EUROPEAN
# BIG DATA VALUE FORUM

30 SEPT - 1 OCT | GALWAY - IRELAND

10 TH EDITION

**1 OCTOBER, 11:30 - 13:00**

# Cross-Border Health Data Sharing in the EU - Current State Of Affairs

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# Aims

- Present **current state of affairs** and **implementing acts** for both **European Health Data Space** (EHDS) directions: **primary and secondary use of data**, next plan of activities and recommendations to Member States from the EC side.
- Dive into **country-level use cases**, including from host country Ireland
  - Addressing both primary and secondary use of health data, in line with EHDS, covering cross-border care delivery and data reuse for research, innovation and policy-making.
- Provide a **realistic snapshot of where Europe stands today**, highlighting successes, remaining barriers, implementation insights, and concrete next steps towards effective cross-border health data sharing in the EU.

KEYNOTE SPEAKER

**FULVIA RAFFAELLI**

HEAD OF UNIT AT
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DG SANTÉ, UNIT C.1 –
DIGITAL HEALTH

# European Health Data Space

## Implementation – state of play

**Fulvia Raffaelli**
Directorate-General for Health and Food Safety (DG SANTE)
Head of Digital Health Unit
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European Commission

# EHDS – what is it about?

## Primary use

*Health data for healthcare*

- Priority categories and the European health record exchange format
- Rights of natural persons over their electronic health data
- Access services for natural persons and health professionals
- MyHealth@EU infrastructure for cross-border exchange

## EHR systems

*Requirements and common specifications*

- Essential requirements
- Harmonised components: interoperability and logging
- Self-assessment and CE marking
- EU database of registered EHR systems

## Secondary use

*Health data for research and public interest purposes*

- Health data access bodies in each Member State
- Data permits, secure processing environments
- HealthData@EU cross-border infrastructure
- Dataset catalogues & descriptions

**Regulation (EU) 2025/327**

In force since 26 March 2025

First common sectorial European data space

Directly applicable, phased entry into application: 2027 ⟶ 2029 ⟶ 2031

# EHDS – Overall timeline for application

EHDS begins to take shape

- Deadline for certain implementing acts
- Deadline for Member States to designate authorities

- Primary use: exchange of the 1st group of priority data categories
- EHR systems: only sell compliant products that process the 1st group data
- Secondary use: general entry into application

- Primary use: exchange of the 2nd group of priority data categories
- EHR systems: only sell compliant products that process the 2nd group data
- Secondary use: selected categories (genomics, -omics, etc.

- Secondary use: third countries and international organisations may apply to join HealthData@EU

# Phases of EHDS implementation

- **Phase 1: Design and development**
  - 2 years - from 2025 to March 2027 (adoption of key IA)
- **Phase 2: Consolidation and deployment**
  - 2 years - from March 2027 to March 2029 (following the adoption of key IA until entry into application of key provisions)
- **Phase 3: Operation and maintenance**
  - From March 2029 onwards (following the entry into application of remaining parts)

# Implementing acts: where we stand

## Adopted and published

### Art. 92 EHDS Board

Implementing Regulation (EU) 2026/771

### Art. 16 Identification management

Implementing Regulation (EU) 2026/2099

Cross-border identification and authentication of natural persons and health professionals

### Art. 23 MyHealth@EU

Implementing Regulation (EU) 2026/2083

Rules on the requirements and operation of the cross-border infrastructure

### Art. 77 Dataset descriptions

Implementing Regulation (EU) 2026/2098

Secondary use: minimum metadata elements and their characteristics for dataset descriptions

# Implementing acts: where we stand

## In the pipeline*

### Art. 15 EEHRxF

European health record exchange format — advanced stages of the process

### Art. 13 Data quality requirements

Quality requirements for the registration of personal electronic health data

### Art. 75 HealthData@EU

Requirements, technical specifications and other rules for the HelthData@EU infrastructure

### Art. 36 EHR systems

Common specifications for the essential requirements of EHR systems

### Art. 70 Templates for secondary use

Templates for the health data access application, the data permit and the health data request

### Art. 78 Data quality and utility label

Visual characteristics and technical specifications of the data quality and utility label

### Art. 40 DTE

Common specifications for the European digital testing environments

### Art. 73 SPE

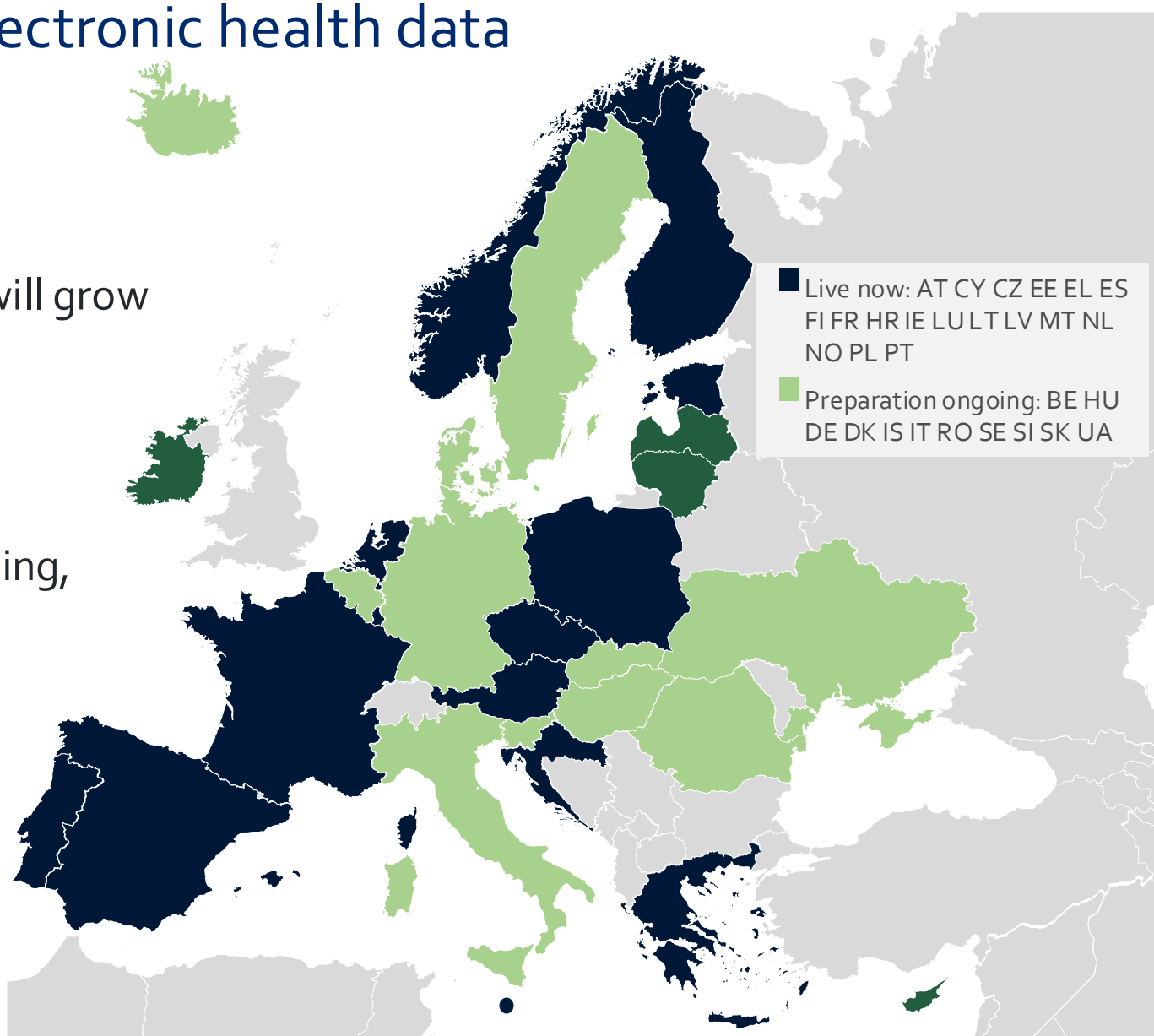
Common requirements for Secure processing environment

* and other implementing and delegated acts (data registration, EHR systems database, proxy services etc)

MyHealth@EU

# Cross-border infrastructure for primary use of electronic health data

- 17 Member States are live (+Norway)
- The number of connected Member States will grow rapidly in the years ahead - most to join MyHealth@EU by 2026.
- 2 services live: patient summary and ePrescription/eDispensatoin
- Expansion ongoing to include medical imaging, medical test results and discharge reports



# EEHRxF Support Centre

### Single Point of Contact (SPOC)

A central access point for questions, requests and guidance related to EEHRxF implementation.

### Knowledge Base & FAQs

Practical guidance, FAQs and reference materials supporting consistent implementation.

### Consultation cycles

Structured stakeholder engagement on priority implementation topics.

### Training & EU Academy

Learning materials and training activities supporting capacity building.

### Digital toolkit

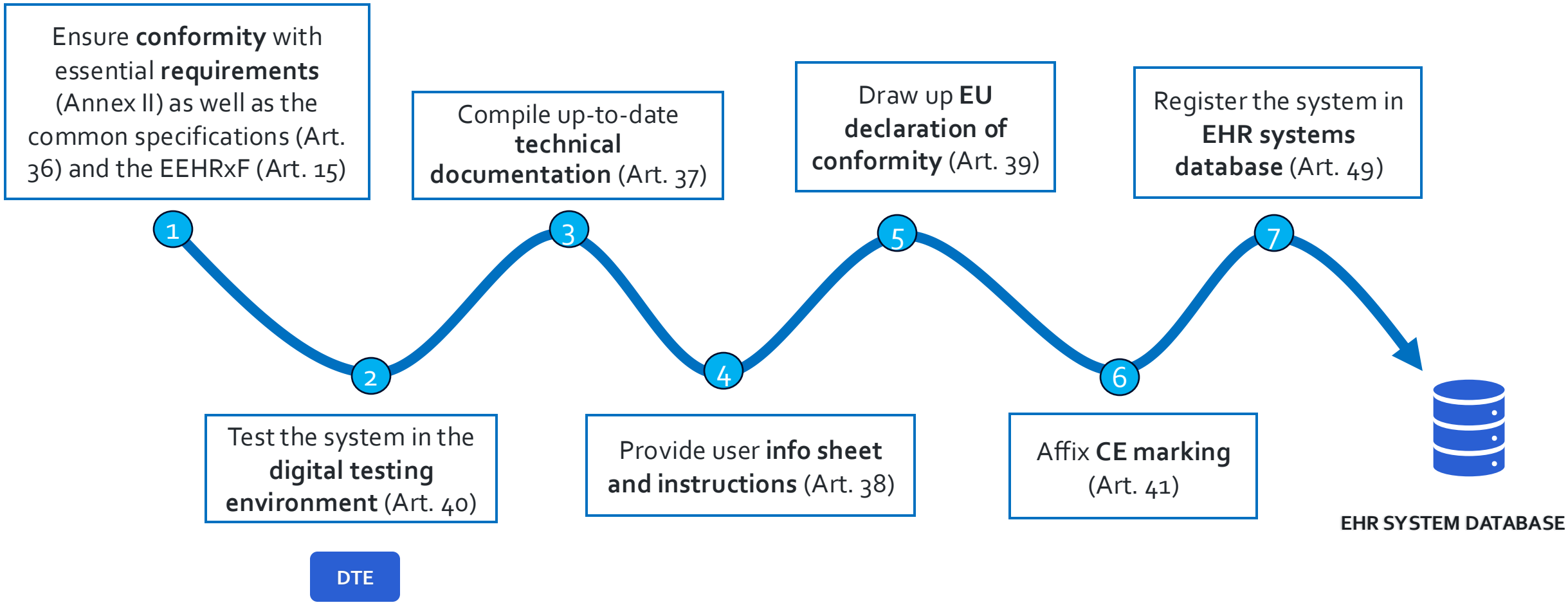
Practical resources, templates and tools supporting EEHRxF implementation, interoperability and security.

