Implementing HL7 FHIR in laboratory systems under the EHDS: observations from Spain

Webinar, 8 May 2025
15.00-16.00 CEST

Online on Teams

HL7 Europe Labs-on-FHIR webinar series

A succession of open, online educational sessions 2023-25
related to the adoption of FHIR specifications
in Europe's laboratory systems and
the HL7 Europe FHIR Implementation Guide for Laboratory Reports

Slides and recordings from previous webinars at www.hl7.tv.

Implementing HL7 FHIR in laboratory systems under the EHDS: observations from Spain
Introductions

- Featured presenter:

  – Dr. Alexander Zlotnik, Directorate of Digital Health and Information Systems, Spanish Ministry of Health

- Panellists:

  – Alexander Henket, NICTIZ (NL)

  – Nikos Kyriakoulakos, HL7 Hellas

  – Catherine Chronaki, HL7 Europe

- Facilitator: Michael Strübin, HL7 Europe

Housekeeping

- To help ensure a successful webinar please:
  - Use the chat (for comments, questions…)
  - Use reactions/emojis during the presentations
  - Raise your hand if you'd like to speak
  - If you are invited to speak, please turn on your video and say who you are

- The webinar will be recorded.
- Link to recording and slides (in pdf) on www.hl7.tv will be emailed to all registered participants.

Implementing HL7 FHIR in laboratory systems under the EHDS: observations from Spain
Agenda

- Welcome, introductions, housekeeping
- Observations from Spain
  - Dr. Alexander Zlotnik
    Directorate of Digital Health and Information Systems, Spanish Ministry of Health
- Panel:
  - Alexander Henket, NICTIZ (NL)
  - Nikos Kyriakoulakos, HL7 Hellas
  - Catherine Chronaki, HL7 Europe
- Discussion and Q&A
- Next steps

End

Labs-on-FHIR webinar on Spain

2025-05-08

GOBIERNO DE ESPAÑA · MINISTERIO DE SANIDAD

Overview

1. Structure of Spain's National Health System
2. MyHealth@EU in Spain
3. EHDS at national level
4. Spanish LRR implementation strategy
5. FHIR LRR IG ES
6. Spanish LRR Technical implementation
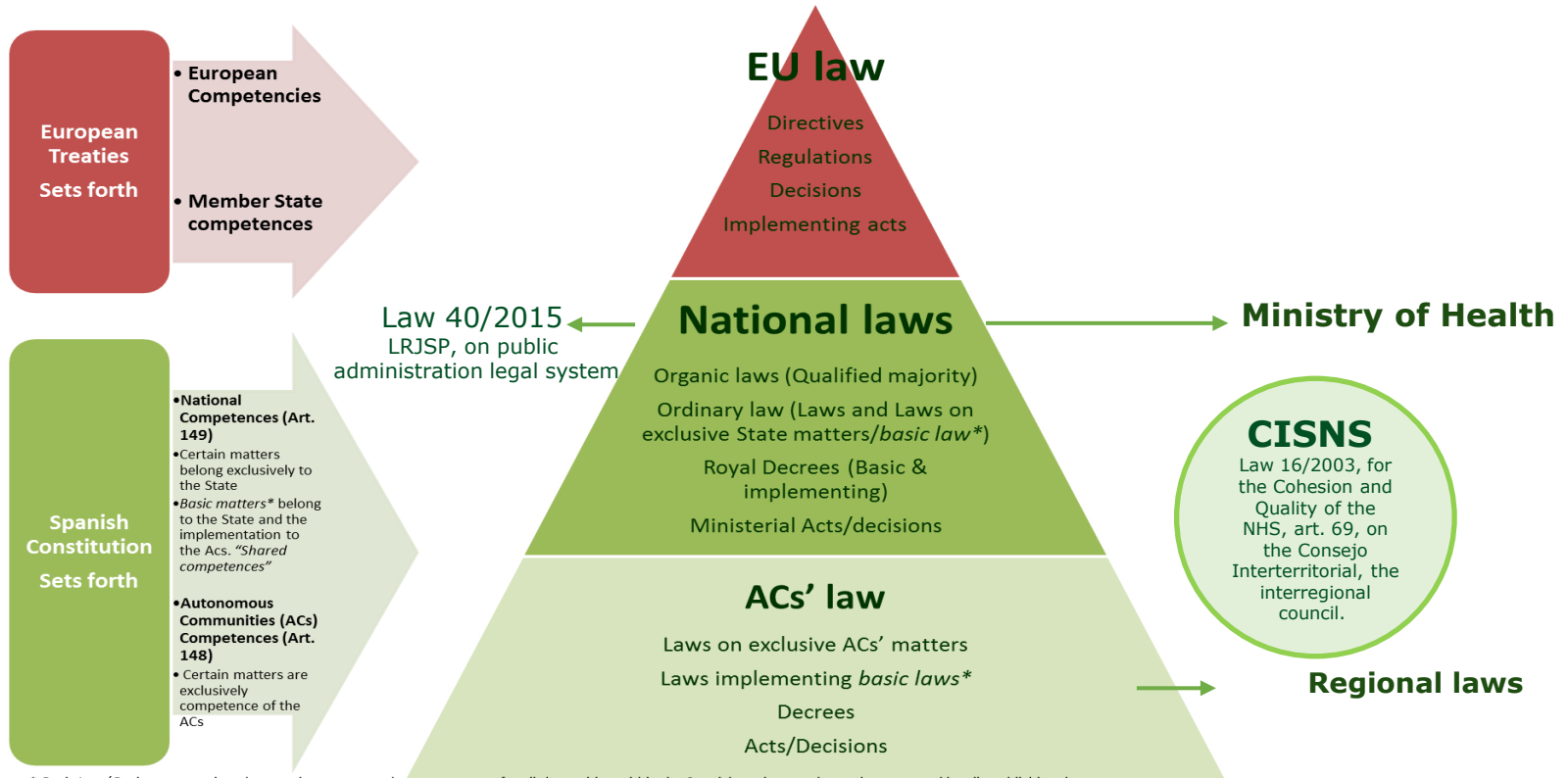7. Key Issues in LRR implementation
8. Q&A

