



European Health Data Space

Oslo Region European Office

Ole Gjerrestad
DG SANTE European Commission

National experts work for the EU, and are paid by their national Government

EFTA National Experts

There are approximately 1 000 national experts seconded to the European Commission from the 27 EU Member States, the EFTA States and other countries. See the full list and contact details of the EEA EFTA national experts in this section.

Nasjonale eksperter

Artikkel | Sist oppdatert: 21.11.2023

Gjennom EØS-avtalen og bilaterale ordninger har Norge nasjonale eksperter i Europakommisjonen, EUs utenrikstjeneste (EEAS) og EUs byråer i Europa, på lik linje med EUs medlemsland.

En nasjonal ekspert er en person som er utlånt fra nasjonale forvaltninger til EUs institusjoner for en avgrenset periode på inntil fire år. Gjennom EØS-avtalen og bilaterale ordninger har Norge mulighet til å ha nasjonale eksperter i blant annet Europakommisjonen, EUs utenrikstjeneste (EEAS) og EUs byråer i Europa, på lik linje med EUs medlemsland.

[> Se mer om to nasjonale eksperter](#)

DG SANTE - Unit C1 – Digital Health



- C1 Digital Health:**
- Primary data
 - Secondary data
 - AI

D DEPUTISING FOR THE DIRECTOR
A MIRROR ENTITY IN AN EXECUTIVE AGENCY
 ENTITIES LOCATED IN LUXEMBOURG
 ENTITIES LOCATED IN IRELAND (GRANGE)
 SECONDED MANAGER: ANNUKKA JALA, SECONDED TO THE CABINET OF COMMISSIONER KYRIAKIDES

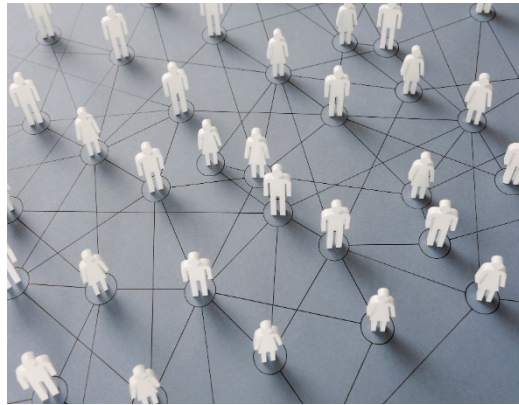
Agenda

1. Introduction to the European Health Data Space
2. Cross border exchange of primary health data
3. European requirements for Electronic health record systems
4. Sharing of secondary health data through common European infrastructures
5. Implementation of the European Health Data Space

The European Health Data Space

Sets out rules, common standards, infrastructures and a governance framework for the use of electronic health data for healthcare, research, innovation and policy making

Empower individuals to access and control their personal health data



Ensure a consistent framework for the use of individuals' health data for research, innovation, policy-making and regulatory activities

Unleash the data economy by fostering a genuine single market for digital health services and products (EHR systems)



EHDS adoption process

- Legislative proposal from the European Commission in May 2022
- Negotiations within co-legislators Parliament and Council until December 2023
- Trilogue negotiations ended with a provisional agreement on 15. March
- Agreement adopted by Council in March and expected by Parliament end of April
- First implementing acts expected adopted autumn 2026
- Deadline for first wave of implementation 2028
- Deadline for second wave of implementation 2030