### COPEF

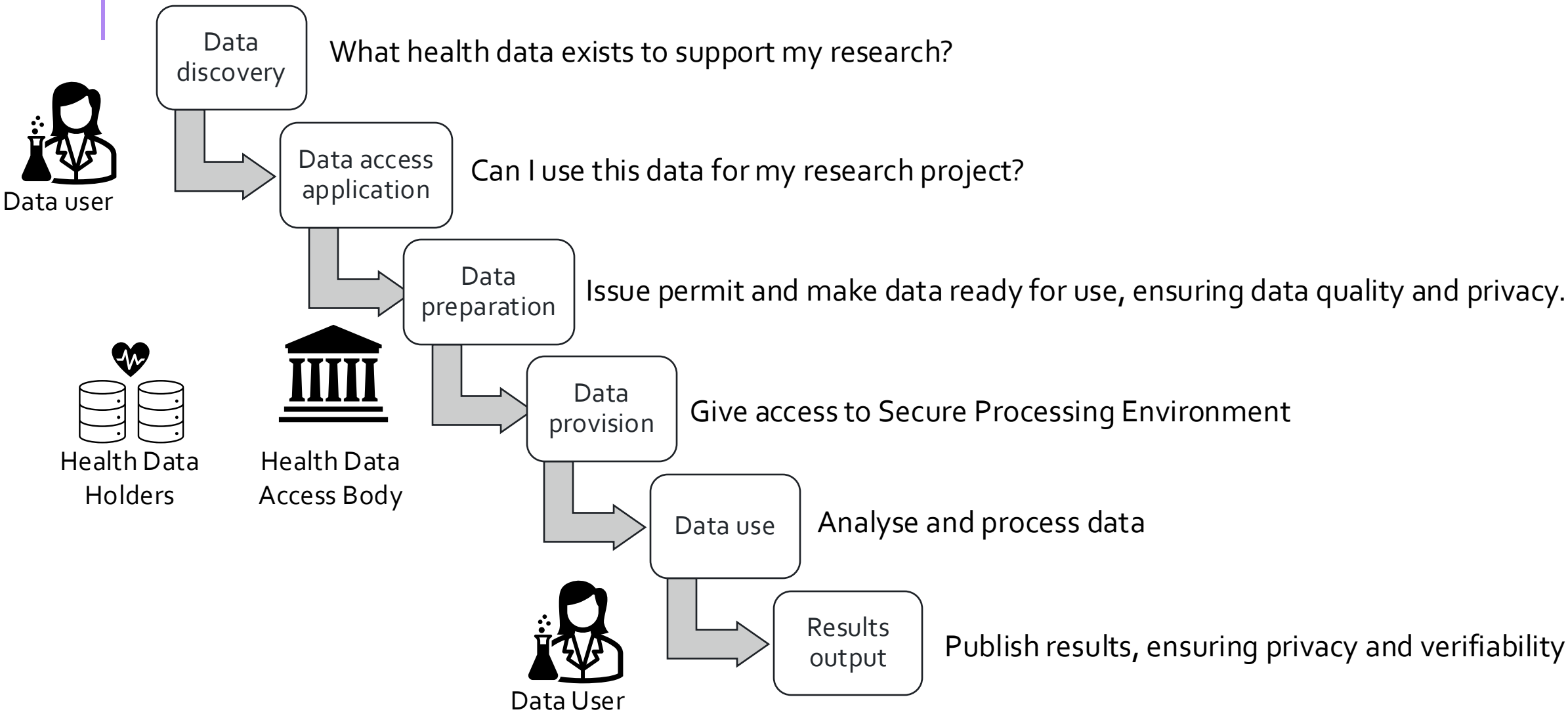
A community of practice supporting collaboration and shared learning.

**More information:** https://acceptance.data.health.europa.eu/ehr-systems/support-center & https://www.linkedin.com/company/eehrxfsupportcentre/

# Certification of EHR systems (simplified)



# User journey – secondary use



# Setting up governance

- EHDS Board and Steering groups for the two infrastructures
  - To be ready Q1/27
- Stakeholder Forum
  - Expect call for applications in Q4/26

# Key steps in 2026–2029

## European Commission

- Continue work on the implementing acts
- Consolidate technical specifications
- Launch the work of the EHDS Board, MyHealth@EU and HealthData@EU steering groups, Stakeholder forum, etc.
- Operate and extend MyHealth@EU central services
- Operate HealthData@EU central services

## Member States

- Designate digital health authorities, national contact points, health data access bodies, market surveillance authorities.
- Build or upgrade health access services, proxy services, DTEs, national data catalogues.
- Onboard to HealthData@EU, operate or delegate operation of SPEs
- Onboard to MyHealth@EU and implement data exchange in the EEHRxF for the 1st group of priority data categories

## Industry and implementers

- Follow the format and EHR system common specifications as they mature
- Engage through the Support Centre and the Stakeholder forum
- Prepare EHR systems for self-assessment, including testing in DTE

# Thank you

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# EAMONN COYNE

DIGITAL HEALTH SPECIALIST AT DEPARTMENT OF HEALTH IRELAND

EUROPEAN BIG DATA VALUE FORUM

# MyHealth@EU from the Irish perspective


Presenter: *Eamonn Coyne*

*Digital Health Specialist – Department of Health Ireland*
*Current elected MyHealth@EU eHealth Member State Expert Group Chair*


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# What supports the EHDS?

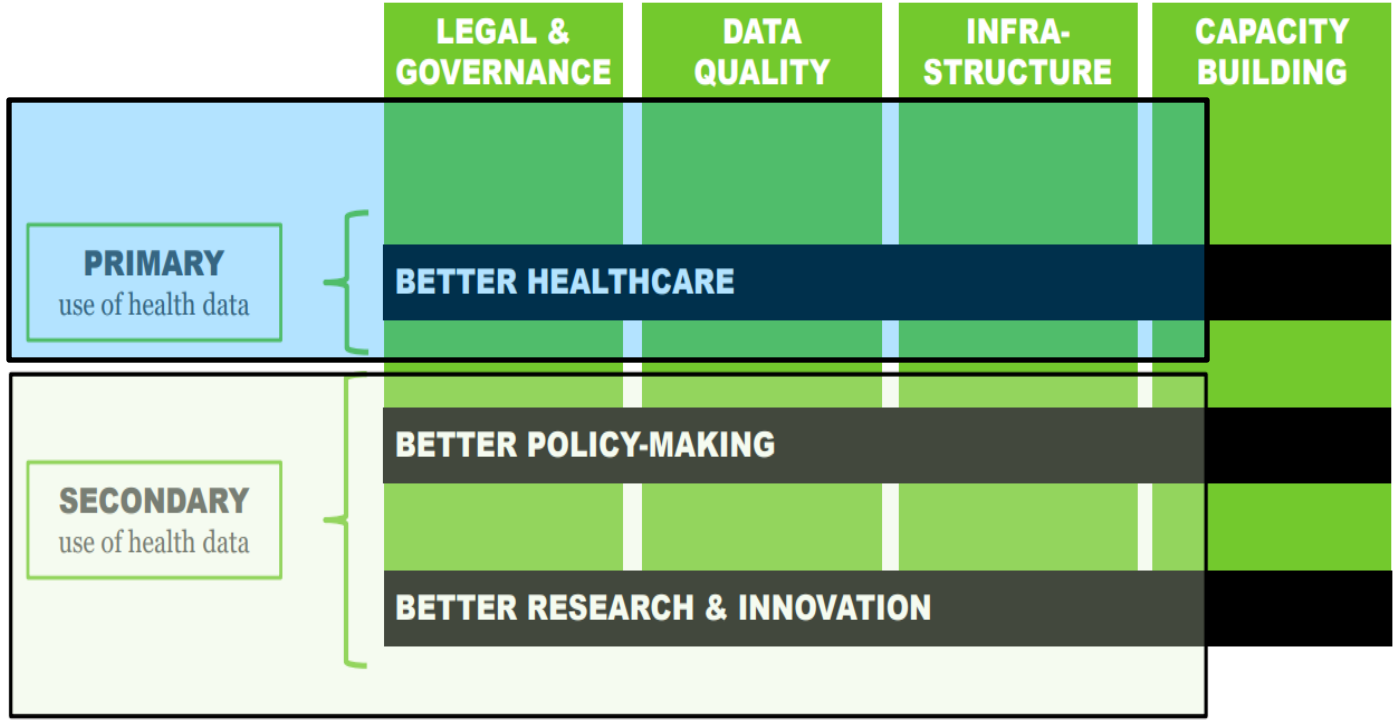
- **Two infrastructures will support access to electronic health information**

