

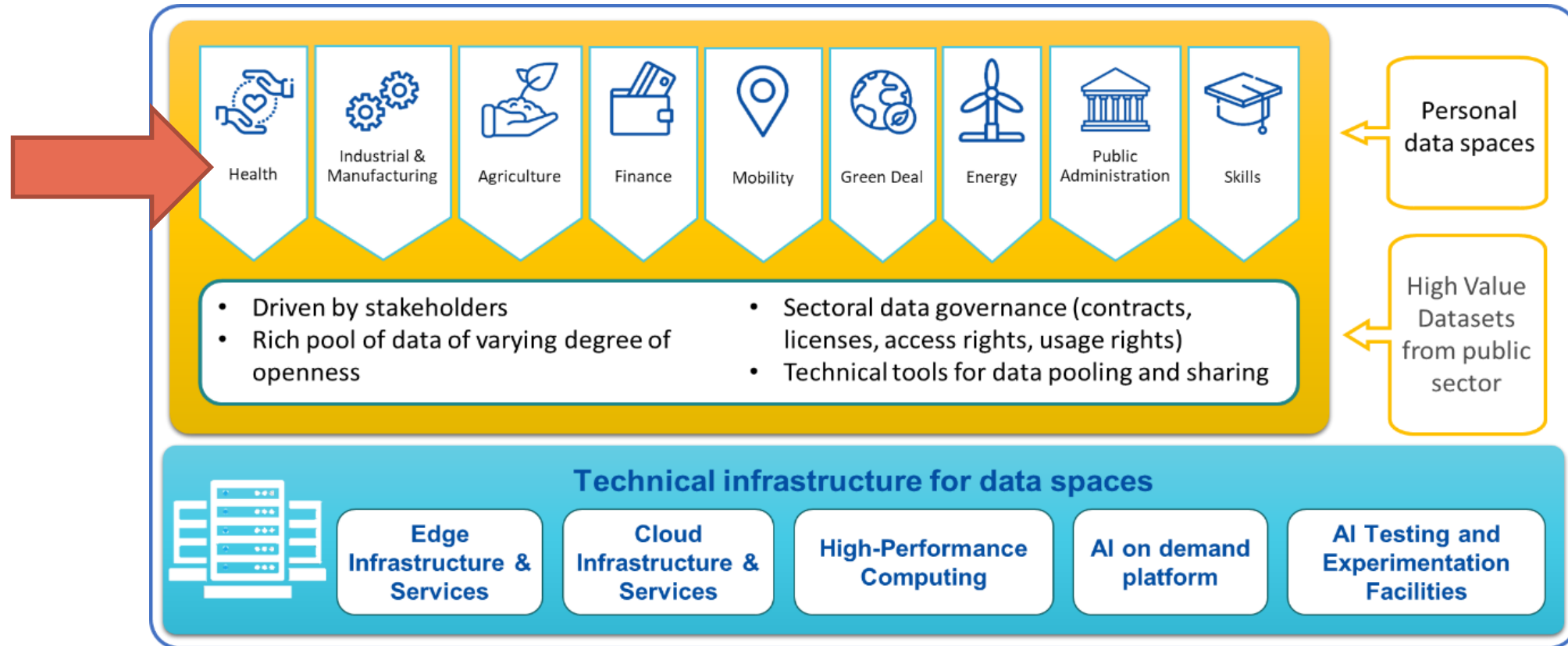


Implementazione del Regolamento e prossime call, di possibile interesse anche per i soggetti che forniscono soluzioni digitali per ospedali e operatori della salute.