Structure of Spain's NHS

18 regional healthcare systems

Ministry of Health's role: coordination policy

STRUCTURE OF THE NATIONAL HEALTH SYSTEM

European Treaties Sets forth

- **European Competencies**
- **Member State competences**

EU law

Directives

Regulations

Decisions

Implementing acts

Law 40/2015 LRJSP, on public administration legal system

National laws

Ministry of Health

Organic laws (Qualified majority)

Ordinary law (Laws and Laws on exclusive State matters/*basic law**)

Royal Decrees (Basic & implementing)

Ministerial Acts/decisions

Spanish Constitution Sets forth

- **National Competences (Art. 149)**
- Certain matters belong exclusively to the State
- *Basic matters** belong to the State and the implementation to the Acs. *"Shared competences"*
- **Autonomous Communities (ACs) Competences (Art. 148)**
- Certain matters are exclusively competence of the ACs

CISNS

Law 16/2003, for the Cohesion and Quality of the NHS, art. 69, on the Consejo Interterritorial, the interregional council.

ACs' law

Laws on exclusive ACs' matters

Laws implementing *basic laws**

Decrees

Acts/Decisions

Regional laws

* *Basic Law/ Basic matters* = law that regulates matters that are common for all the entities within the Spanish territory and must be respected by all, stablishing the common Minimum requirements on a specific topic that concerns "*shared competences*" between the State and the Acs.
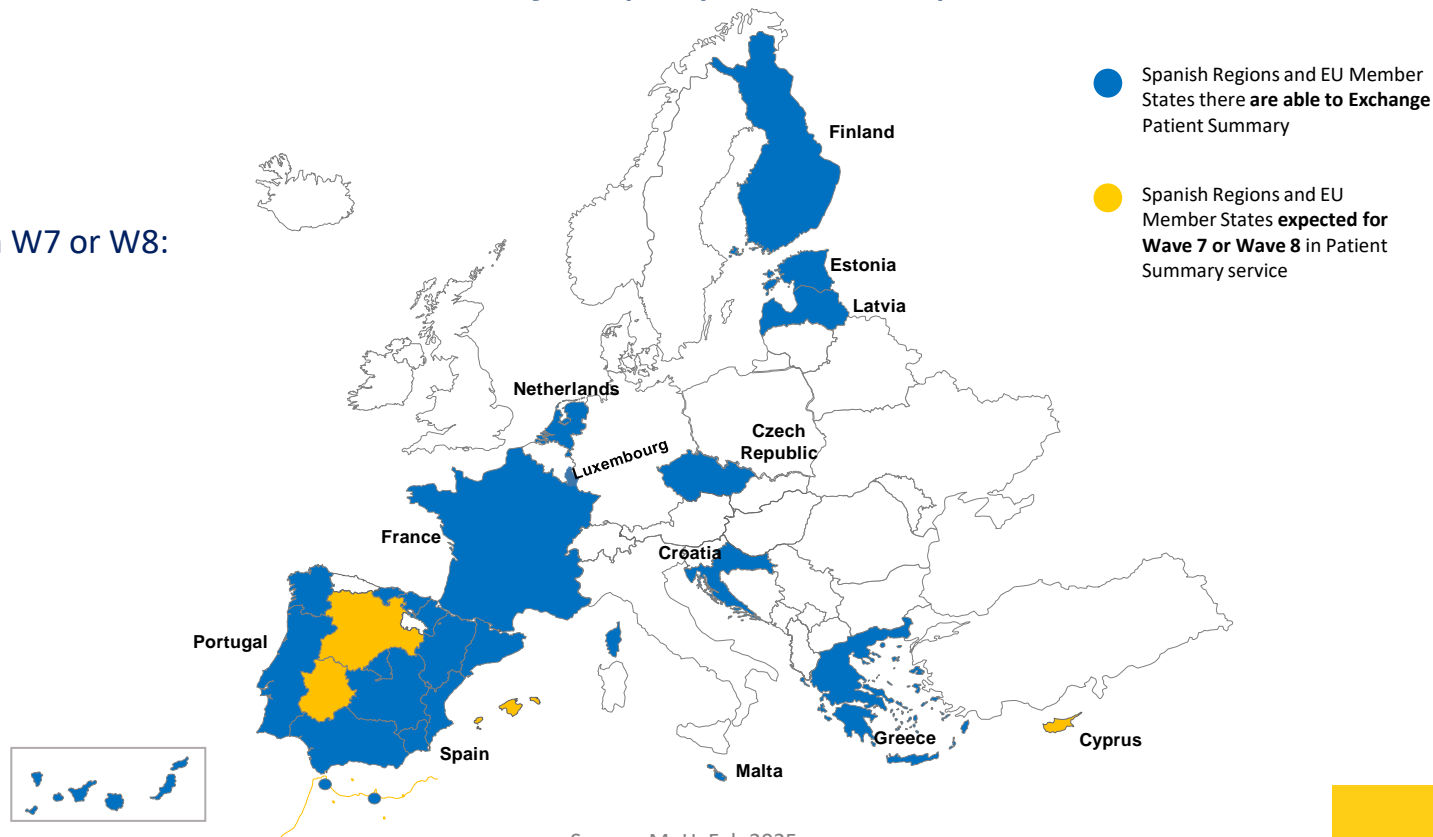
Source: Spanish MoH, Sep 2024

