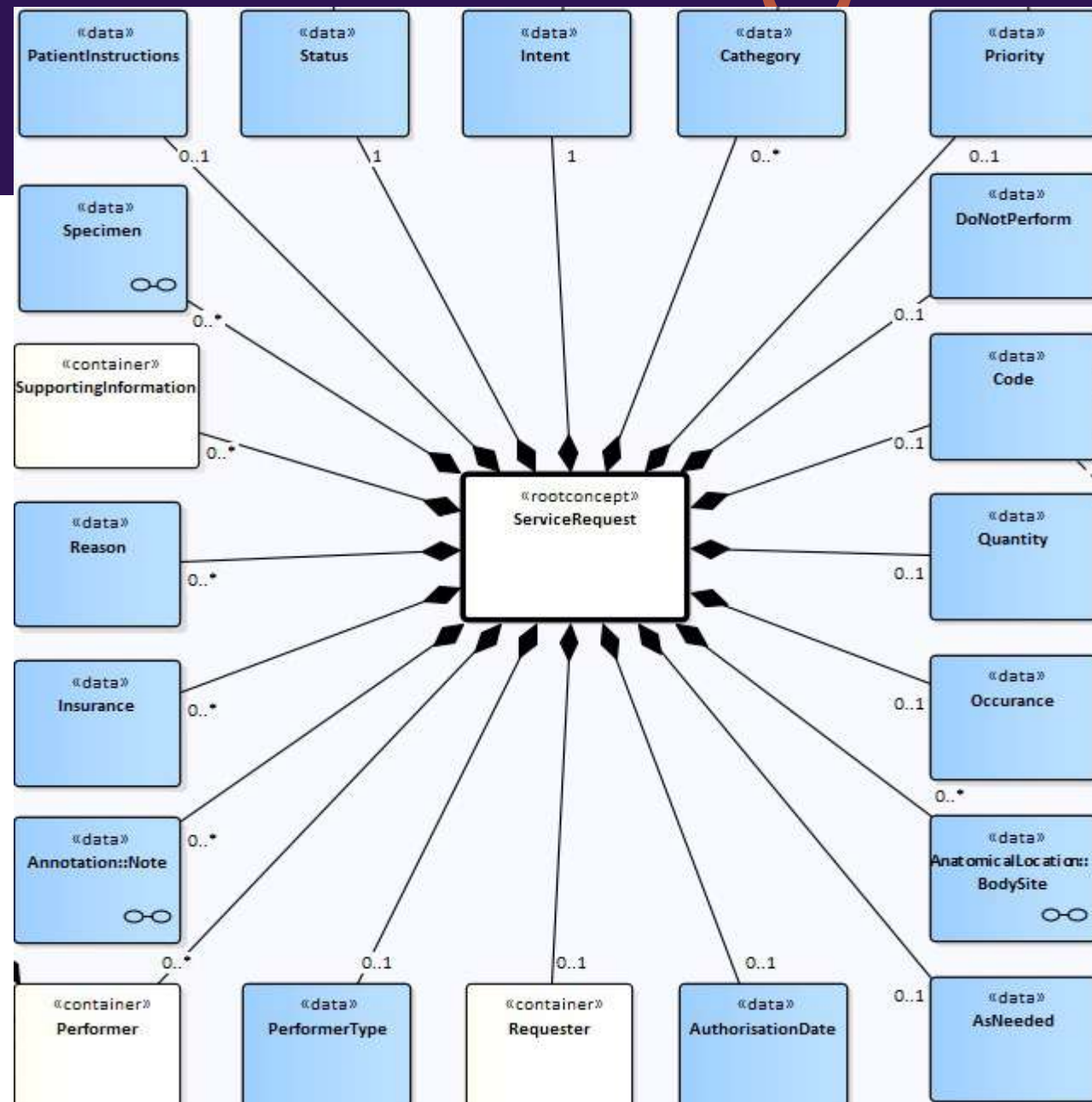
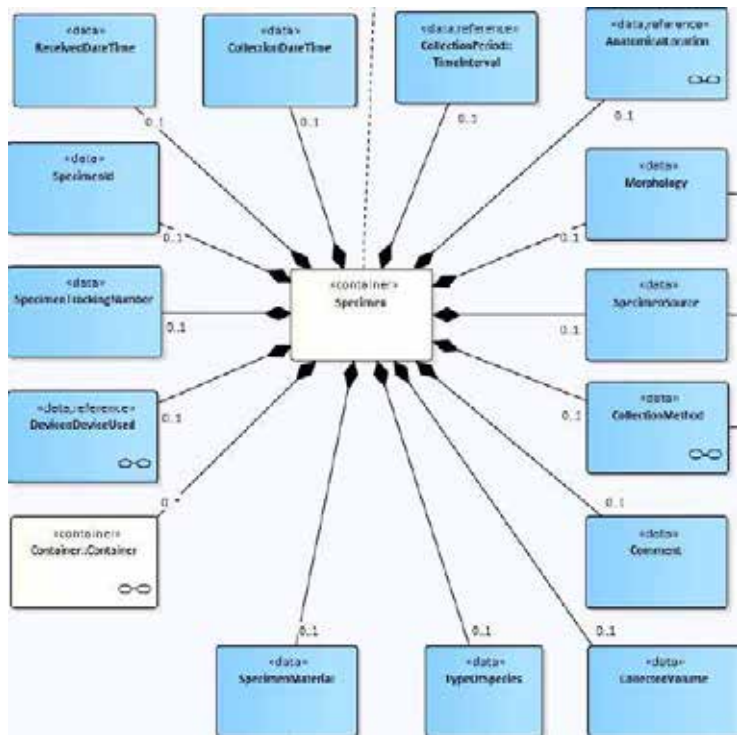
## INFORMATION VIEW: LOGICAL INFORMATION MODEL