**MyHealth@EU**

**standardised and interoperable Electronic Health Records within the EU.**

**HealthData@EU**

**A consistent, trustworthy and efficient set-up for the use and re-use of health data**



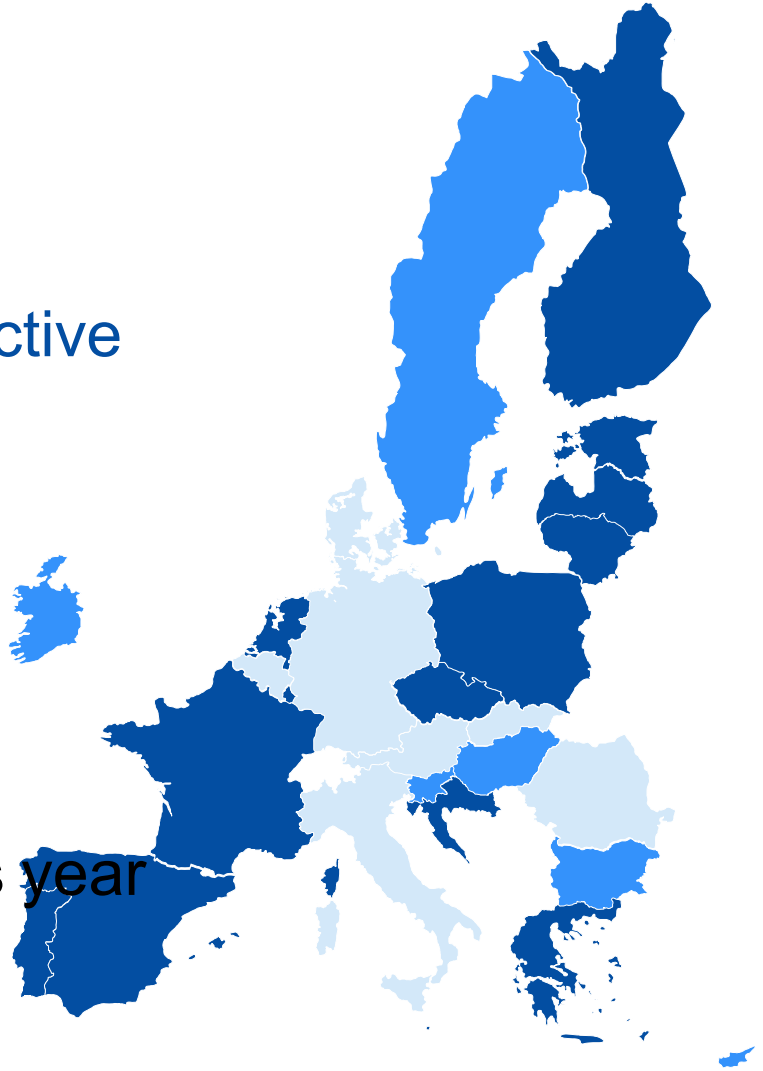

Through **MyHealth@EU** – each person will have access to their personal health records for medical treatment (in Ireland and the EU).

Through **HealthData@EU** – access to health datasets for public interest uses.

MyHealth@EU

## MyHealth@EU under Cross-border Healthcare Directive

- **Voluntary system** for exchanging patient summaries, prescriptions and dispensations (≈ first group of priority categories)
- **Health Data** structured **according eHealth Network guidelines**
- **15 MS** live with at least one service, **more** scheduled to go live with additional service(s) this year



## Evolution of MyHealth@EU for the EHDS

- Voluntary => mandatory

# What is MyHealth@EU?

MyHealth@EU is an infrastructure ensuring the **continuity of care for European citizens** while they are **travelling abroad in the EU**. This gives EU countries the possibility to **exchange health data** in a secure, efficient and interoperable way.

## What information can/will be shared within MyHealth@EU?

MyHealth@EU

- *Patient summary*
- *ePrescription/eDispensation*
- *Original Clinical Documents*
- *Medical Test Results*
- *Hospital Discharge Reports*
- *Medical Images/image reports*

**(EEHRxF)**
**European Electronic Health Record Exchange Format**

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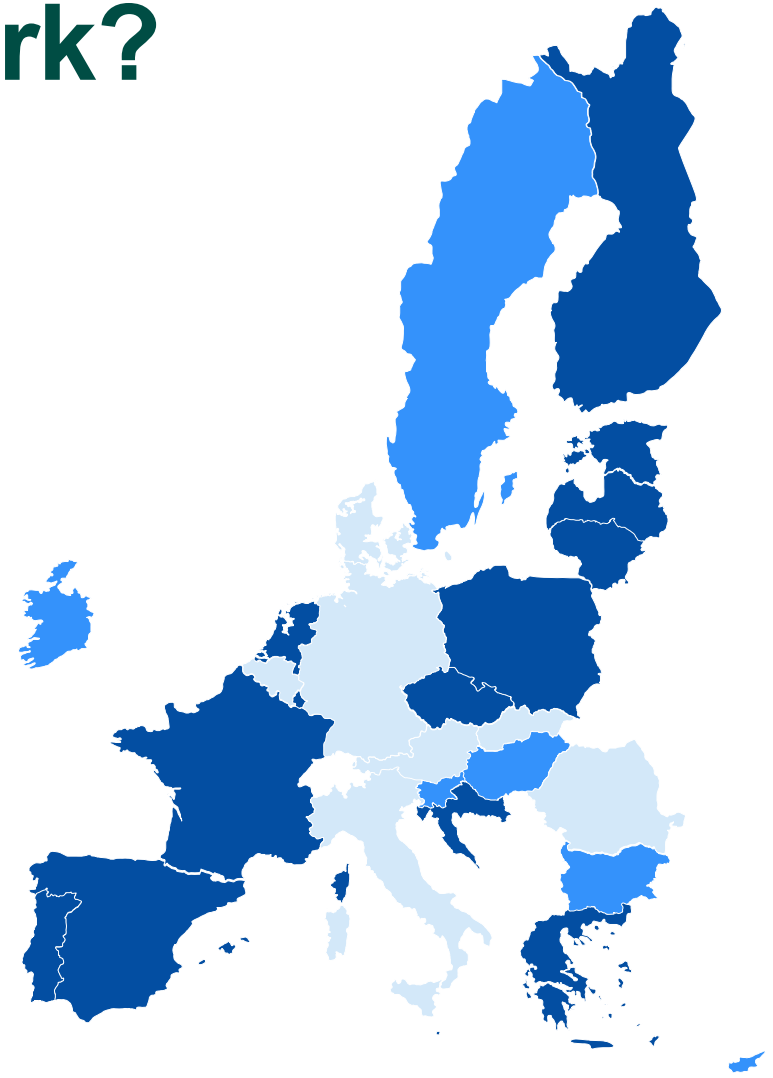
# MyHealth@EU, how does it work?



# Meet Alan from Ireland

Alan is a Business consultant.

An Irish citizen aged 65, he travels regularly for his work.

Alan exercises often and has a healthy lifestyle.

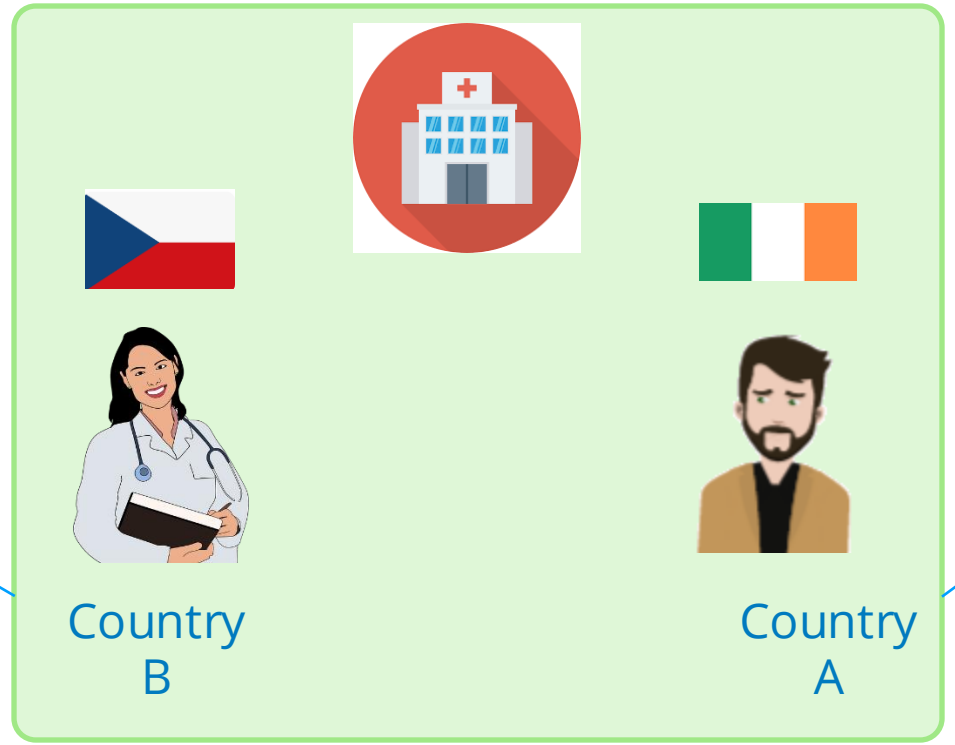
He has been diagnosed as a Type 2 diabetic.

Co-funded by
the European Union

# Imagine the Scenario

On the second day of a business trip to Czechia, **Alan starts feeling shaky, light headed with chills and clammy skin**. **He recognises** these as **a sign of potential hypoglycaemia**. He has missed a few meals with his recent busy schedule and becomes concerned. **He presents to an Emergency Department**. **If only the healthcare professional could access Alan's relevant medical information** in the healthcare professional's language.

Country B is the country of treatment. Member state of treatment means the **territory healthcare is actually provided** to the patient abroad.




Country A is the country of affiliation and is the country that **holds information about the patient** and where the patient can be unequivocally identified and where their data may be accessed.