GOBIERNO DE ESPAÑA
MINISTERIO DE SANIDAD

MyHealth@EU in Spain

MyHealth@EU in Spain
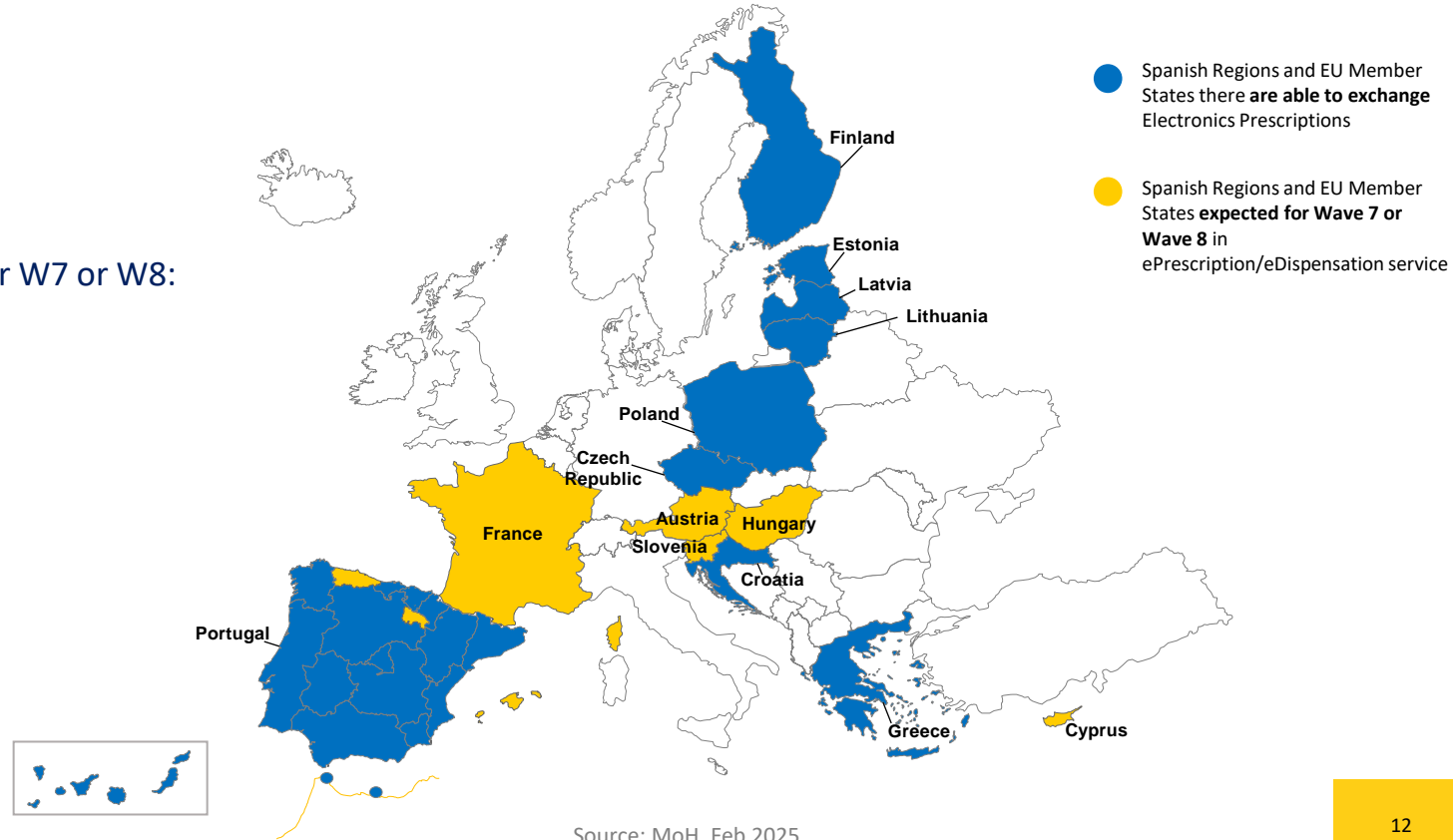
Current status of the **EU ePrescription/eDispensation** deployment in Spain.

