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EUROPE | DAYS

**BRUSSELS 2026**  
25-26 MARCH 



## Keynote: European Commission



Fulvia Raffaelli  
Head of Digital Health unit at European  
Commission

**SIEMENS**  
Healthineers

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HealthCare

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# European Health Data Space

State of play

IHE-Europe Experience Days 2026

*Fulvia Raffaelli – Head of Unit C1 – Digital Health – DG SANTE European Commission*

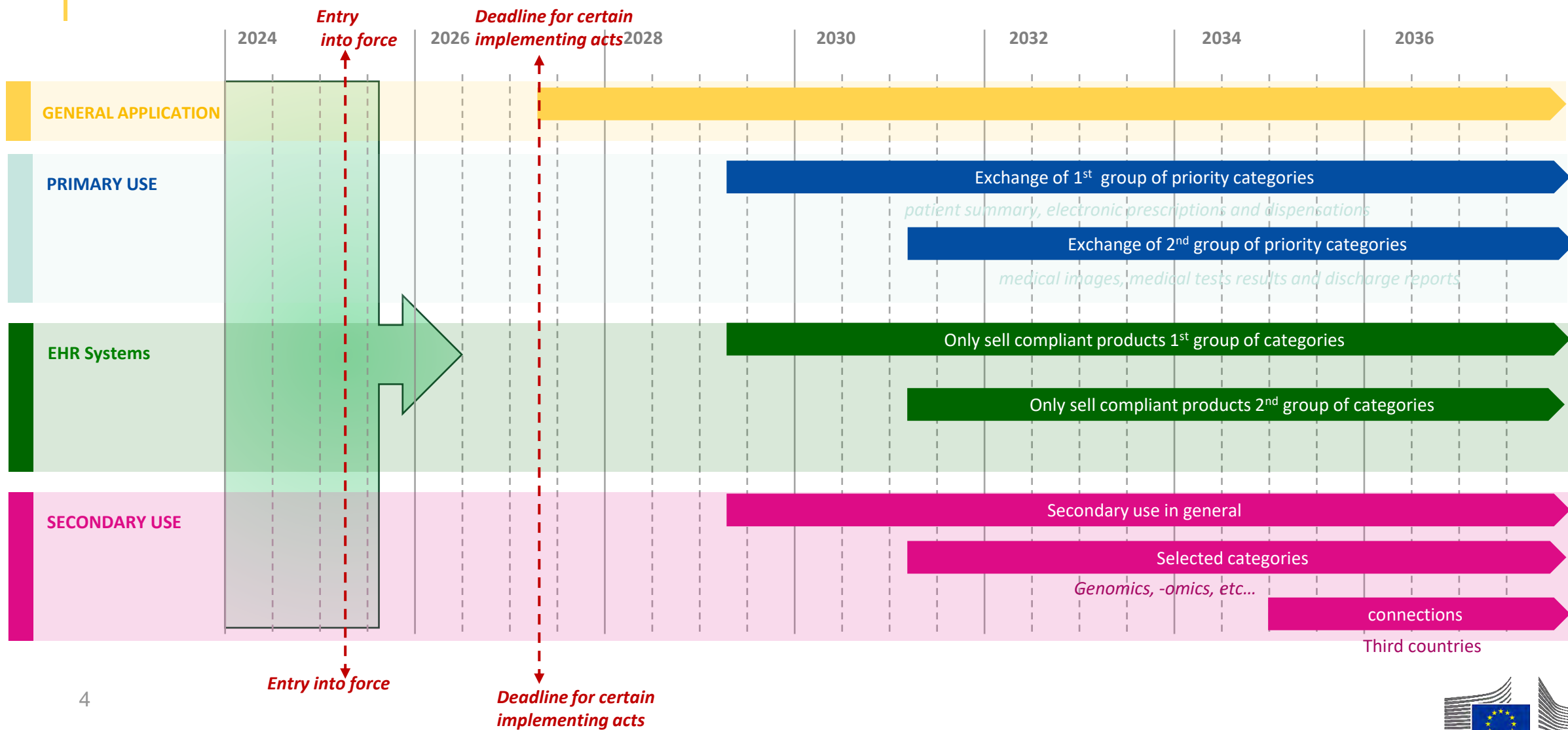




One year ago,  
Europe took a  
**historic** step.