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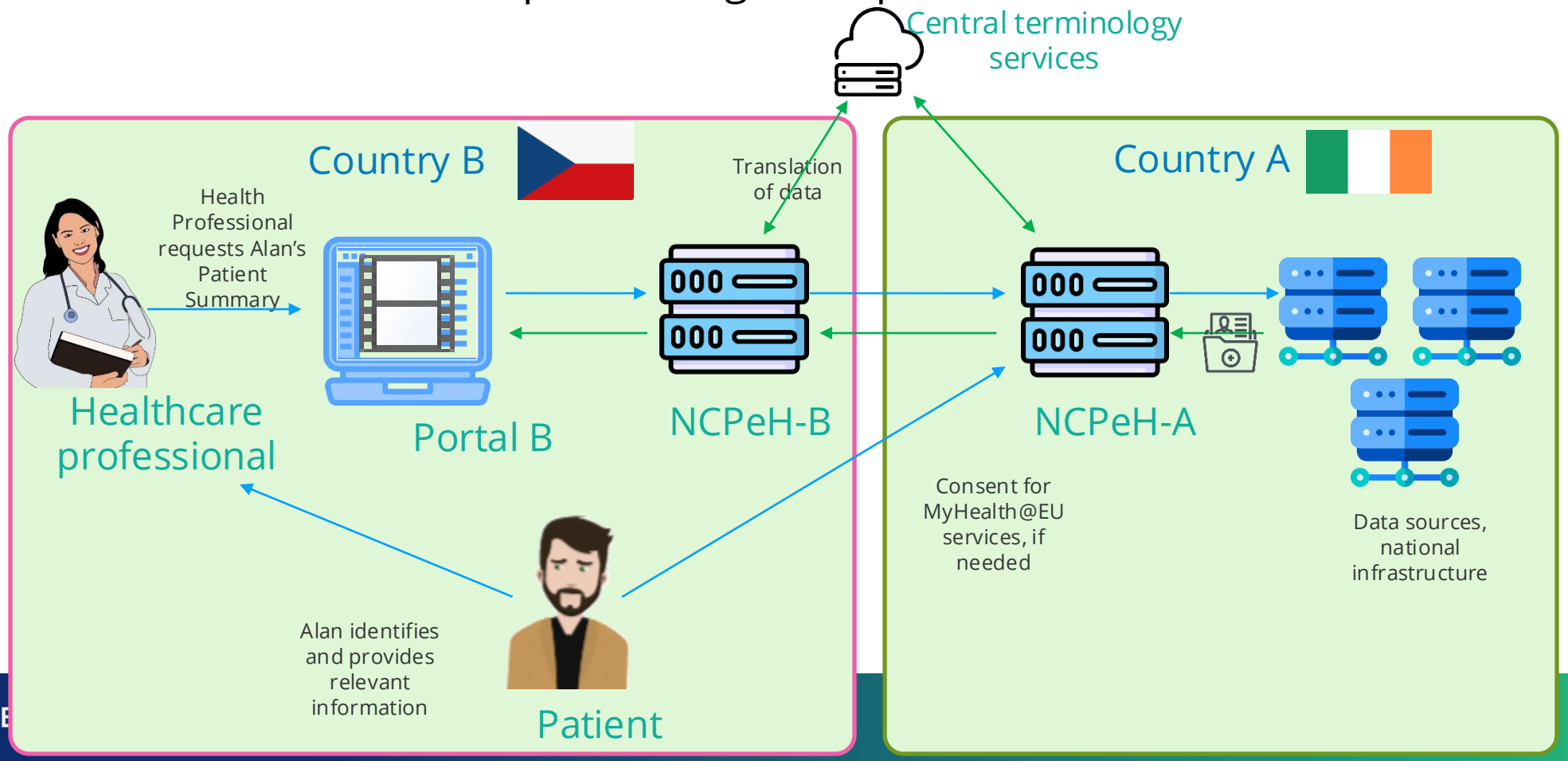
# Current supporting MyHealth@EU infrastructure

The current MyHealth@EU infrastructure connects Member States National Contact Points for eHealth (NCPeH) giving **healthcare professionals access to the patient's data** via a Portal.

In this case he Patient Summary is returned and displayed in the portal to the healthcare professional in their own language thereby **enhancing the patient's treatment**. **Reducing the potential for clinical errors** and duplicate diagnostic procedures.




Country B country of treatment.

Country A country of affiliation.



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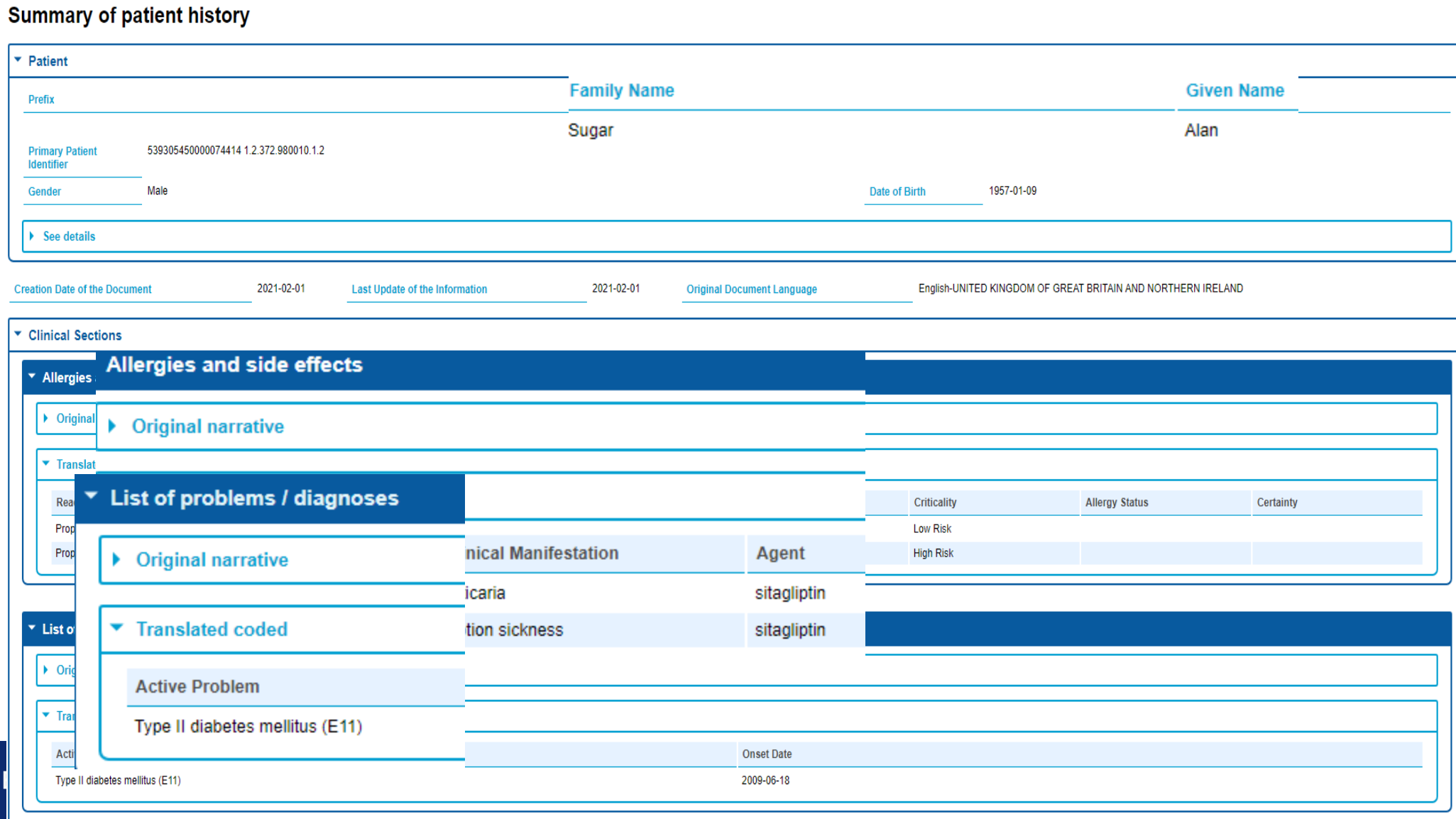
# Current supporting MyHealth@EU infrastructure in action

Here you can see how a **healthcare professional in Cyprus can access** Alan Sugar's **healthcare data in real time**.

The Patient Summary Gives the Healthcare professional access to:-

- ✓ Patient Demographics.
- ✓ Allergies
- ✓ A List of Current Medical Conditions
- ✓ A History of Medication
- ✓ Implanted Medical Devices
- ✓ Surgical History



**What we have learned;**

**Building capability through European collaboration**

- ✓ Participating in MyHealth@EU testing since 2018
- ✓ Learning through collaboration with European partners
- ✓ Building technical, semantic and operational expertise
- ✓ Capability for bi-directional exchange through existing infrastructure

**National enablers under Digital for Care**

**Digital for Care foundations for MyHealth@EU**

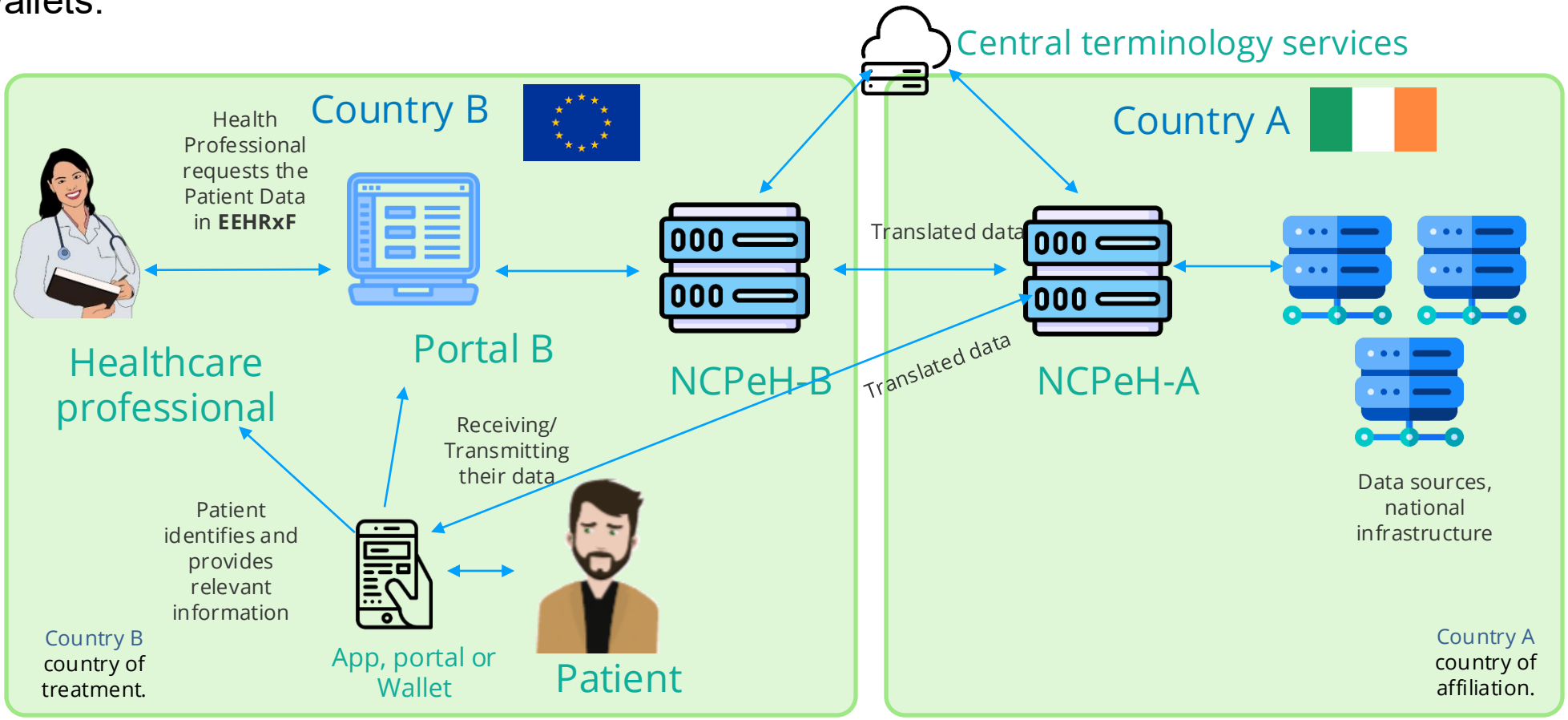
- ✓ Shared Care Record
- ✓ One Health Record
- ✓ HSE Health App
- ✓ ePrescribing & ePharmacy
- ✓ National Identifiers
- ✓ SNOMED CT & Terminology Services
- ✓ National Clinical Information Systems(MedLIS, NIMIS etc)

***European experience + National Digital Health Transformation = Cross-Border Care Readiness***

# The future

**Driving Europe forward** by delivering these services we can…

- ✓ **Support EU Healthcare Professionals** with **access** to **clinical data** enhancing the **continuity of care.**
- ✓ **Empower European citizens** to **access** their **own healthcare data** via portals, mobile applications and digital wallets.