Currently operational:
- 15 regions
- 9 countries

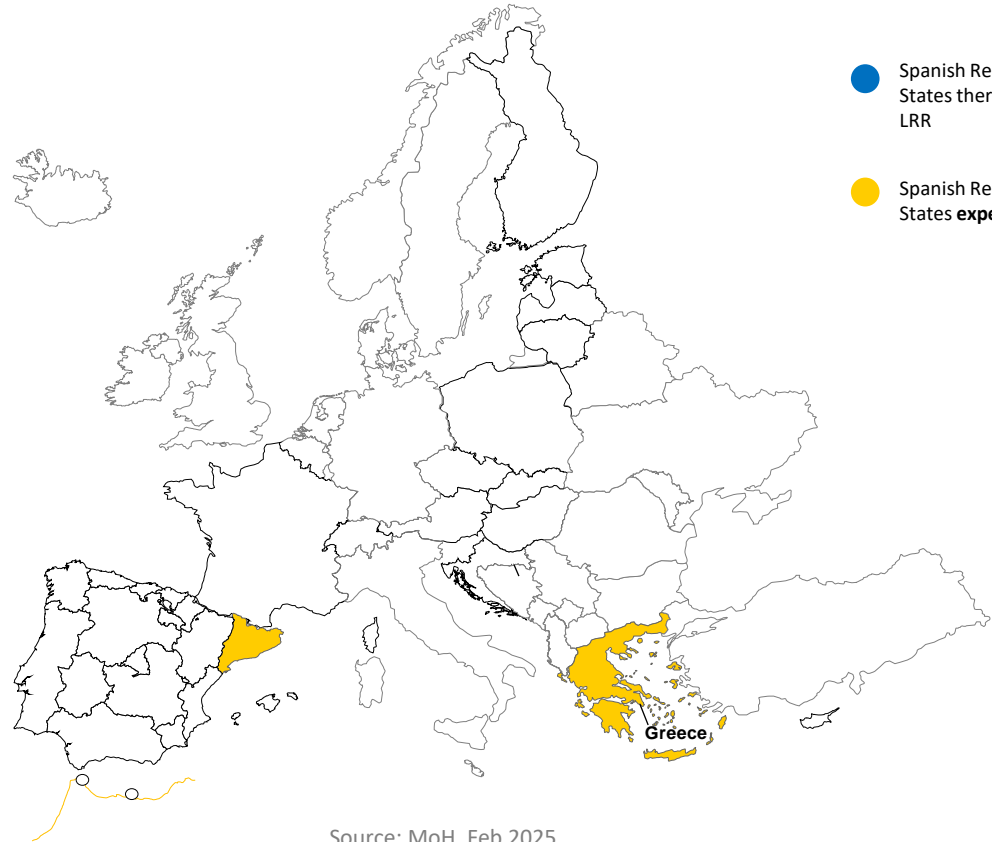Expected operational for W7 or W8:
- 18 regions
- 14 countries