Webinar spazio europeo dati sanitari

*Fulvia Raffaelli, HoU Digital Health,  
DG SANTE*

# Health is the first common EU data space



# Timeline for the EHDS regulation



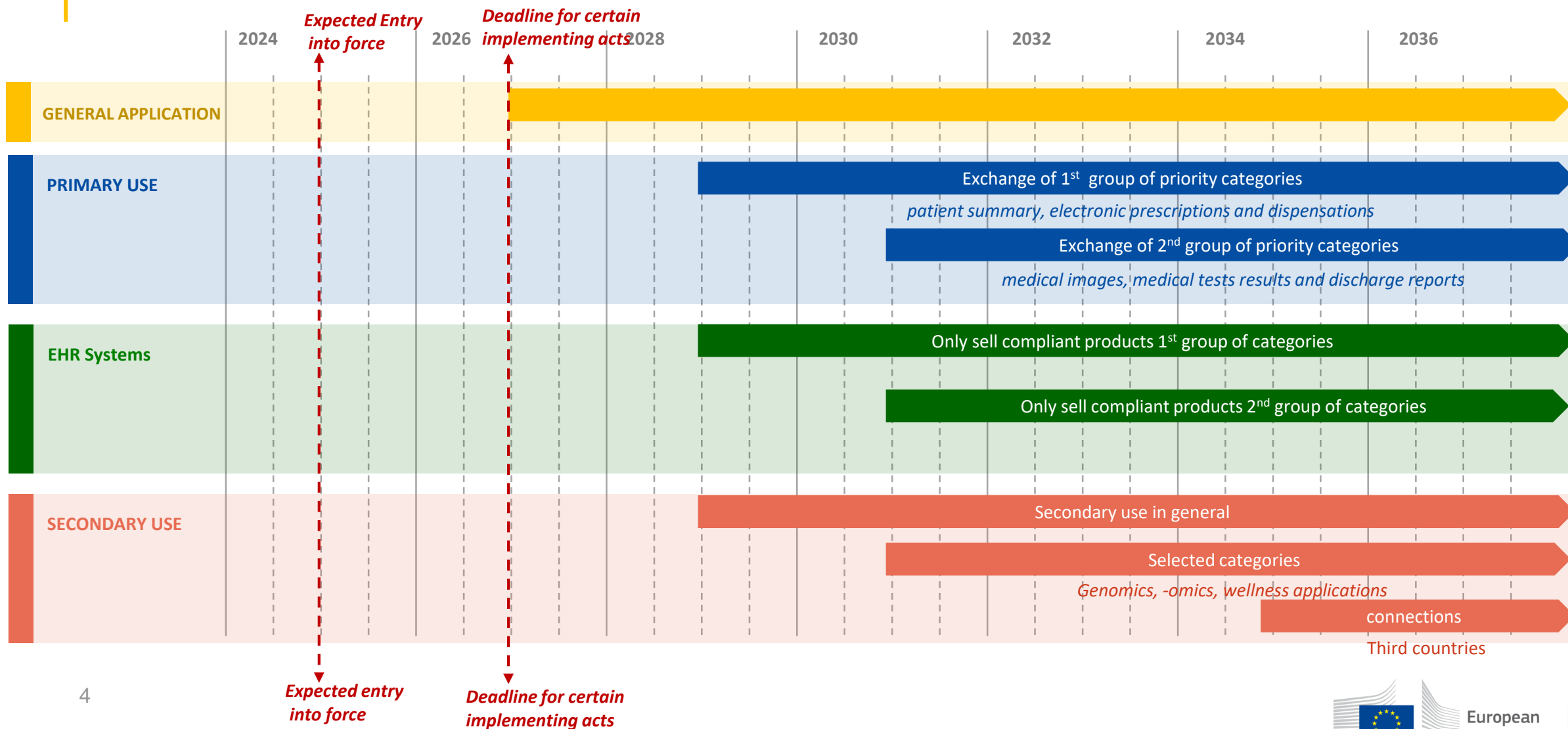
## Previous steps

- **Provisional agreement** during the fifth trilogue 14/03/2024.
- Examination of the compromise by MS in COREPER on 22/03/2024
- Vote in EP ENVI-LIBE joint committee meeting 09/04/2024
- Vote in plenary session in EP **24/04/2024**

## Is it done? Almost...

- Corrigendum procedure: Expected final English version 25/10 - Other language versions 27/10
- Expected final adoption in EP (Second November Plenary): Corrigendum procedure, as a package.
- Corrected text to be published in Official Journal of the EU (OJ), expected: **autumn 2024 or early 2025.**

