European Health Data Space
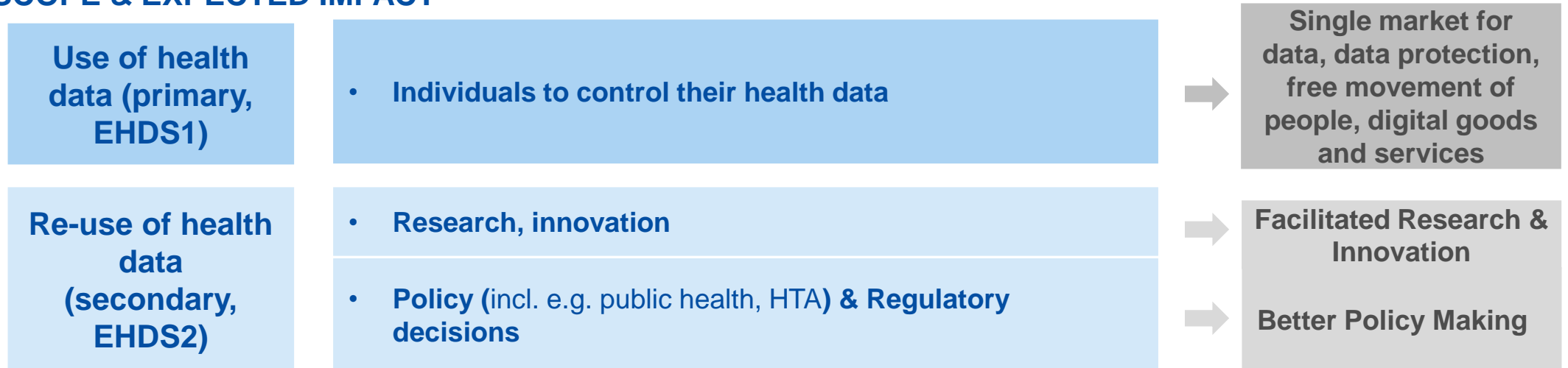
European Health Data Space (EHDS)

▶ OBJECTIVES

> **Timely and simplified *exchange of* and *access to* health data**

▶ SCOPE & EXPECTED IMPACT

|		
Use of health data (primary, EHDS1)	• **Individuals to control their health data**	**Single market for data, data protection, free movement of people, digital goods and services**
Re-use of health data (secondary, EHDS2)	• **Research, innovation**	**Facilitated Research & Innovation**
	• **Policy (**incl. e.g. public health, HTA**) & Regulatory decisions**	**Better Policy Making**

European Commission

Main problems

Individuals have difficulty accessing and controlling their health data

Healthcare professionals have difficulty accessing health data
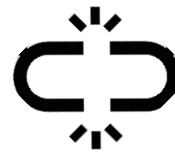
Providers of digital health services and products face barriers

Policy makers and regulators cannot easily access health data

Limited innovation takes place on the basis of health data

European Commission

Objectives

Empower citizens to have control over their health data

Assist policy makers and regulators in accessing relevant health data

Better diagnosis and treatment, improved patient safety, continuity of care and improved healthcare efficiency