● Spanish Regions and EU Member States there **are able to exchange** Electronics Prescriptions

● Spanish Regions and EU Member States **expected for Wave 7 or Wave 8** in ePrescription/eDispensation service

Source: MoH, Feb 2025

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MyHealth@EU in Spain

Current status of the **EU Laboratory Result Report (LRR)** deployment in Spain.

Currently operational:

- None

Expected operational for W7 or W8:

- With 1 country (Greece)

Spanish Regions and EU Member States there **are able to exchange LRR**

Spanish Regions and EU Member States **expected for Wave 8 LRR**

Greece

EHDS at national level

Audit/compliance checks at the national level

- **Same audit scheme than the EC**: Spain enforces the same European Commission criteria when carrying out the compliance checks of the 18 Regional Healthcare Services, meeting all requirements before connecting with Europe.

- **The primary goal:** to ensure Confidentiality, Integrity and Availability of patient's clinical data for cross-border services.

- **Audit requirements based on:** eHDSI Requirements v2.1.
  - eHDSI Readiness Criteria Checklist v2.2.0.
  - EU Regulation 2016/679 on personal data protection (GDPR).
  - Spain's Law 3/2018 on personal data protection and digital rights.
  - Spain's Royal Decree 311/2022 or Spain's National (Cyber)security Scheme, a mandatory, 75-measure security framework.

- **Relevant cybersecurity controls:**
  - Exclusive use of cypher suites: TLS v1.2 and TLS v1.3.
  - 2-factor identification and authentication for health professionals.
  - End-to-end encryption of patient data.

Spanish LRR implementation strategy

ES LRR implementation strategy

Phase 1 → Phase 2 → Phase 3 → Future work

Phase 1

Technical goal:
Implement the first FHIR service within the Ministry of Health capable of interoperating with a Member State (Greece).

Out of scope:
Visualization and semantic enrichment.
The content is basic compared to future iterations.

Phase 2

Technical goal:
Add a Spanish region (Catalonia) to the phase 1 circuit.

Semantic enrichment goal: Release FHIR LRR IG ES. The region of Catalonia implements it using laboratories as data sources.

Visualization goal: Spain releases a display tool for its regions.

Phase 3

Go-live:
Address all associated requirements.

Future work

Continue adapting EU resources to Spanish requirements.

Connect to more MS.

Connect to more Spanish regions.