- Originates from Dutch HCIM
- Model comprises all X-eHealth domains
- Reusable building blocks
- ~ 60 models
- IM is based on ISO/TS 13972:2015 standard methodology
- EA tooling





# LABORATORY TEST ORDER





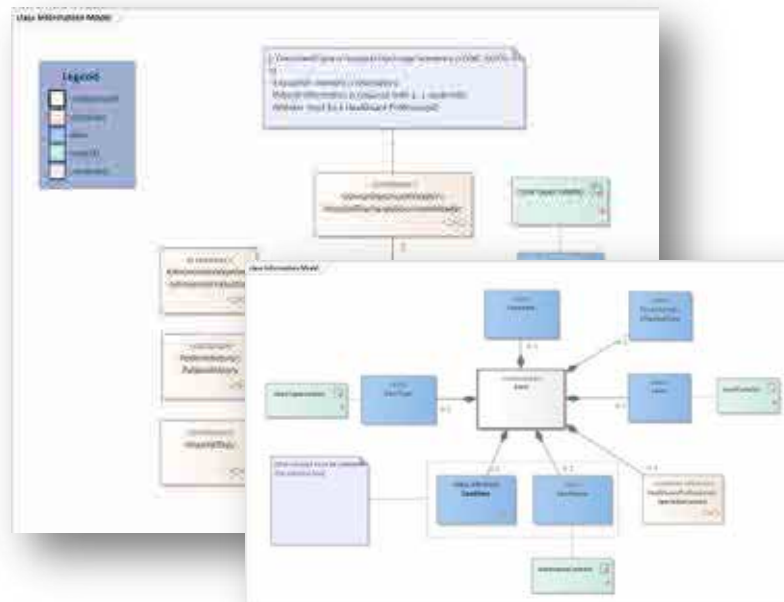
# SEMANTICS : MAIN CODE SYSTEMS FOR LAB ORDERING AND REPORTING


- Test coding
  - **LOINC** – used by several member states (IT, AT, NL, EE, PT), ex: **Leukocytes: NCnc: Pt: CSF: Qn: Manual count**
  - **NPU** – Czech Republic\*, Denmark and Nordic countries (SE, NO), ex: **Cerebrospinal fluid–Leukocytes; number concentration = ? × 106/L**
  - Other (local)

As member states use different laboratory test coding systems, not only the code and a test name but also additional constituents of the test specification and result should be taken into consideration in order to apply proper code mapping.