# EHDS – Overall timeline for application

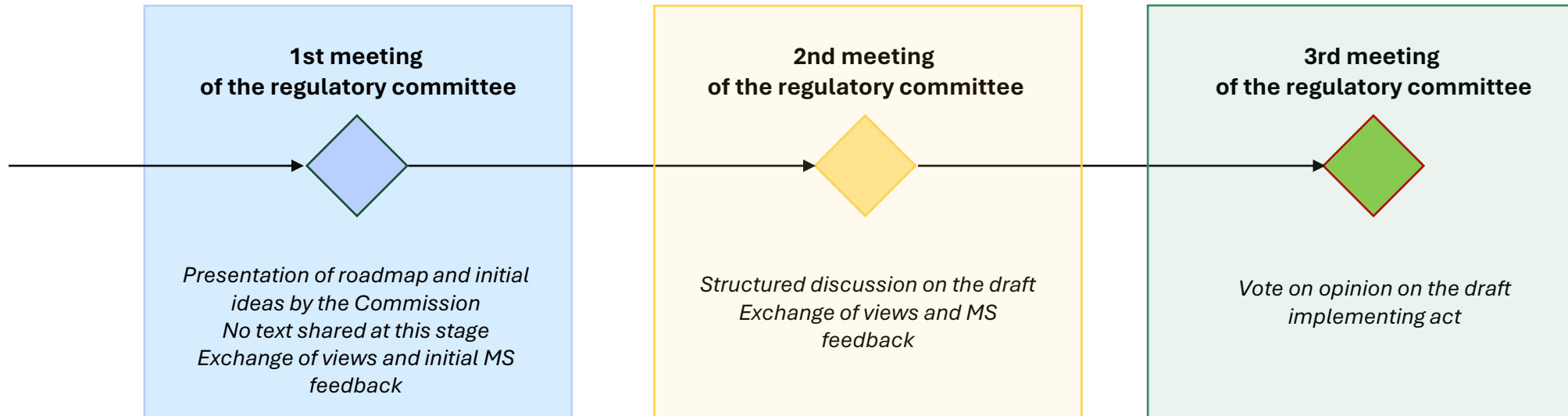


# Phases of implementation

- **Phase 1: Design and development**
  - 2 years - from now 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)



# Implementing acts



**Internal Preparatory Work**  
Internal preliminary drafting  
Mapping key issues and options

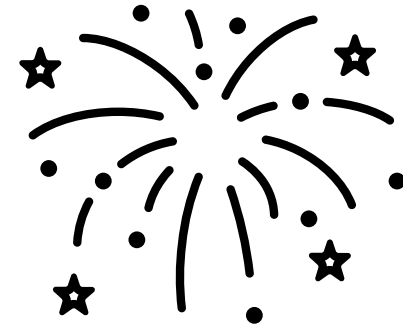
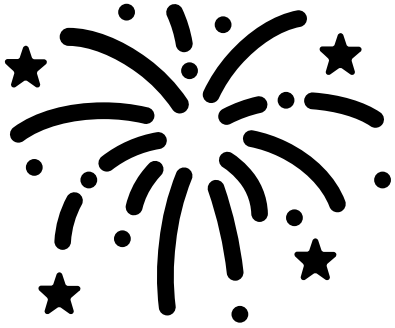
**Consolidation**  
Pre-consultation with key Commission services  
Finalisation of draft texts

**Finalisation**  
Formal Inter-Service Consultation  
Feedback mechanism  
Finalisation of the legal text





# Consensus built on the EHDS Board



The first Implementing Act on the EHDS Board (Article 92)  
received full support from Member States!



# EHDS Board and Steering Groups

## EHDS Board

- Strategic perspective on EHDS
- Non-binding guidelines, technical specifications, exchanges of best practices for DHAs, HDABs...
- Link to Stakeholder Forum

## Steering Groups

- Operational management and further development of the two infrastructures
- Relationship between MS and COM as solution provider



No hierarchical relationship between the Board and the Steering Groups in the EHDS Regulation. This is different from the current situation between eHN and eHMSEG!