FHIR LRR IG ES

FHIR Laboratory Result Report Implementation Guide – Spanish adaptation
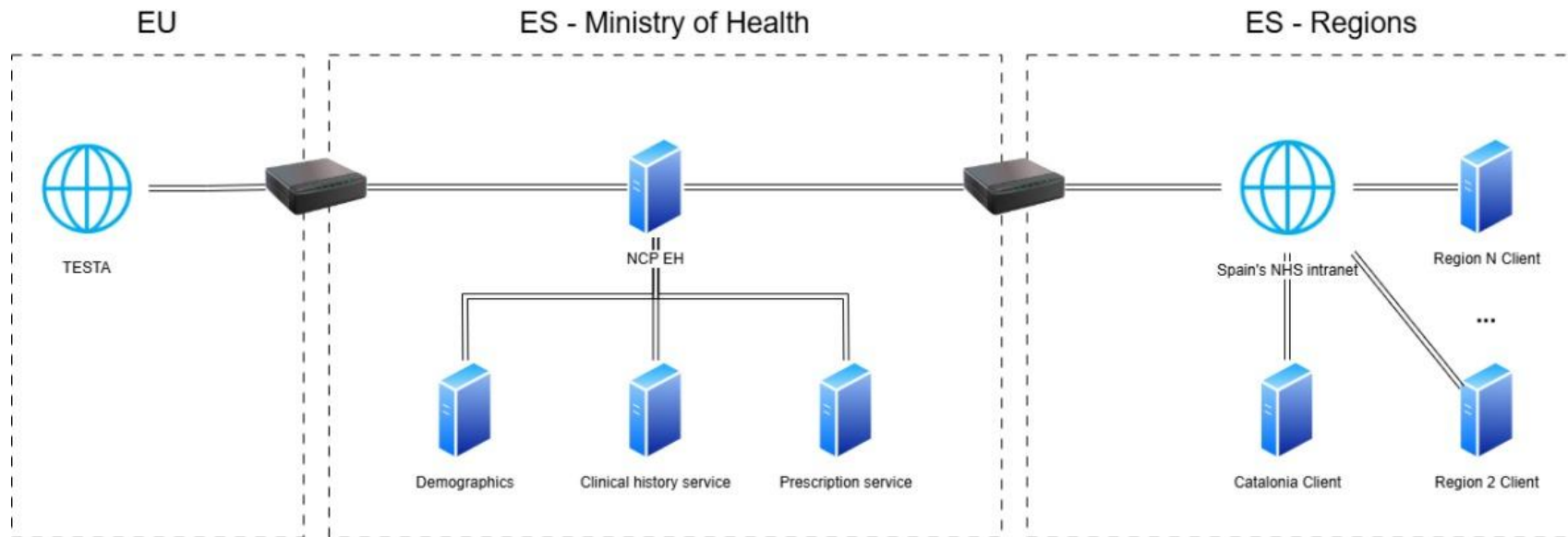
ES Laboratory Result Report IG

- ES FHIR LRR IG builds upon MyHealth@EU specifications.
- Resources published by MyHealth@EU will be adapted to ES requirements incrementally.
- If a particular resource has not yet been tailored to Spanish requirements, the MyHealth@EU definitions will apply by default.
- Fully conformant with the MyHealth@EU framework.
- Null flavor OTH for concepts not addressed at EU level.

Spanish LRR technical implementation

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

Spain's technical implementation

Key Issues in LRR implementation

Key Issues in LRR implementation

Semantic Issues

FHIR EU LRR guidelines conflicts with several national requirements.

Communication Barriers

The current FHIR EU LRR guideline is highly flexible — real use cases need to be analyzed to determine if it will meet practical needs. Its usage is rather challenging in multidisciplinary teams.

High Variability in Lab Reports

Laboratory result reports differ greatly between regions and institutions.

It's unlikely we can anticipate every scenario - real-life implementation and production interoperability will reveal both strengths and limitations of the technical guidelines.

Technical Constraints

Challenges in implementing FHIR-based APIs for Oracle Service Bus.

Time Needed for Regional Adoption

Regional teams need time to integrate and test the new Spanish distribution packages in their systems.

Thank you!

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- Next steps

End

Alexander Henket

Interoperability Specialist

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Over 25 years of experience

Interoperability Specialist at Nictiz, competence centre for digital information management in healthcare

Active member of HL7 Netherlands, HL7 Europe and HL7 International

Member of IHE NL

Nictiz

Catherine Chronaki, *Secretary General HL7 Europe*

- Software engineer by training
- Believer in the vision of HL7:
  a world in which everyone can securely access and use the right health data when and where they need it.
- Past president of EFMI
- Member of the EC eHealth Stakeholder Group
- Scientific coordinator of the xShare project, and earlier projects
- OpenECG, trillium bridge, eStandards

HL7
Europe

Vision: Everyone can effortlessly share their health data in the European EHRxF with just a **click-of-a-button.**

Key Points

1. **xSHARE Button & Label:** A user-friendly feature across health portals and apps.

2. **Data Portability:** Empowering people to exercise GDPR rights, sharing health data securely.

3. **European Electronic Health Records Exchange Format (EEHRxF) Impact:** Fosters citizen (and patient) engagement, driving research and innovation in the European Health Data Space (EHDS).

4. **Digital Compass 2030:** Aligns with EU's vision for a human-centered, sustainable digital future.

Benefits

- Simplifies sharing of trusted health data.

- Strengthens digital resilience.

- Fosters citizen science.

- Advances global leadership in digital health standards.

The Hub

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HL7
Europe

Next steps

- Slides and recording on www.HL7.tv, notification to all registered attendees

- Please complete our feedback survey https://forms.office.com/e/cmR5arVaSr

- Join HL7 at the next WGM in Madrid, 10-16 May 2025 https://info.hl7.org/may-2025-wgm

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Thank you !

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