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# And when we do…

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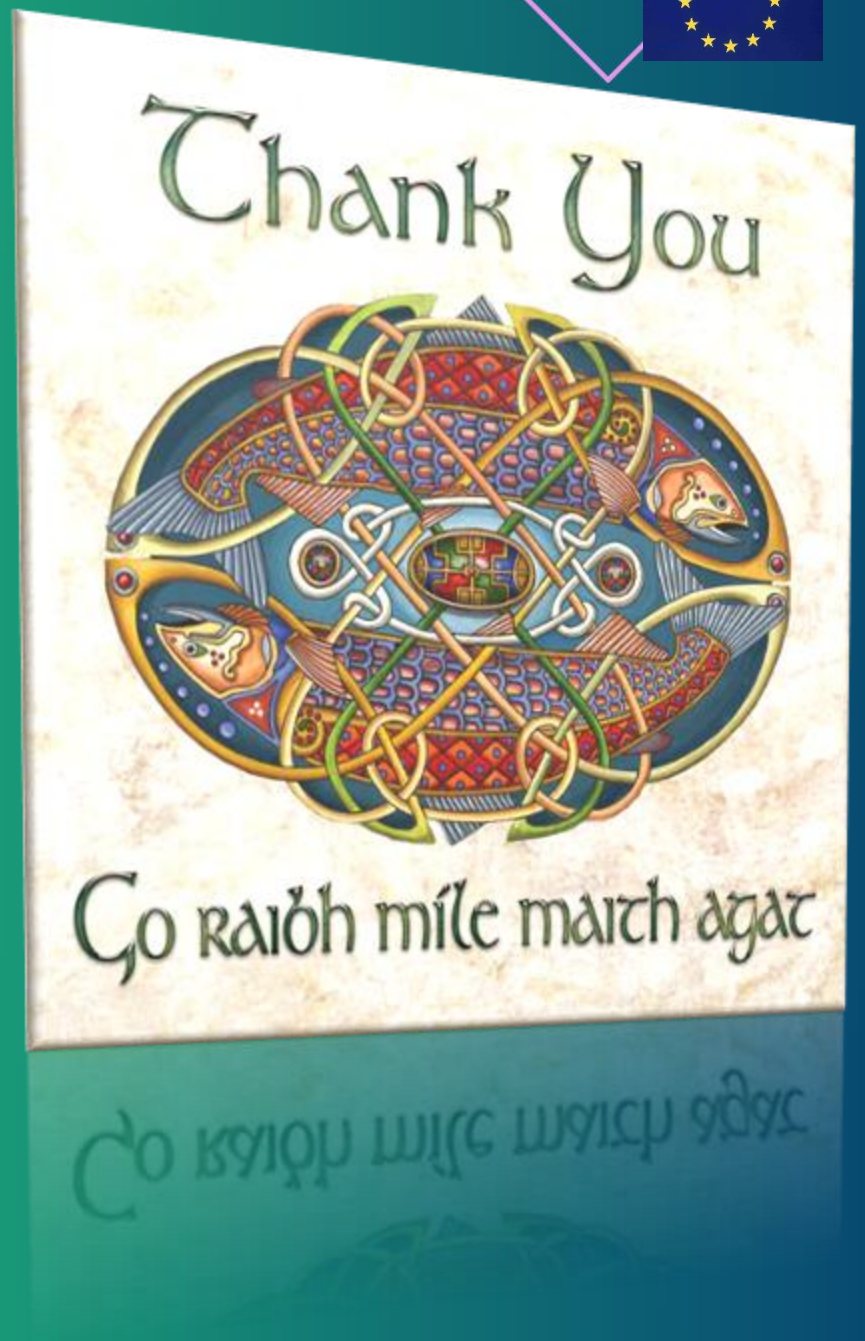


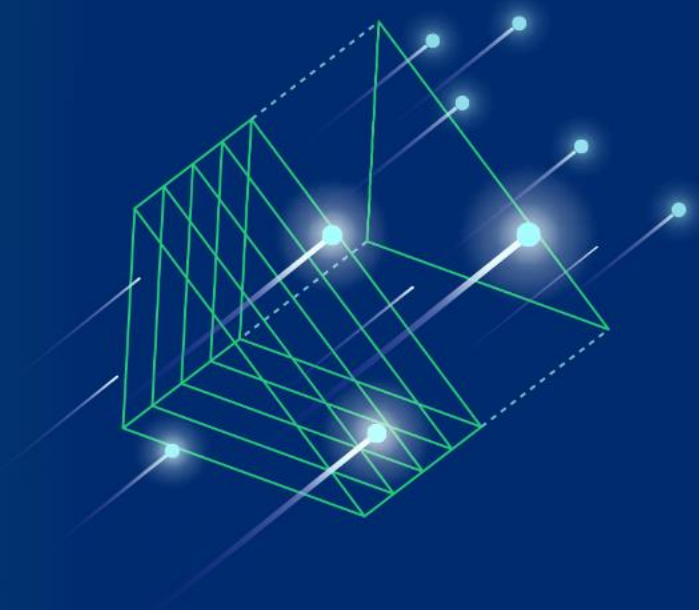

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# Questions?

**SUZANNE BARROR**

HEALTH INFORMATION PROGRAMME MANAGER AT HIQA (HEALTH INFORMATION AND QUALITY AUTHORITY)

Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

# Cross-border health data sharing in the EU – Current state of affairs

Suzanne Barror

Programme Manager

Health Information and Standards Directorate

**01 October 2026**

# Health Information and Quality Authority (HIQA)

## About HIQA

### Independent authority

HIQA is an independent authority in Ireland established under the Health Act 2007 to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

### Responsibilities

HIQA's responsibilities include setting standards for health and social care services, regulating health and social care services, monitoring services, health technology assessment, health information, and the national care experience programme.

### Safer, better care

HIQA supports the Irish digital health and health information landscape to ensure safer, better care. The standardisation of health information improves the quality and safety of care by facilitating timely access to data, helping to inform clinical decision-making.

### Person-centred care and support

To do this, HIQA develops person-centred standards, guidance and recommendations that are underpinned by principles of a human rights-based approach, safety and wellbeing, responsiveness, and accountability.

# HIQA's strategic approach to Health Information

To enhance the use of health and social care information for primary and secondary purposes, support EU requirements and support national digital projects:

## National HI standards

- Promote and guide safe, consistent and accurate sharing of health information.
- Support health and social care services, enable people to access their information, improve safety and quality of care.

## Implementation Support

- Support the health and social care sector to produce high-quality health information.
- Enhance and standardise practice.

## Assurance and Review

- Drive quality improvements by identifying areas of good practice and improvement.
- Benchmark across data holders and review change overtime.

## Evidence for Policy

- Support compliance with the EHDS regulation.
- Align with national digital health developments.
- Drive standardisation of practice.
- Develop national health dataset catalogue

# Health Information Standards

HIQA is developing a suite of national health information standards informed by and aligned with EU regulation and national projects:

**EHDS priority categories of data**

Patient summaries
Electronic prescriptions
Electronic dispensations
Medical imaging
Laboratory reports
Discharge reports

**National digital infrastructure projects**

Electronic health record
Shared care record
National Electronic Prescribing Service
HSE Health App

# Health Information Standards

## Current work programme

**Draft national standards developed – ready for testing**

- Draft National Standard for a Demographic Dataset for Health and Social Care (NOCA took part in pilot)
- Draft National Standard for Hospital Discharge Reports

**Draft standards in development**
(data to be integrated by March 2029)

- Draft National Standard for Electronic Prescriptions and Electronic Dispensations
- Draft National Standard for a Patient Summary

**Draft standards to be set from 2027**
(data to be integrated by March 2031)

- National Standard for Laboratory Results
- National Standard for Medical Imaging Reports
- National Standard for Discharge Reports

# HealthData@IE Overview

Funding from EU Commission to establish health data access services for Ireland

Collaborative approach - DoH, HIQA, HRB, HSE and key stakeholders

National Steering Committee - HealthData@IE

5 working groups established and PPI panel

## Key areas for advancement

- **WP2** Programme of engagement, education and training*
- **WP5** National data access application management system
- **WP6** National health dataset catalogue*
- **WP7** Secure processing environments
- **WP8** Data quality enhancement*