- Test panel/order groups
  - **LOINC**
- Specimen type, body location, collection method
  - **SNOMED CT**


- Test result value
  - **UCUM** (measurement units)
  - **SNOMED CT**
    - Organism (410607006)
    - Substance (105590001)
    - Evaluation finding (441742003)
    - Presence findings (260411009)
    - Absence findings (272519000)
- Devices (collection device type, container type, analyzer device type)
  - SNOMED CT:** < 260787004 | Physical object
  - SNOMED CT:** < 434711009 | Specimen container



**XeH Discharge Report** – 

**History (17)**

**Title** 2.16.840.1.113883.2.51.10.12 

**Status**  Draft

**Name** XeHDischargeReport

**Description**

**Context** Pathnames




**Classification** CDA Document Level Template


**Open/Closed** Open (Other than defined elements are allowed)

**Used by / Uses**

- Used by 0 components and 0 templates, Uses 50 templates

**Relationship**

- Adaptation: template 2.16.840.1.113883.10.2.1.1 International Patient Summary (2020-01-01) 
- Adaptation: template 2.16.840.1.113883.10.1.1.1 (2015-12-20) 
- Adaptation: template 2.16.840.1.113883.10.12.1 CDA ClinicalDocument (2005-09-07) 

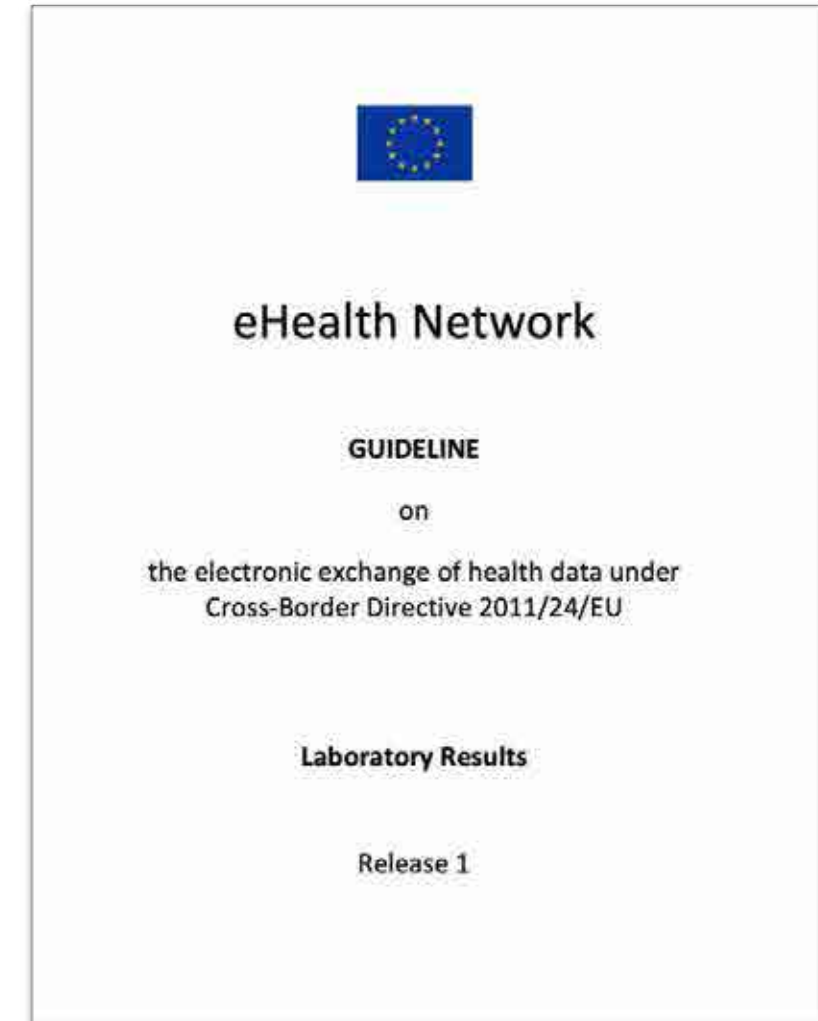
**Example**  Example

Item	DT	Card	Conf	Description
* 24 / UniversalDocumentHeader			R	CDA Header
a17: cda18Code	CS	0..1	R	This attribute signals the impl should not be used for identification

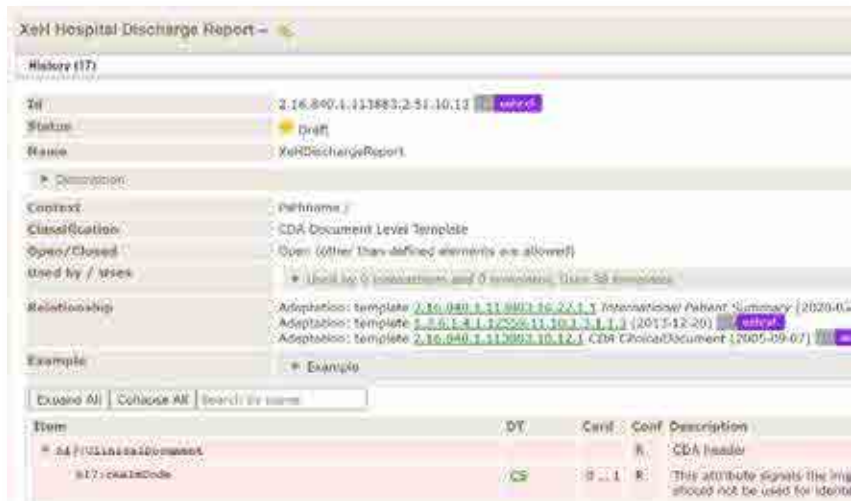
Feature	reqId	Letter	Type	Requirement in UML notation
Comorbidity	1	1.1	Classical Requirement	Hospital Discharge Report composition