# EHDS – Overall timeline for application

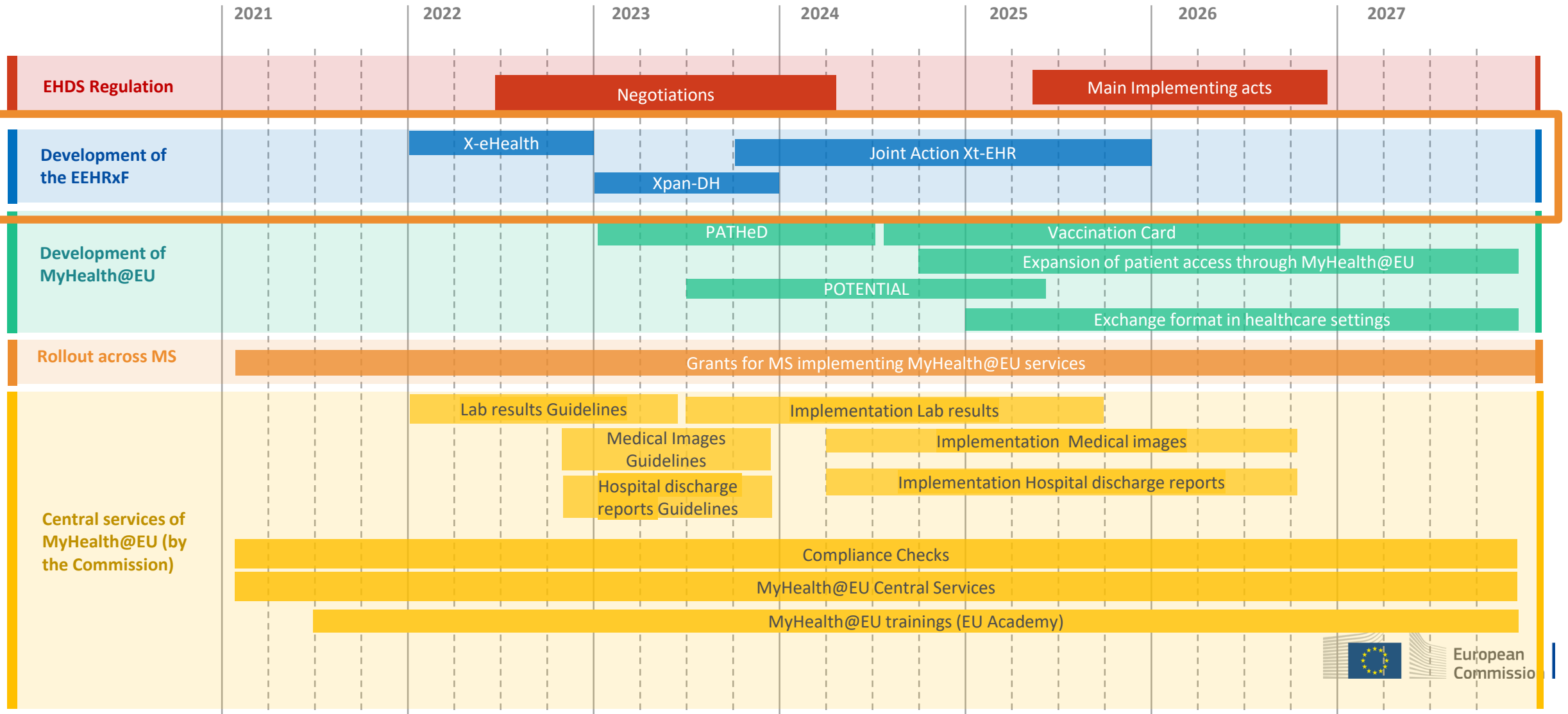


# Transition & Implementation Planning

By when will all of this happen?  
How do we get there?

# EHDS1 – Implementation

Timelines are indicative.