*HIQA leading on this programme of work

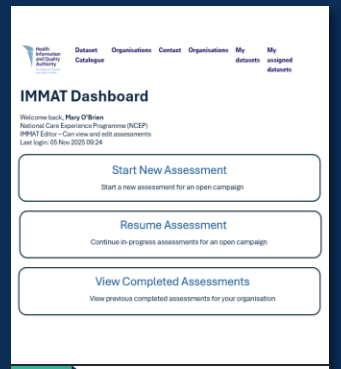
# Readiness Assessment

**Summary of findings**

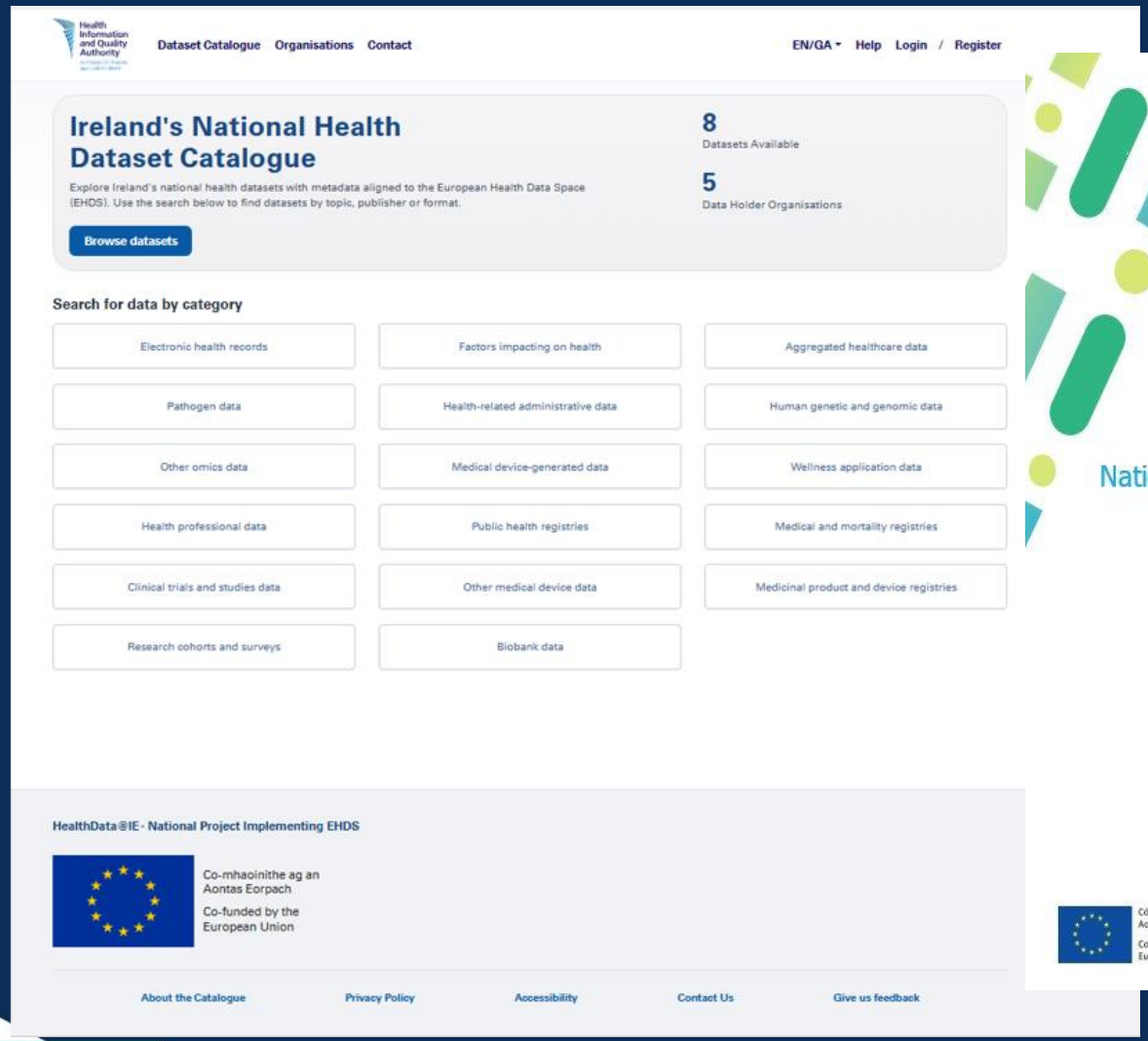
- 16 data holders in Ireland
- Maturity, expertise and capacity differs significantly across organisations
- Implementation of National Standards for Information Management was associated with higher levels of preparation
- Steps are being taken to prepare the system, but further support is needed to prepare data holders to ensure they can meet future obligations under the EHDS Regulation.
- Organisations welcomed participation and acknowledged it as an opportunity to gain and share knowledge

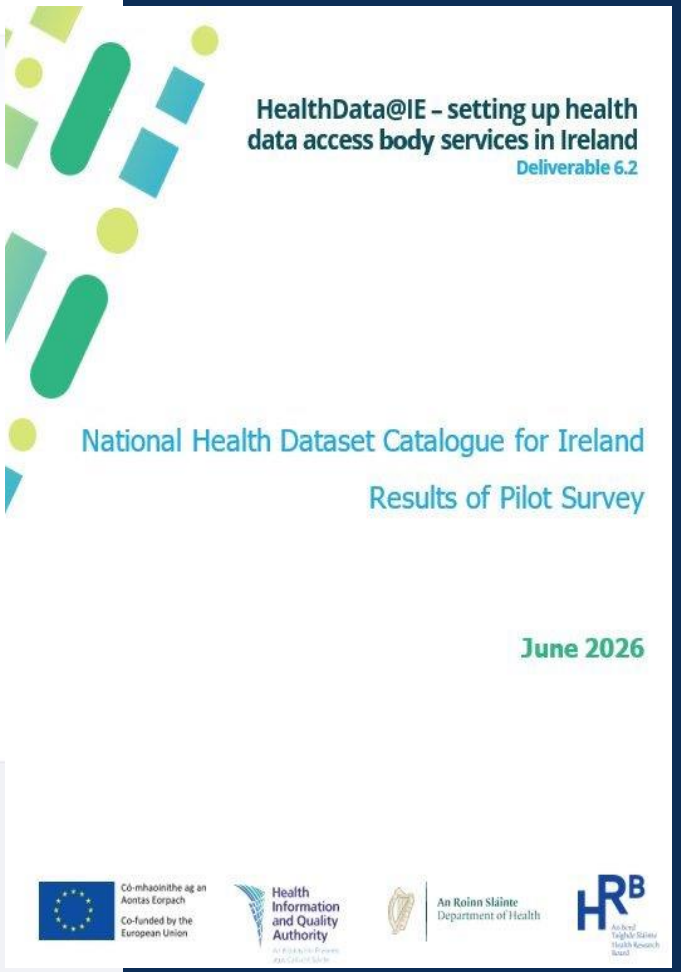
- **Next Steps**

  Findings are informing HealthData@IE deliverables including:
  - National health dataset catalogue (NHDsC)
  - Data quality guidance and training for data holders
  - National Interoperability Framework (NIF) for providing data to a HDAB service
  - Online peer support network for data holders
  - Strategic programme of engagement with data holders



# **National Health Dataset Catalogue-** Making Health Data Discoverable

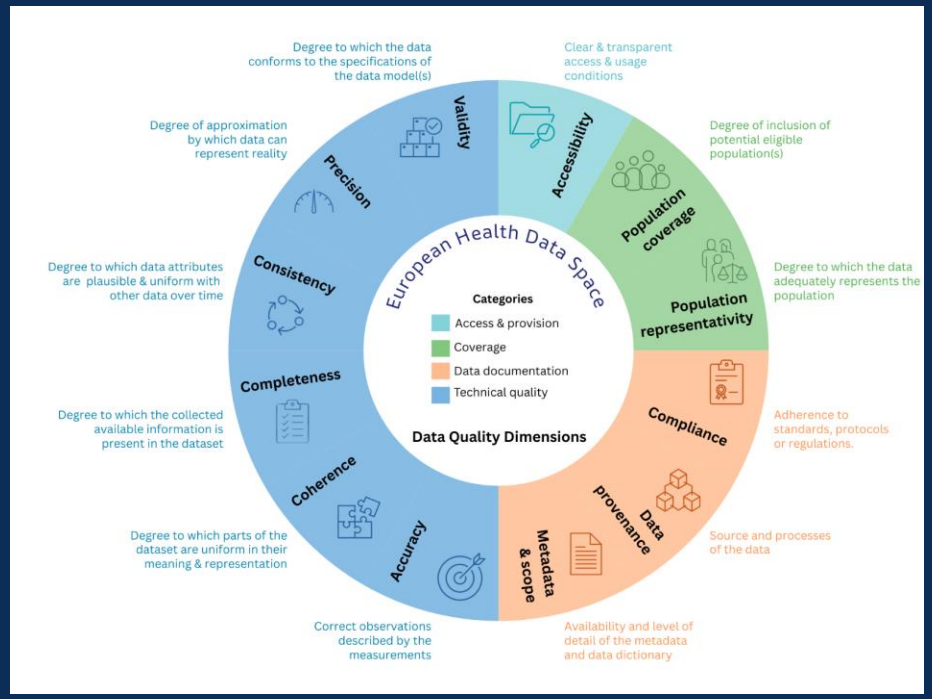



- Under the EHDS, data holders of 17 categories of health data will be obliged to make their data discoverable in a National Health Dataset Catalogue (nHDC)
- In 2026, HIQA developed a catalogue based on our previously published nHDC: Requirements & Specifications
- The catalogue has been piloted with 8 data holders and modifications to the catalogue have been made based on feedback received
- First phase of roll out to data holders is due in November 2026

# Data Quality Enhancement

QUANTUM
THE HEALTH DATA QUALITY LABEL




- Under the EHDS, publicly-funded health data holders will be required to apply a **data quality and utility label (DQUL)** to all datasets available on the National Catalogue
- QUANTUM – recommendations in relation to application of DQUL (Art. 78)
- HIQA updating review programme to include thematic assessments of data quality, using the newly developed **Compliance Assessment Framework for Data Quality**

# Engagement, Training and Dissemination

### Improving awareness and understanding of HDABs and EHDS through dissemination

Development and delivery of public facing information, digital resources and national and international presentations improve awareness, accessibility and understanding of the EHDS and HDAB services.

### Strengthening stakeholder engagement through collaborative groups

Establishment and facilitation of working groups, Public and Patient Involvement (PPI) panel and engagement with relevant stakeholders inform approaches to improving content, accessibility and effective engagement.

### Building capacity through training, guidance and peer support

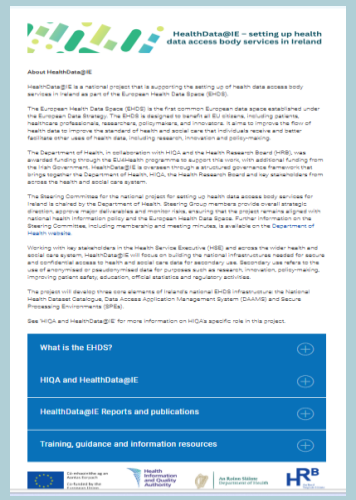
Development and delivery of webinars, guidance materials and training helps to build knowledge, skills and preparedness among health data holders, health data users and public.

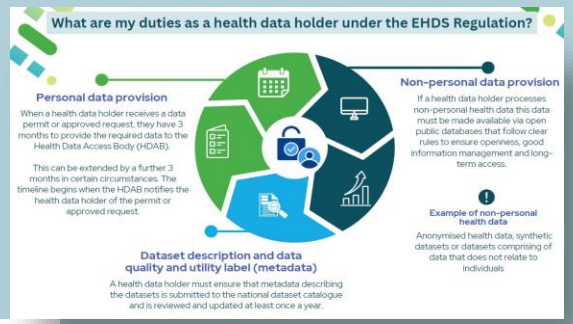
**WP2**

**WP6** the National Health Dataset Catalogue

**WP8** Data quality enhancement, guidance and peer support

# Engagement, Training and Dissemination





Health Information and Quality Authority
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# Thank you

**For further details:**

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HIQA Health Information

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# Questions?

**SERGE EIFES**

PRINCIPAL DATA SCIENTIST AT LUXEMBOURG NATIONAL DATA SERVICE (LNDS)

EUROPEAN BIG DATA VALUE FORUM

# Cross-border health data sharing in the EU

## Building cross-border secondary use: the Luxembourg perspective

Serge Eifes, Principal Data Scientist, LNDS

Galway, October 1st 2026

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# Cross-border health data sharing: four perspectives from Luxembourg

From national Data Governance Act (DGA) and EHDS implementation to complementary cross-border initiatives.

1 **How can cross-border access work?**
*HDAB-LU:* Building on national capabilities and connecting them to HealthData@EU.

2 **How can specialised data be shared across countries?**
*1+MG / Genome EDIC:* Federated European access to genomic and associated health data.