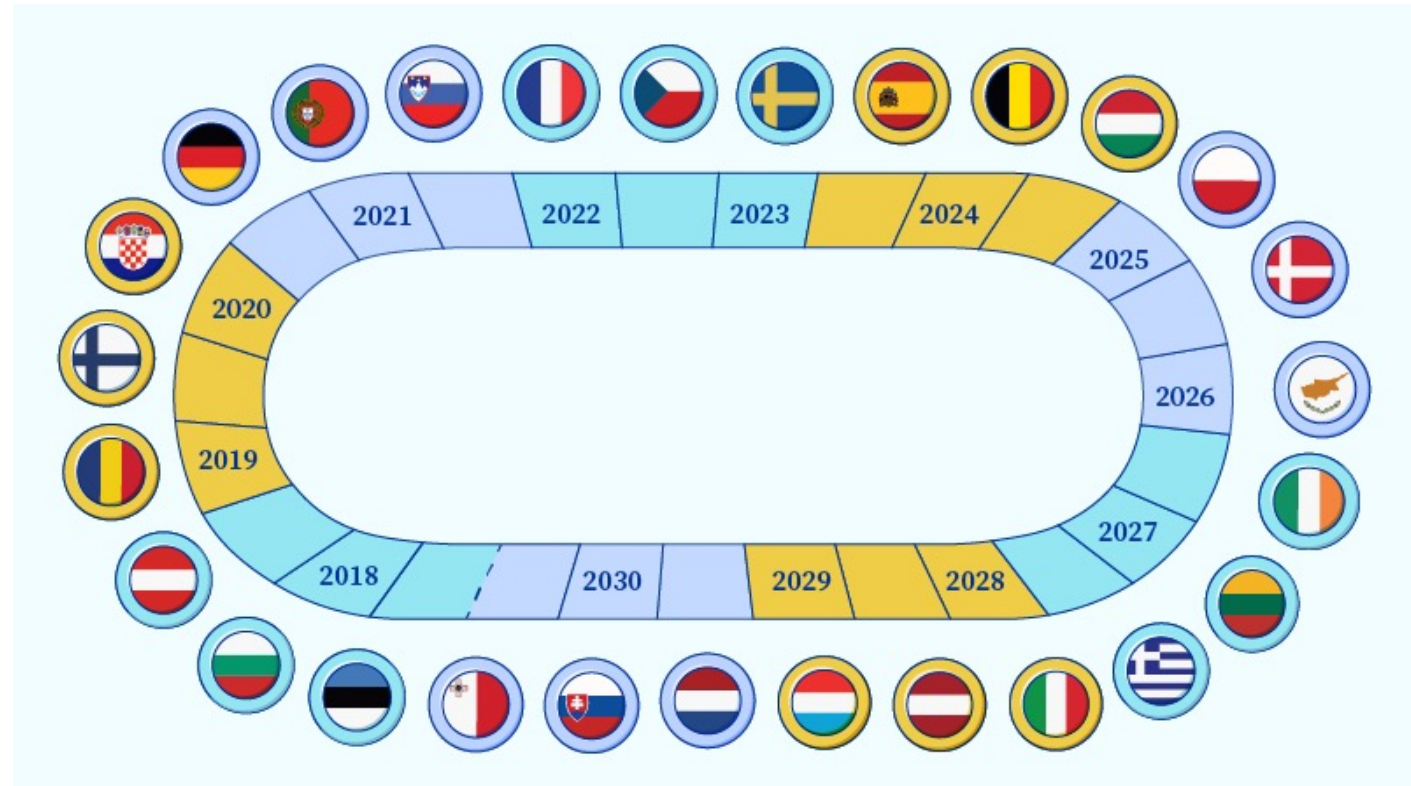
**Rapporteur ENVI
Tomislav SOKOL**

European Parliament
Committee on the
Environment, Public
Health and Food
Safety



**Rapporteur LIBE
Annalisa Tardino**

Civil Liberties,
Justice and Home
Affairs

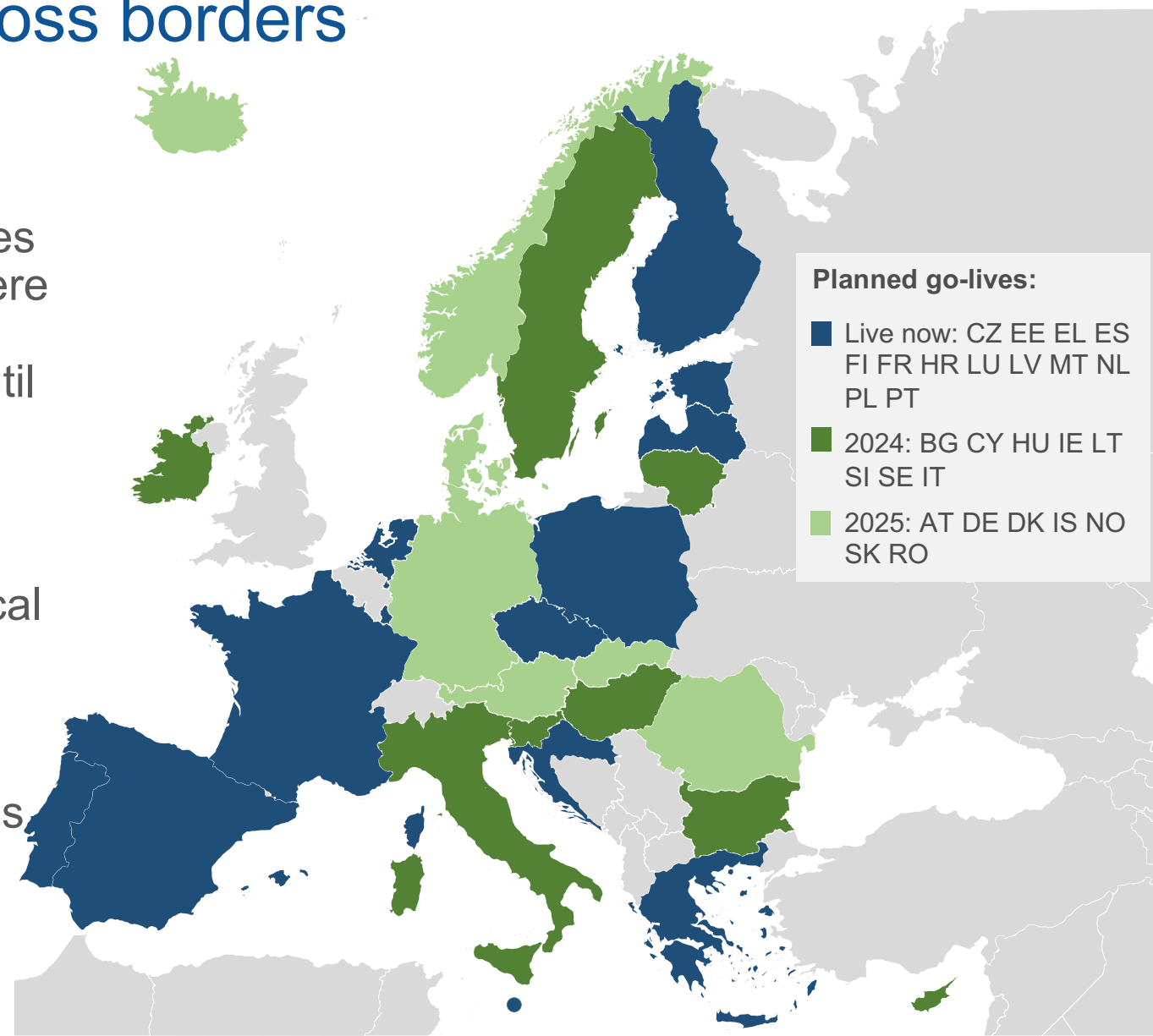


Primary use of health data



Myhealth@EU and data across borders

- Currently 13 Member States are live
- 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** until 2025.
- Currently there are 2 services: Patient Summary and ePrescription
- This is being expanded to include Medical images, Laboratory results, Discharge reports and other health information categories
- A Pilot project will explore Patient Access to their health data in MyHealth@EU