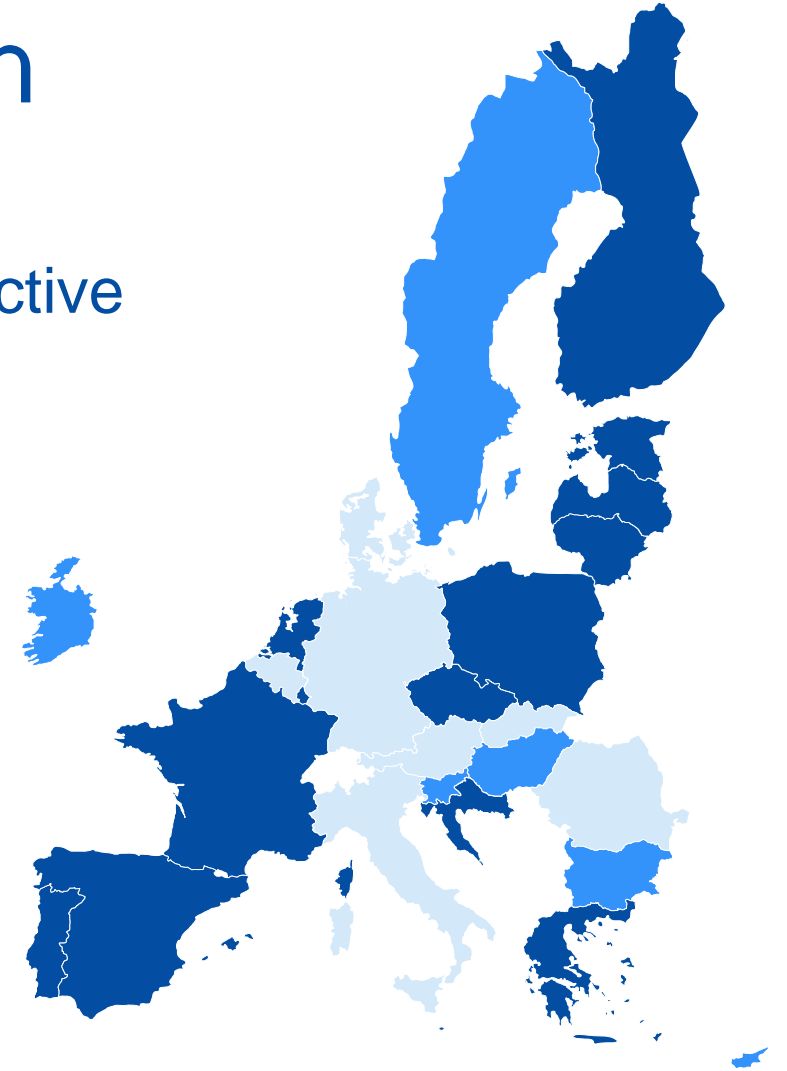
# Building on existing cooperation

## MyHealth@EU under Cross-border Healthcare Directive

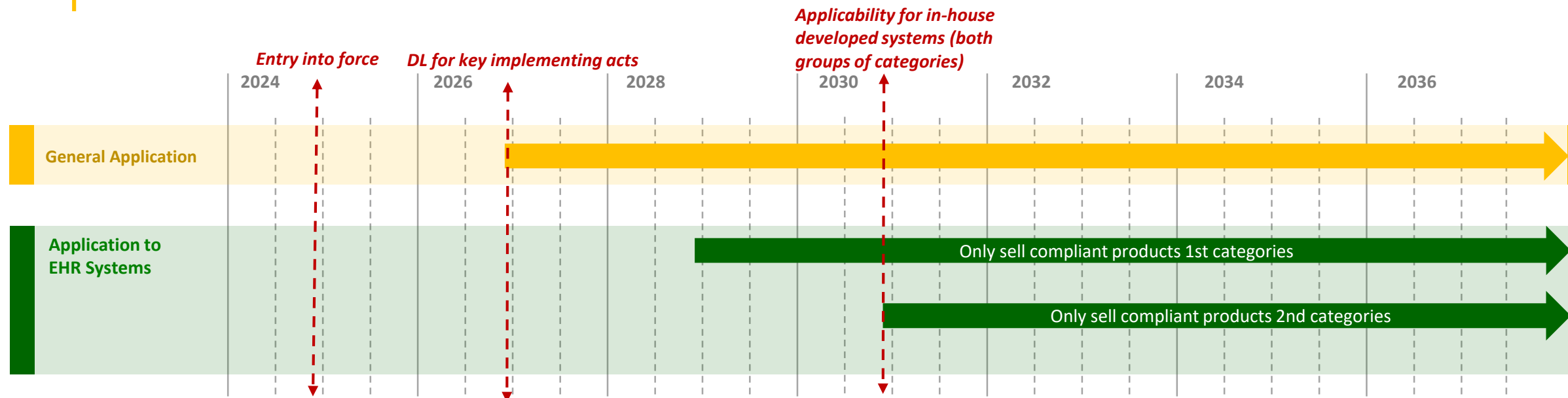
- **Voluntary system** for exchanging patient summaries, prescriptions and dispensations (≈ first group of priority categories)
- **Health Data** structured **according eHealth Network guidelines**
- **14 MS** live with at least one service, **6 more** scheduled to go live with first service(s) this year