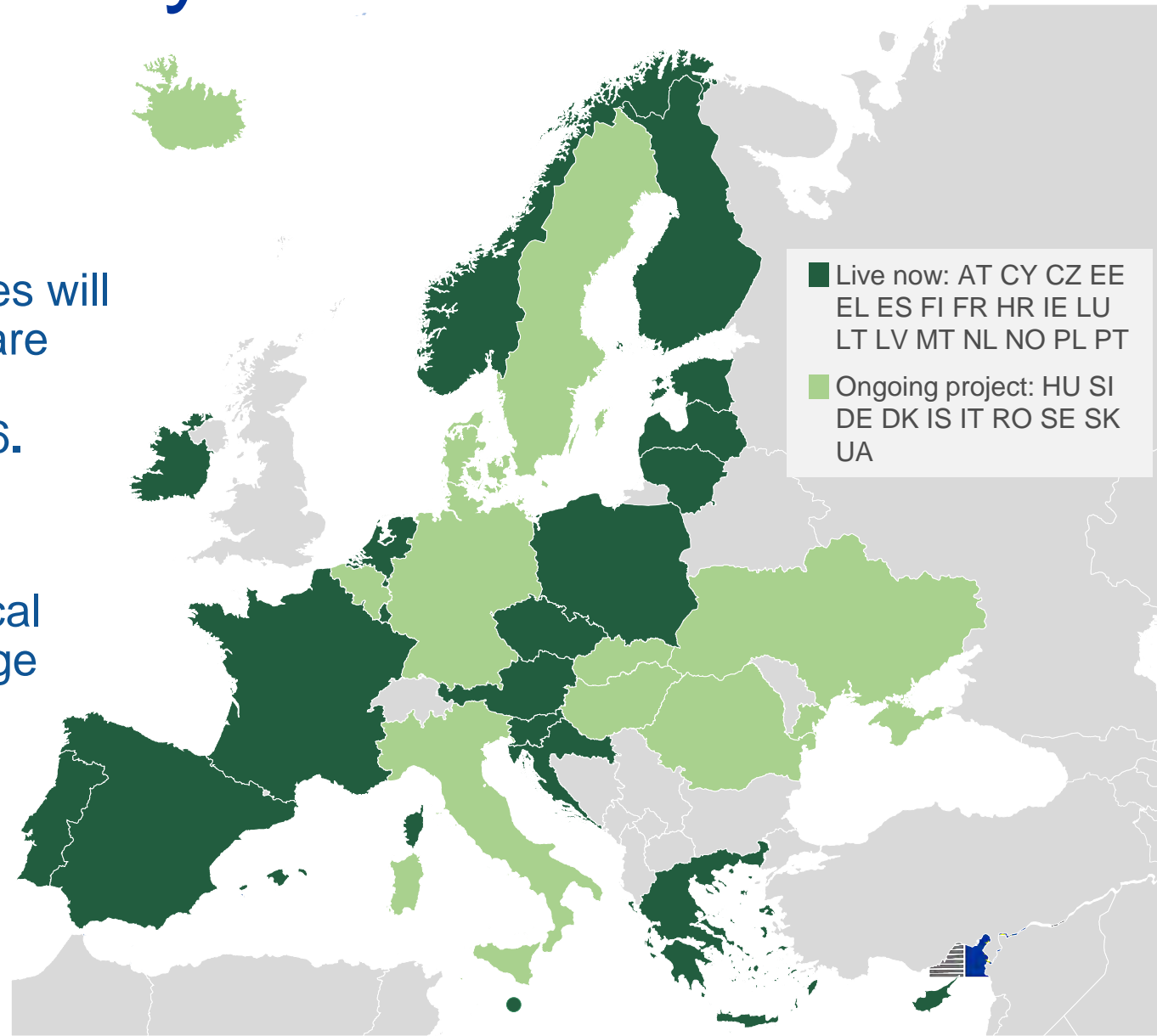
# MyHealth@EU



# MyHealth@EU (primary use of health data)

- 17 Member States are live (+Norway)
- The number of connected Member States will grow rapidly in the years ahead - there are plans for most Member States and EEA countries to join **MyHealth@EU** by 2026.
- Currently there are 2 services: Patient Summary and ePrescription
- This is being expanded to include Medical images, Laboratory results and Discharge reports

Last updated March 2026



# Adapting MyHealth@EU to the EHDS

## In work plan 2026

- To better prepare for the discussion to transition to FHIR, **proof-of-concept (POC) by Solution Provider on FHIR for eP and PS [article 15]**

## DL: Change proposals deadline September 30<sup>th</sup> 2026 (WAVE 11)

- Implementing the EEHRxF for PS and eP [article 15]
- Proxy services in the context of MyHealth@EU [article 4]
- Break the glass scenario in the context of MyHealth@EU [article 11(5)]
- Online pharmacies and MyHealth@EU [article 23(6)] – digital authentication
- Telemedicine [article 23(5)]
- Aligning identification requirements to EHDS Article 16
- Possibly other

## DL: Change proposals deadline September 30<sup>th</sup> 2027 (WAVE 12)

- Implementing the EEHRxF for MI, LRR, DR [article 15]