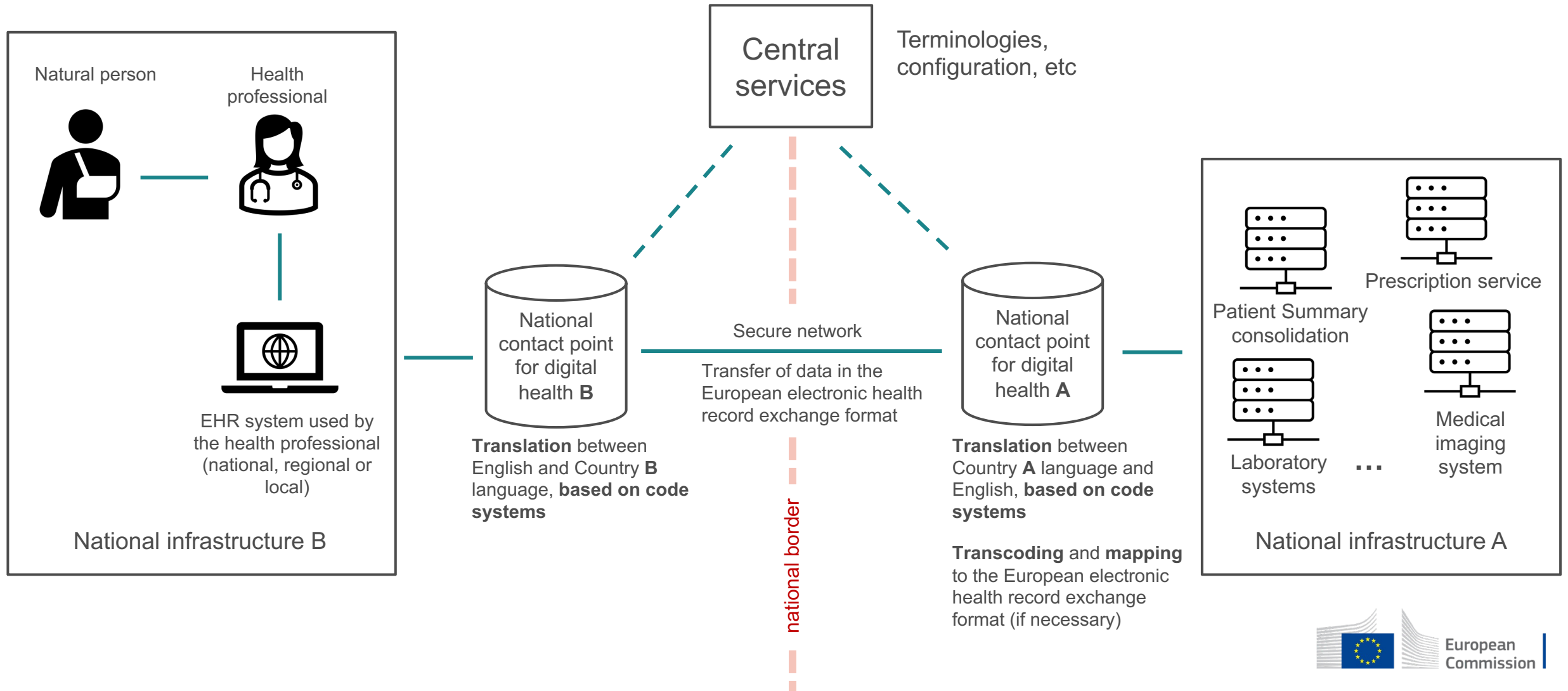


Cross-border electronic prescription in action

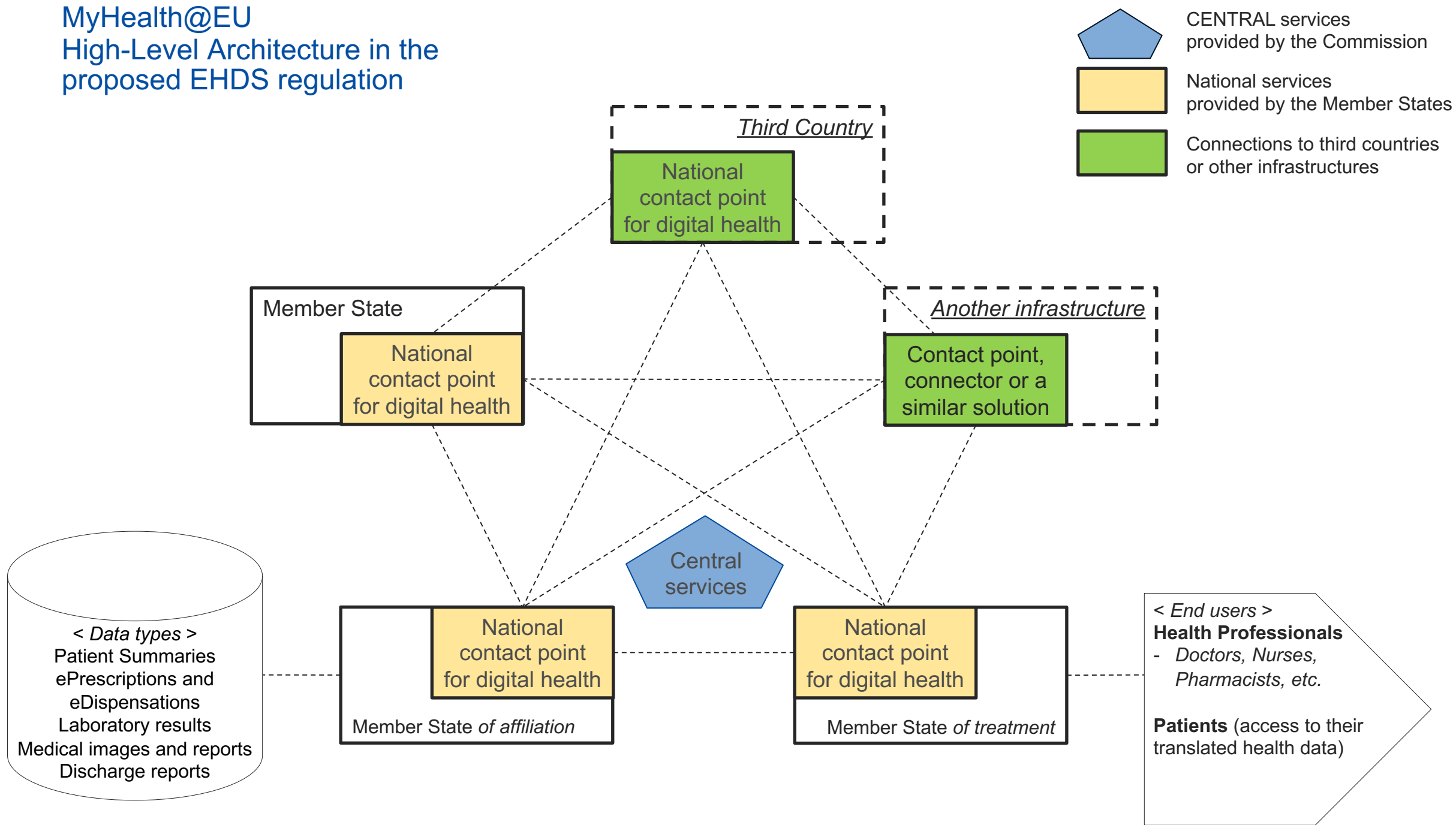


MyHealth@EU

Basic data flow in a face-to-face healthcare service



MyHealth@EU High-Level Architecture in the proposed EHDS regulation



MyHealth@EU roadmap

EHDS regulation

Mandatory participation in MyHealth@EU for all Member States with transitional periods for different services (pending decision by the European Parliament)

Pilot on Patient Access

PATHeD: enable citizens to access health data in MyHealth@EU (Jan 2023-Jun 2024).



New services

Lab results (2025), Medical imaging (2026), Hospital discharge reports (2026), etc.