## Evolution of MyHealth@EU for the EHDS

- Voluntary => mandatory
- New services
- New data categories



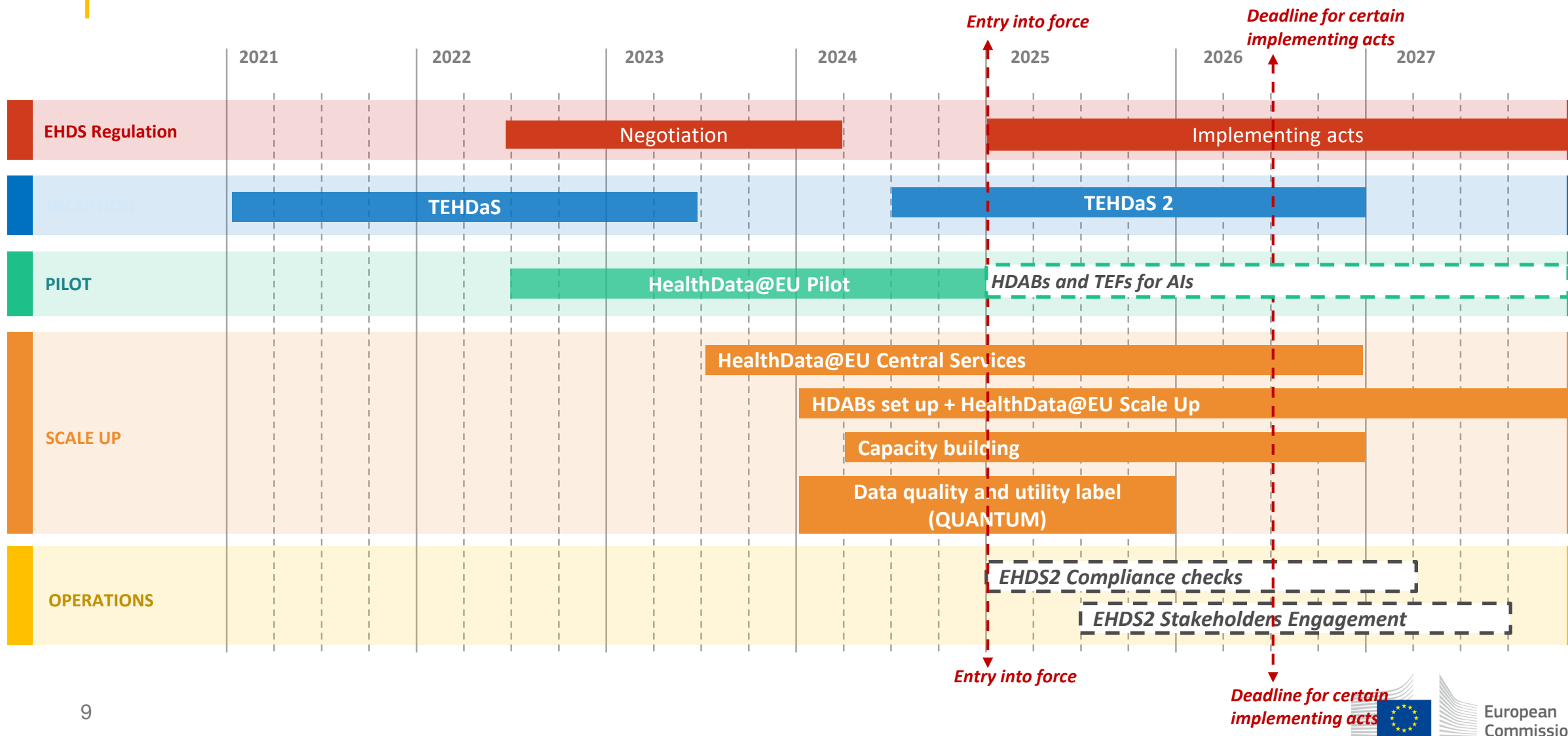
# Timeline for EHR requirements



- Common specifications for harmonised components and software package for automated testing environments to be available late 2026
- Leaving two more years to ensure conformity