**Disclaimer:** The actual content will depend on implementing acts!

**Subject to outcome of the implementing act on the EEHRXF**

**Subject to outcome of the implementing act on electronic identification**



# EHR systems



# DTE and EU database for EHR systems



Electronic health record (EHR) systems and labelled wellness applications



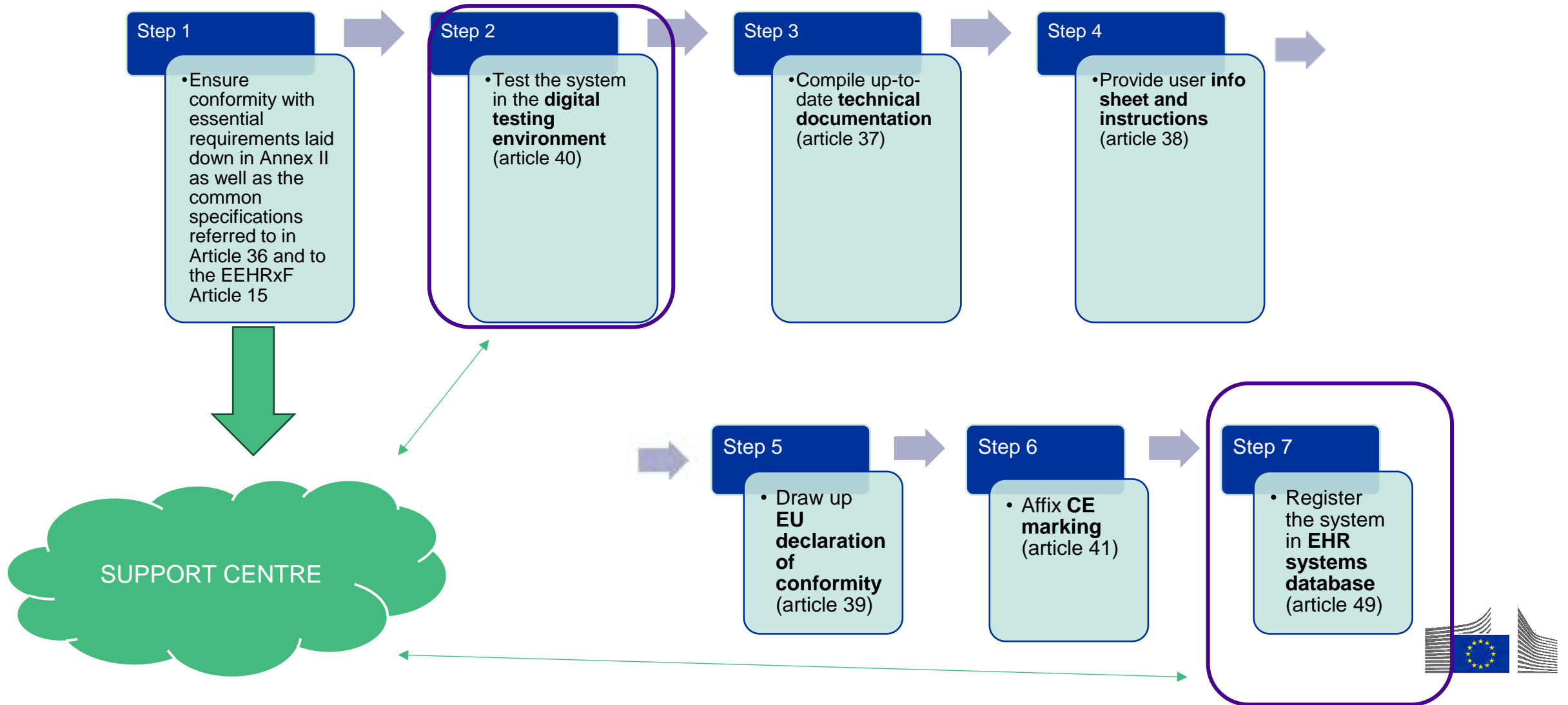
Medical devices and in vitro diagnostic medical devices claiming interoperability with



High-risk AI systems claiming interoperability with EHR systems

Registration will take place in the AI

# Certification of EHR systems (simplified)



# DTE and EU database for EHR systems

Release 3 of the DTE and EU database for EHR systems:  
<https://acceptance.data.health.europa.eu/ehr-systems/>



**Your feedback is much appreciated!**



# Support Centre specific objectives

1. Establish and operate a support centre for relevant stakeholders (SO1);
2. Create, manage, support and moderate a **community of practice** (CoP) (SO2);
3. Consolidate, publish and maintain **requirements** and **specifications** for the harmonized components of EHR systems and define validation rules for the assessment of harmonized components of electronic health record systems (SO3);
4. Develop an **integrated digital toolkit** for the harmonised components of EHR systems (SO4)



# To simplify the main tasks are:

- Community of Practice for EEHRxF (task 3)
- Requirements consolidation + validation artefacts (task 4)
- Digital tools (task 5)





**Happy birthday EHDs!!!**

# Thank you !



[https://health.ec.europa.eu/ehealth-digital-health-and-care\\_en](https://health.ec.europa.eu/ehealth-digital-health-and-care_en)