Enhancement of available services using EU Digital Identity Wallet technology

POTENTIAL Large-Scale Pilot (includes the ePrescription use case)

New Member States joining MyHealth@EU

More Points of Care to be connected (2023 and beyond)

Electronic Health Records systems

Chapter III EHR systems and wellness applications (Commission proposal)

- **Definitions**

- ‘EHR system’ (electronic health record system) means any appliance or software intended by the manufacturer to be used for storing, intermediating, importing, exporting, converting, editing or viewing electronic health records;

- **Scope**

- Covers both *placed on the market or put into service*
- Medical devices and high-risk AI systems claiming interoperability with EHR systems: need to comply with their respective regulations and with the essential requirements under the EHDS

Chapter III EHR systems and wellness applications (Commission proposal)

- **Self-certification - Manufacturers must (non-exhaustive list):**
 - ensure that their EHR systems are in conformity with the **essential requirements** and with the **common specifications**;
 - draw up the **technical documentation** of their EHR systems;
 - ensure that their EHR systems are accompanied, free of charge for the user, by the **information sheet** provided and clear and complete **instructions for use**;
 - draw up an **EU declaration of conformity**;
 - affix the **CE marking**;
 - comply with the **registration obligations**;

Secondary Use of Health Data

Data User journey



Data discovery

What health data exists to support my research?

Permit application

Can I use this data for my research project?

Data preparation

Issue permit and make data ready for use, ensuring data quality and privacy.