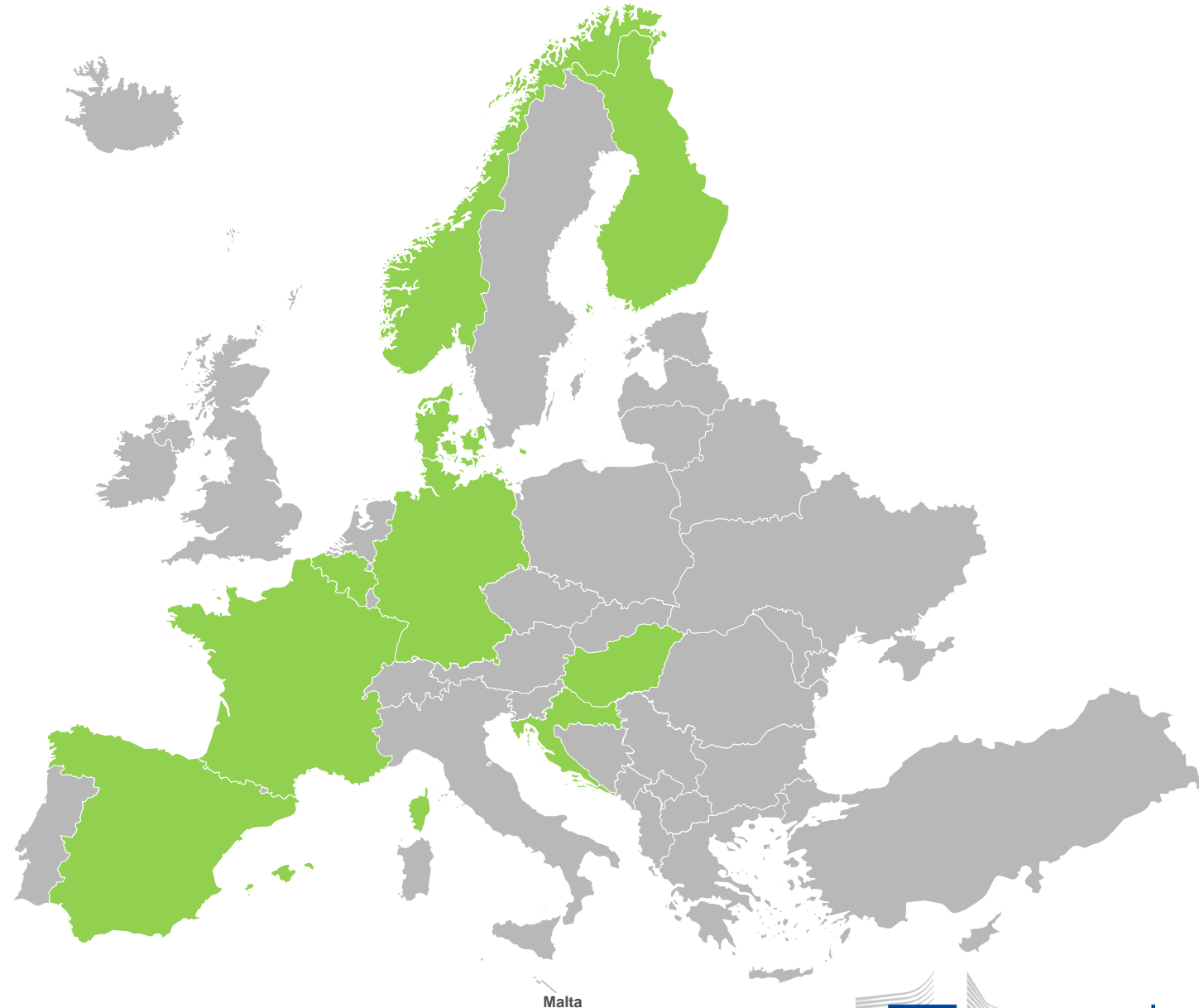


# EHDS2 – Roadmap



# HealthData@EU

- **Pilot**
  - Duration: Oct 2022 to Dec 2024
  - Budget: 5M€
  - Partners (17)
    - **HDABs:** FR, BE, DK, DE, NO, HU, HR, FI
    - **EU Health Agencies:** EMA; ECDC
    - **Data Holders and Data Users:** IACS, BBMRI, eBrains, Elixir, Orphanet, EUPHA
- **Scale up (HDABs set-up grants)**
  - Kick-off: 2024 Q1
  - Duration: ~ 36 months
  - Community of Practice



# What's up for 2025

## ❑ Projects starting in 2025

- HDABs and AI: developing and testing AI tools through HDABs
- Demonstrating the in-service use of the European Electronic Health Record Exchange Format in healthcare settings

## ❑ New calls in 2025

- EHDS2 Stakeholders engagement
- EHDS2 Compliance checks
- Support centre for the European Electronic Health Record exchange Format (EEHRxF) and for the interoperability and security of electronic health record systems

# Thank you



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