3 **How can cross-border data access support AI use cases?**
*SCAILED:* Connecting EHDS, health-data infrastructures and AI Factories.

4 **How can collaboration work when data stay local?**
*Clinnova:* Practical experience with federated, multi-country analysis.

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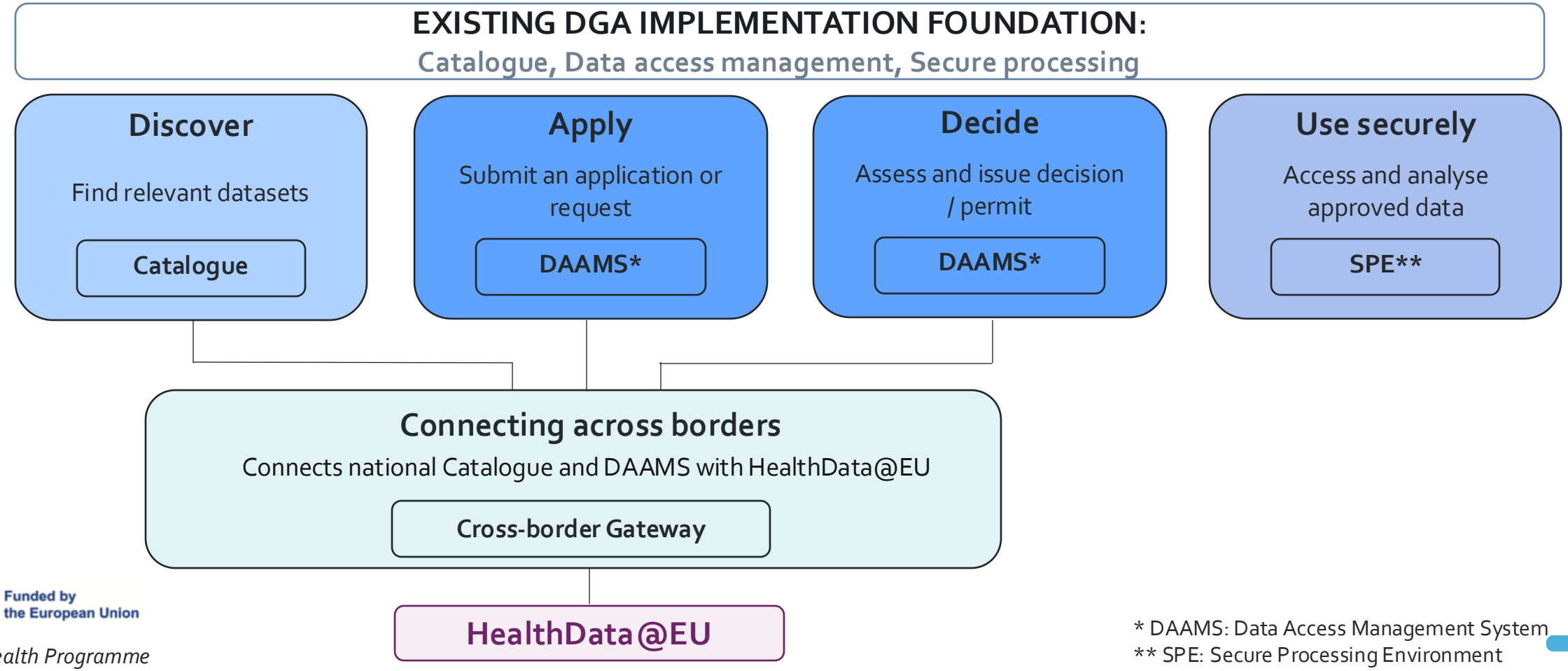
# HDAB-LU: building Luxembourg's data-access infrastructure for EHDS

Luxembourg builds on existing DGA capabilities and adapts them for secondary use under EHDS.




Funded by the European Union

*EU4Health Programme*

* DAAMS: Data Access Management System
** SPE: Secure Processing Environment

# HDAB-LU: where the four capabilities stand today

## Key implementation highlights from the HDAB-LU project

| Capability | Current implementation highlight |
| --- | --- |
| Catalogue | Catalogue MVP with HealthDCAT-AP-based metadata capture |
| DAAMS | MVP tested with national and cross-border applications |
| SPE | Secure workspace for approved data access implemented |
| Cross-border Gateway | Dataset publication and connectivity with HealthData@EU tested |

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# Cross-border interoperability: what we have tested in practice

## Testing Luxembourg's connection to the European health data infrastructure

### Practical experience

- ✓ Cross-border dataset publication flow successfully tested
- ✓ Secure connectivity with the European infrastructure established
- ✓ Capability to test conformance with European interoperability specifications established
- ✓ Cross-border application workflow tested from submission to decision

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# HDAB-LU: current challenges and next steps

## WHAT ARE WE LEARNING

**Catalogue**

Progress on the EHDS **Data Quality and Utility Label** is limited by remaining uncertainties

**Alignment** on **data description best practice** to facilitate cross-border data discovery

**DAAMS**

Need for **national customisation** while maintaining **European interoperability**

**SPE**

**Alignment** with an **evolving** European compliance framework

## WHAT COMES NEXT

**Transition capabilities to national implementation**

Adapt the four capabilities to support Luxembourg's operational HDAB.

**Complete multi-country application workflows**

Further integration with the HealthData@EU central platform.

Develop a multi-country test case with other Benelux countries.

**Connect the four capabilities end-to-end**

Catalogue · DAAMS · SPE · Cross-border Gateway

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# 1+Million Genomes / Genome EDIC: enabling cross-border access to genomic data

**1+Million Genomes initiative** Overarching European initiative for cross-border access to genomic and associated health data

Projects and activities advancing the 1+ MG objectives

**B1MGplus**

**Organisational setup**

Supports establishment of the Genome EDIC

**European Genomic Data Infrastructure**

**Technical infrastructure**

Builds the infrastructure for federated genomic data access

**GOE GENOME OF EUROPE**

**Representative dataset**

Creates a representative genomic reference dataset across Europe

## Genome EDIC

Long-term legal and organisational framework for European genomics

**Luxembourg elected as the legal seat**

Co-funded by the European Union

*Digital Europe Programme*

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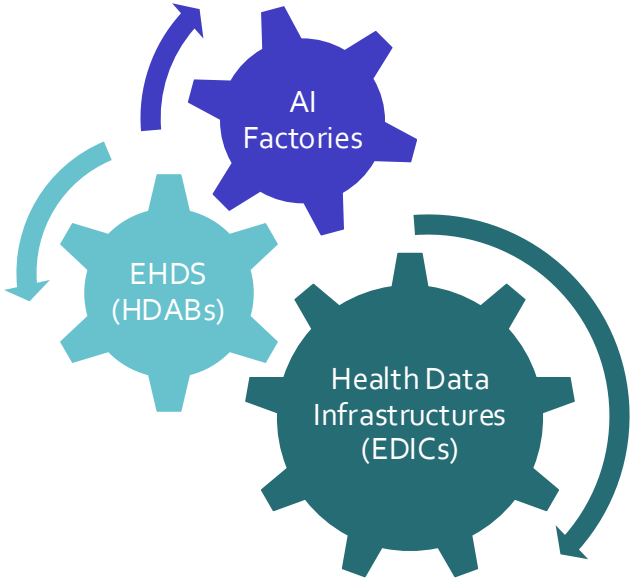
# SCAILED: connecting health data and AI across Europe

## Linking EHDS, health-data infrastructures and AI Factories for biotech AI

**Supporting responsible biotech AI innovation**




**European cross-border consortium**

**50 partners • 17 Member States**

EHDS experts & HDABs • health-data infrastructures • AI Factories • healthcare & research • patient organisations • biotech industry

**36 months • Start: 1 October 2026**

**Cross-border health data access can enable responsible AI use**

Funded by the European Union
*EU4Health Programme*

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# Clinnova: federated cross-border collaboration in practice

Federated health-data collaboration across four countries with local data control

**25+ partners • 4 countries • Phase 2 underway**

## What it connects

- Clinical and research data
- Three disease cohorts: IBD, MS and rheumatic disease

## Cross-border experience

- Federated analysis across sites
- Distributed architecture with local data control

**Relevance to EHDS secondary use**

**Practical experience with federated multi-country health-data analysis.**

LNDS: governance participation and Phase 1 pseudonymisation/TTP proof of concept

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# What does it take to make cross-border secondary use work?

- **Common access mechanisms**
  *HDAB-LU*
- **Interoperable specialised infrastructures**
  *1+MG / Genome EDIC*
- **Connecting data access to AI use cases**
  *SCAILED*
- **Federated approaches with local data control**
  *Clinnova*

**The challenge: making the components work together across borders.**

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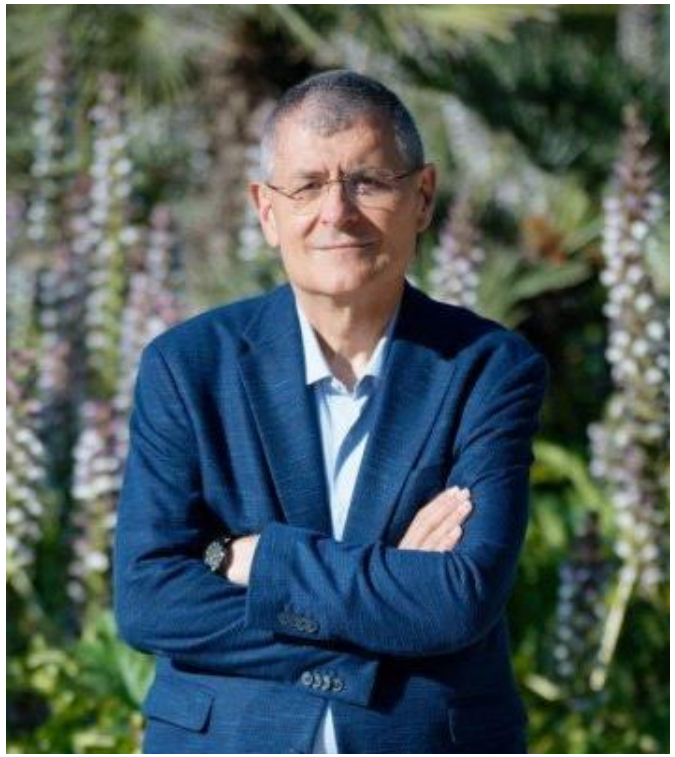
EUROPEAN BIG DATA VALUE FORUM