Data provision

Give access to Secure Processing Environment

Data use

Analyse and process data

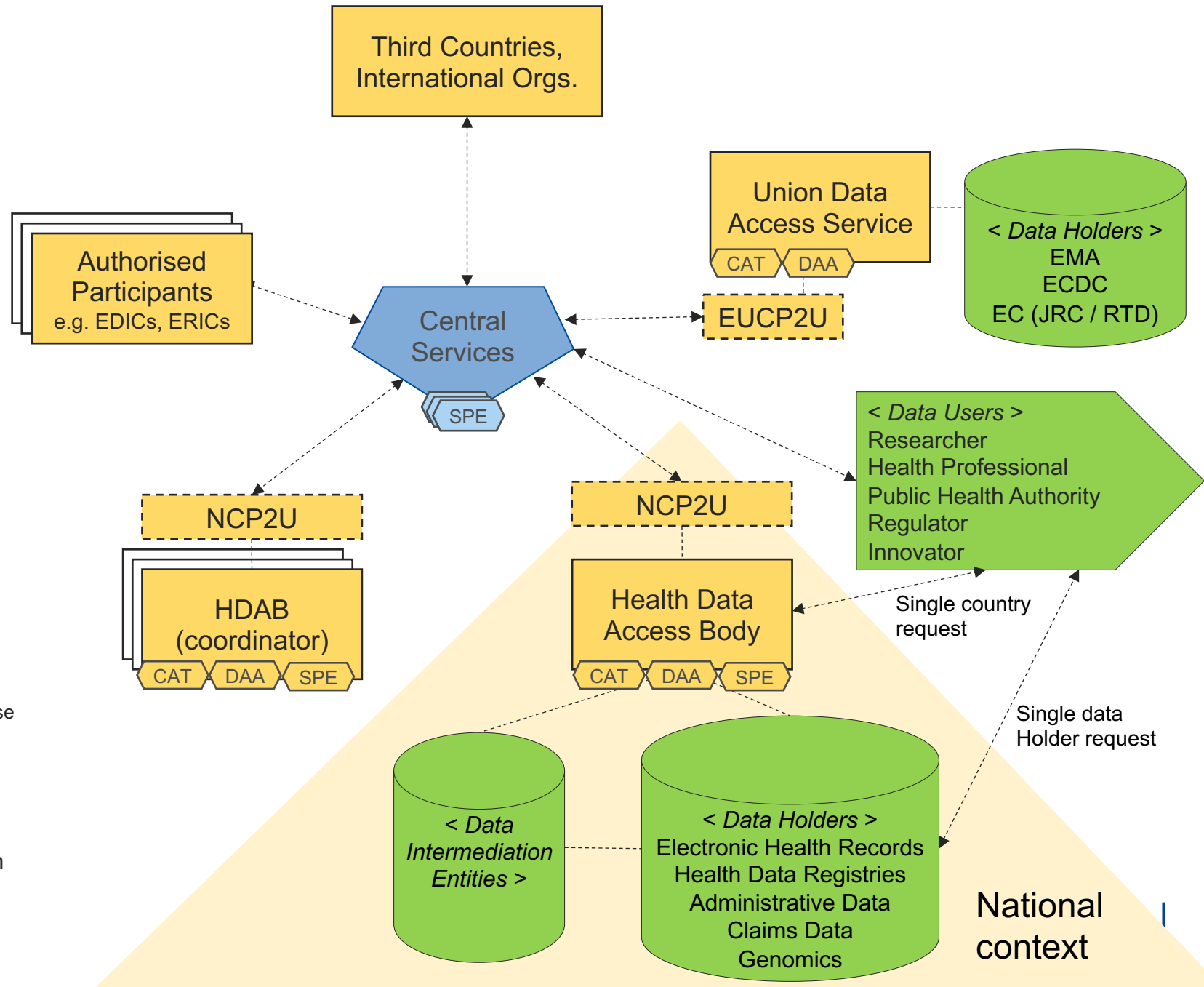
Results output


Publish of results, ensuring privacy and verifiability





Cross-border secondary use infrastructure

HealthData@EU



 Central support services provided by EC


 NCP2U - National Contact Point for Secondary Use
EUCP2U - European Contact Point for Secondary Use

 Data access services

 CAT National dataset/metadata catalogue

 DAA Data Access Application Management system

 SPE Secure Processing Environments

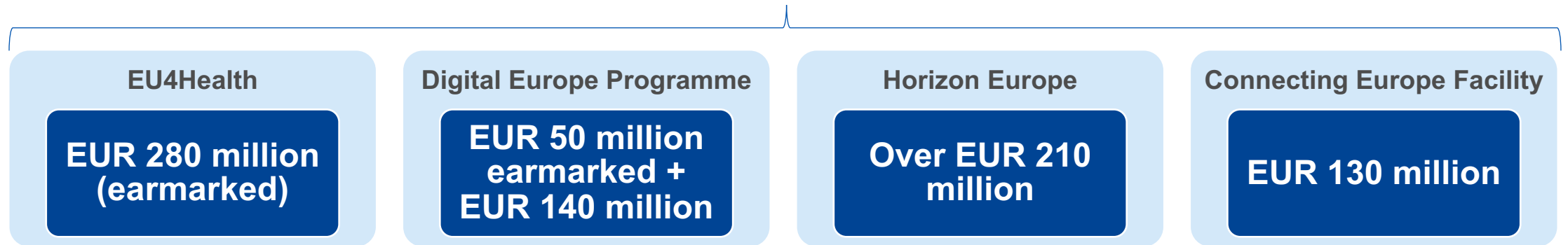
 Local services provided by/to local partners