test	2	2.1	Scenario	Test software of the semantic for primary diagnosis of the
storedata	3	3.1	Scenario	Service organization elements for this composition
status	4	4.1	note	prehistory - final - secondary - outcome to be
type	5	5.1	ExecutableRequirement	Kind of composition ("Hospital Discharge Report")
edited	6	6.1	ReferenceRequirement (Note)	Required Patterns At least the following
Observation	7	7.1	Requirement	only occur when the composition is active
date	8	8.1	Scenario	composition - primary - secondary
author	9	9.1	ReferenceRequirement (Note)	composition - primary - secondary
note	10	10.1	Scenario	composition - primary - secondary
comorbidity	11	11.1	Scenario	composition - primary - secondary
author	12	12.1	Scenario	composition - primary - secondary
note	13	13.1	Scenario	composition - primary - secondary
comorbidity	14	14.1	Scenario	composition - primary - secondary
author	15	15.1	Scenario	composition - primary - secondary



- X-eHealth WP5 -> EHN SGS
  - Laboratory guidelines R1
    - accepted by EHN on 1.July 2022
  - HDR, Imaging guidelines
    - work started
- X-eHealth WP7 -> eHDSI
  - CP for MyHealth@EU
- X-eHealth WP6 -> eHDSI & EHN TIO
  - CDA IG
  - FHIR IG



## SPECS AVAILABLE ON-LINE



<https://art-decor.org/art-decor/decor-templates--eehrxf-?section=templates&id=2.16.840.1.113883.2.51.10.12>



<https://build.fhir.org/ig/hl7-eu/x-ehealth>





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&  
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