# Questions?

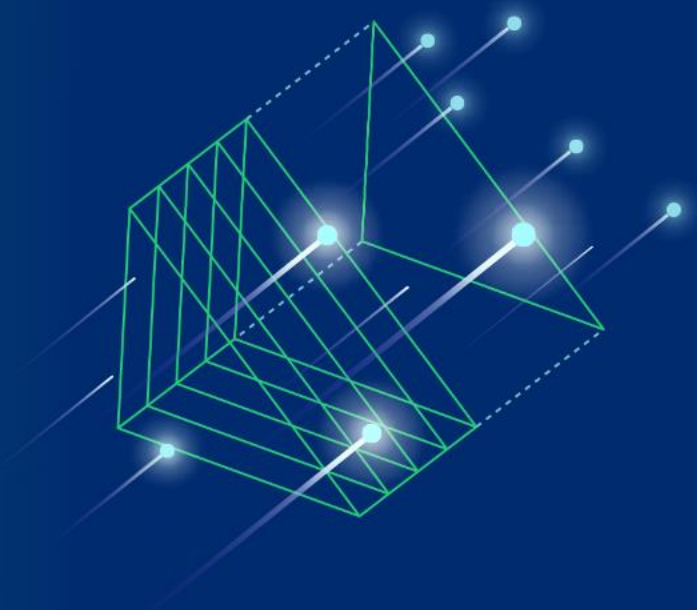


# RICARD MARTÍNEZ MARTÍNEZ

ASSOCIATE PROFESSOR AT UNIVERSITY OF VALENCIA

EUROPEAN BIG DATA VALUE FORUM

# How to build an European Data Space Infrastructure: lessons learned



Dr. Ricard Martinez.
University of Valencia
EUCAIM Project
BreastScan Project

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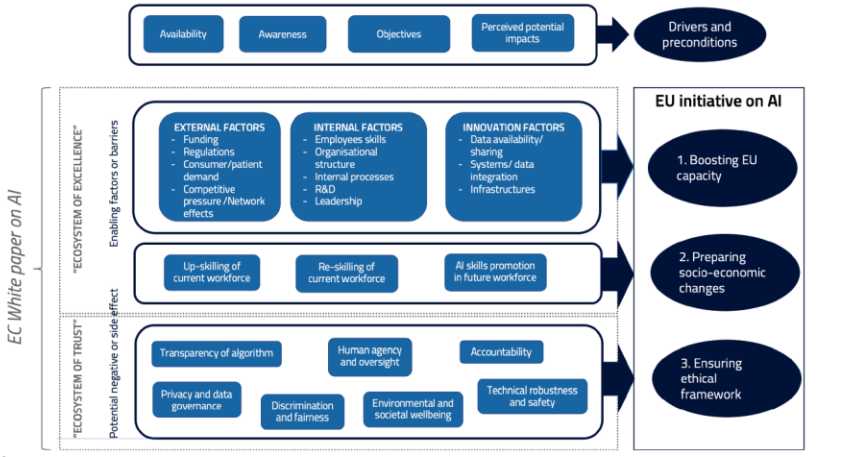
# European Union Approach

## Human centered approach and Rule of Law guarantee:

- Ensure fundamental rights.
- Ensure the avoidance of physical, social and environmental harm.
- Prevent systemic risks to democracy and freedoms.

## Product-oriented approach:

- Risk-based cataloguing of AI systems.
- Specification of product design processes.
- Supervision and certification by notified bodies.
- Post-market surveillance.
- Integration with Medical Devices Regulation.



# Applicable legal framework: legal and ethical compliance

- **GDPR & national law:** articles 6 and 9 for health data, secondary-use compatibility, DPIA, national safeguards and opt-out.
- **EHDS Regulation:** *Lex specialis* for secondary use, authorised/prohibited purposes and Secure Processing Environments.
- **Ethical requirements**: new scope of ethics authorisation (including reuse by third parties via EUCAIM/EHDSR) and AI act approach.

# Our pproach

- **Human & Fundamental Rights-centered approach**: protecting patient privacy and safety
- **Risk-based approach**
- **Data protection** (compliance by design)
- **Alignment with scientific objectives**

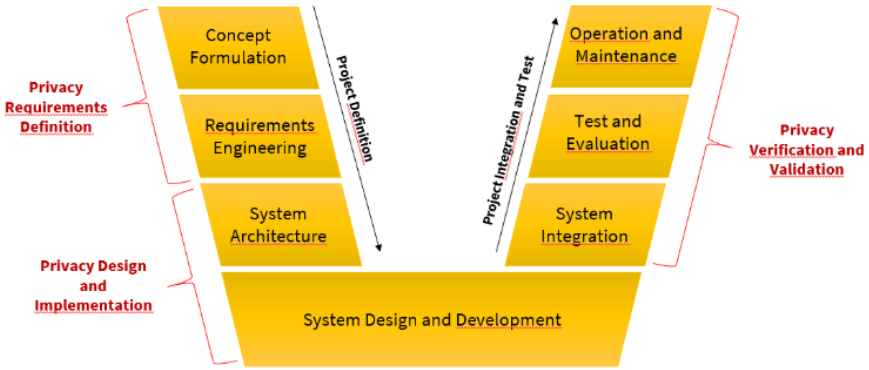
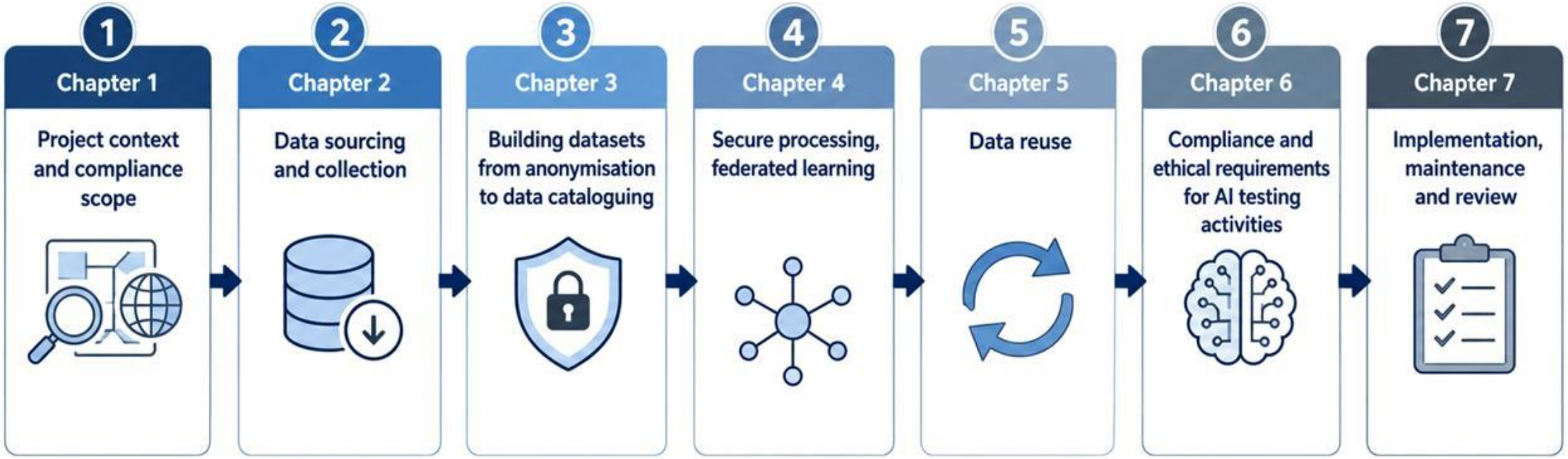



Figure 4 - Privacy Engineering [28]

Agencia Española de Protección de Datos (AEPD). *A Guide to Privacy by Design*. October 2019.

Datatilsynet. *Software Development with Data Protection by Design and by Default*. 2019.

# Building blocks



# Data Protection Impact Assessment

**Threat focus:**

- Large-scale processing of special-category data from cancer patients
- Multi-partner ecosystem → purpose specification deviations, secondary uses, cybersecurity and integrity risks
- Innovative technologies
- Overarching concern: safeguarding human dignity and patient safety

**DPIA goals:**

- Systematically map all processing activities, data flows and actors across the multi-partner project
- Categorise risks by severity and prioritise proportionate safeguards (technical, organisational, governance)
- Integrate GDPR with medical research ethics to ensure patient-centred, fundamental-rights-oriented risk management
- Achieve demonstrable residual risk reduction acceptable to regulators, ethics committees and participants

# Most common risks

- **Re-identification risk**: Differences in anonymisation maturity across Data Holders, mosaic attacks from growing external datasets, retention of staging data, and degradation of static anonymisation over time can enable re-identification of patients.
- **Governance and accountability gaps:** Federated two-layer architectures require robust governance frameworks, complete asset inventories, clear allocation of responsibilities between nodes and the central platform, and proper segregation of duties to prevent accountability failures.
- **Identity and Access Management weaknesses**: Combining external authentication with internal authorisation can cause synchronisation failures, orphan accounts, and excessive access persistence unless user management and identity verification are very strict.
- **Security maturity heterogeneity**: Federated nodes may have inconsistent security maturity, requiring independent verification of platform design, risk analysis, and, where appropriate, third-party certification to ensure uniform protection.
- **AI-specific risks**: Federated learning and AI model development introduce risks of model inversion, membership inference, gradient leakage, bias, discrimination, and lack of transparency or explainability in AI-based tools.

# Dual based strategy

## ANONYMISATION

- **Anonymisation as preferred solution**, with pseudonymisation as a residual, conditional option where anonymisation would make research unfeasible
- Anonymisation as a processing operation subject to Article 5 GDPR and linked to the original legal basis and research purpose; **requires risk-based, contextual assessment** (singling-out, linkability, inference) **and documentation of techniques, tools, risk tests and residual risks**
- Integrates anonymisation into DPIA and structured risk analysis at both partner and infrastructure level, and **connects dataset preparation to interoperability and cataloguing** (EUCAIM Common Data Model, FAIR principles, HealthDCAT-AP metadata)

## SECURE PROCESSING ENVIRONMENT

- Focuses on **Secure Processing Environments as legal and technical safeguard** (GDPR security, EHDSR requirements), with components such as access control, traceability, incident and breach reporting, availability and output control

**Dual strategy**: anonymisation at source as foundational rule and SPE intermediation as a second protection layer, including privacy-preserving computation and strict limits on pseudonymised data and re-identification

# Requirements

**Legal Compliance**

Ensuring adherence to regulations like EHDSR, GDPR, and the AI Act is crucial for data integrity. **DPIA AND FRIA ARE THE MAIN TOOLS.**

**Technical Excellence**

Achieving technical excellence involves anonymization, cataloguing, and ensuring interoperability across systems.

**Security First**

Prioritizing security through robust SPEs and federated processing safeguards data against breaches.

**Ethical Foundation**

Implementing frameworks like ALTAI and FRIA fosters an ethical approach to data handling and AI.

**Human-Centered Approach**

A human-centered approach ensures that technology is developed to serve humanity effectively and empathetically.

# Thank you for your attention

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# Questions?

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# Time for your Valuable Feedback!

## Menti poll

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# Thank you!