National context

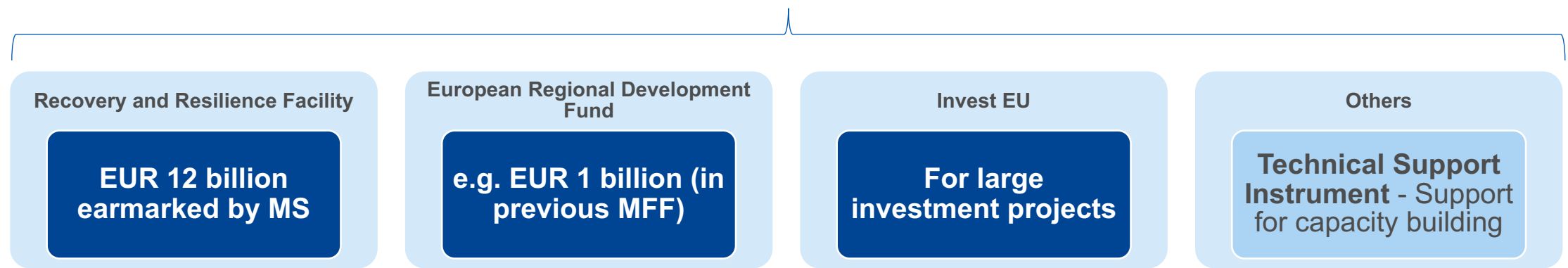
Implementation of EHDS

EU financing of the EHDS 2021-2027

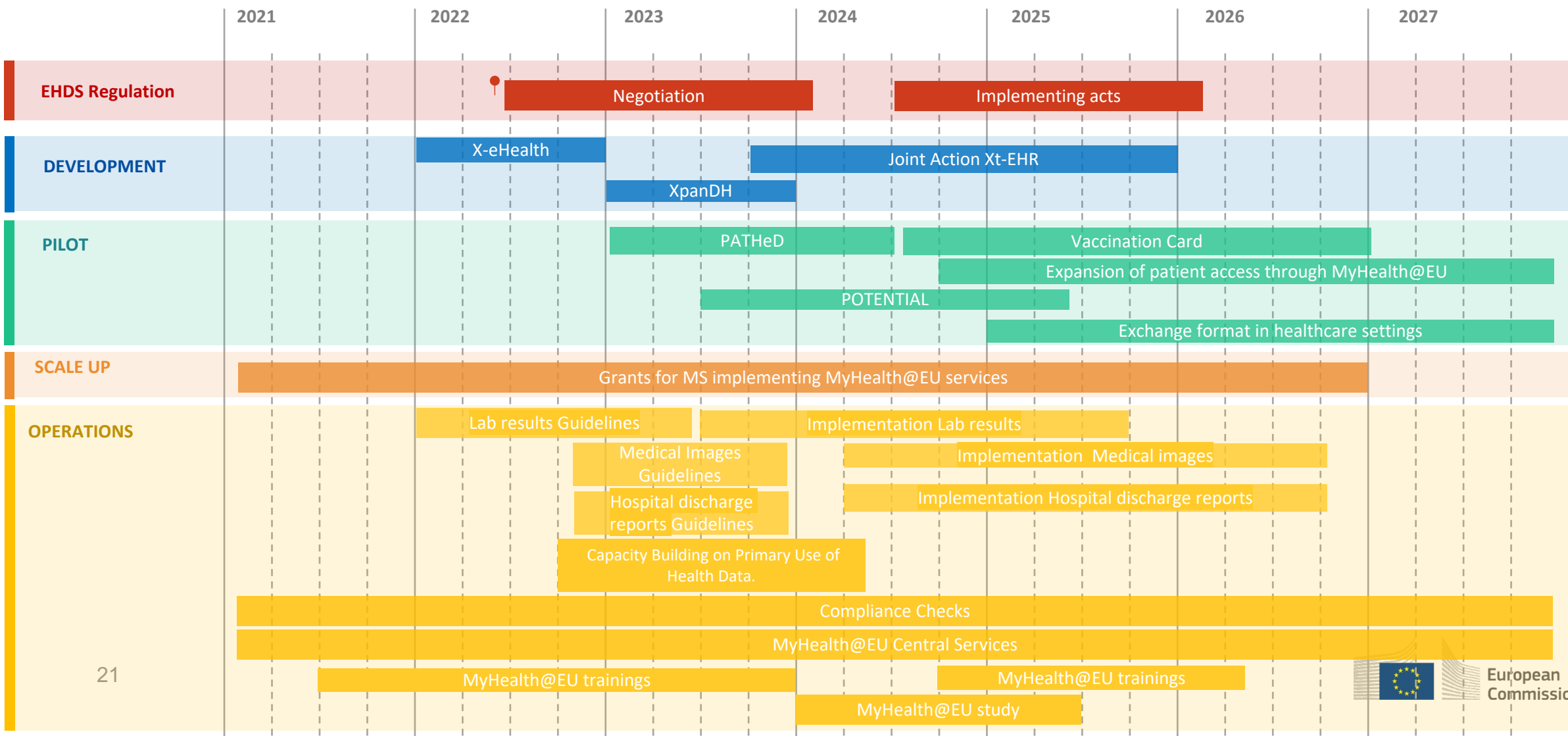
EUR 810M



EU support for national investments



Primary use of data – Overall timeline



EHDS2 – Overall timeline