Better health policy, greater opportunities for research and innovation

Health data from apps and medical devices

Facilitate access to health data for innovators in industry

Health data in registries

Electronic health records

Enable healthcare professionals to have access to relevant health data

Grant access to health data for researchers

EHDS and other EU regulatory frameworks

Cross-border healthcare Directive

GDPR

Data Governance Act

AI Act

Data Act

MDR

eIDAS
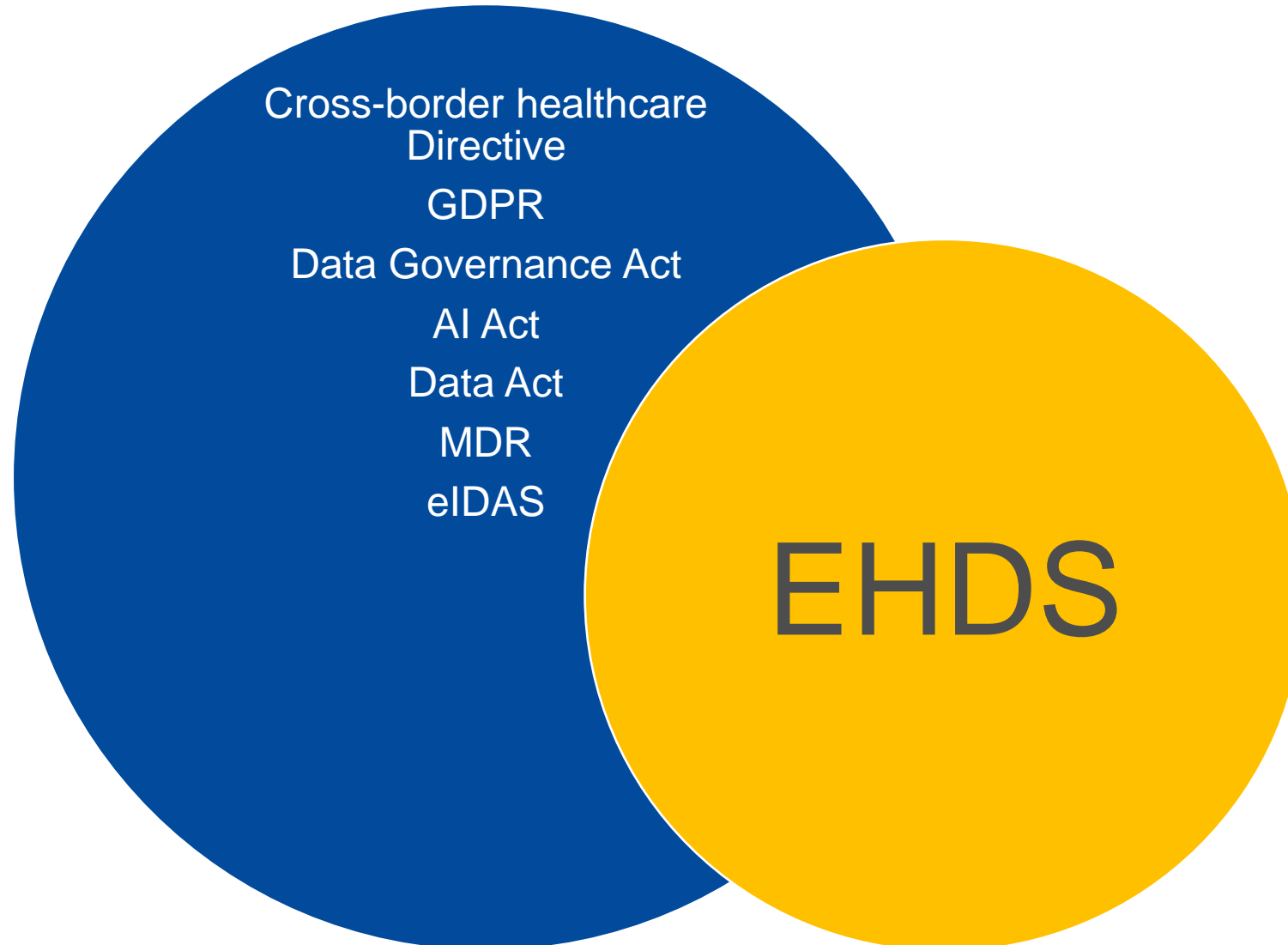
EHDS

The scope of EHDS

Strengthens the rights of individuals in relation to greater control over their electronic health data:

Access, share health data with health professionals nationally or cross-border, *add* information, *rectify* errors, *restrict* access, *know* what health professional accessed data, issue and accept health data *in a common European format,* strengthen interoperability.
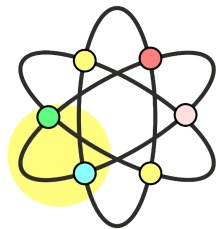
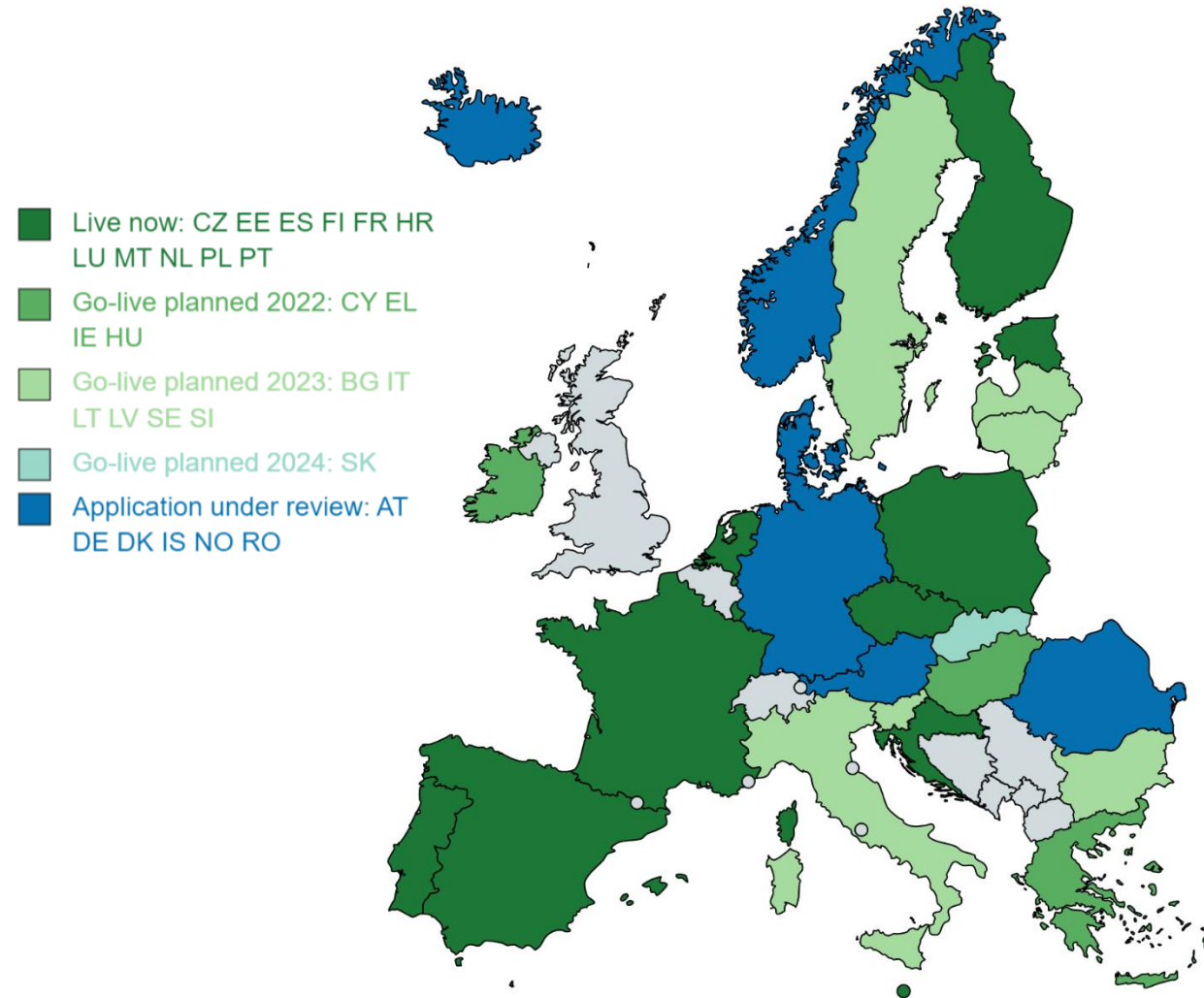**Rules for electronic health record systems (EHR systems)**

Rules and mechanisms supporting the secondary use of electronic health data

Mandatory cross-border infrastructures for primary and secondary use of health data

- **MyHealth@EU**
- **HealthData@EU**

MyHealth@EU

Live now: CZ EE ES FI FR HR LU MT NL PL PT

Go-live planned 2022: CY EL IE HU

Go-live planned 2023: BG IT LT LV SE SI

Go-live planned 2024: SK

Application under review: AT DE DK IS NO RO

- Currently 11 Member States are live

- The number of connected Member States will grow rapidly in the years ahead - there are plans for all Member States 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 letters, Rare disease data and other health information categories

- A Pilot project will explore Patient Access to their health data in MyHealth@EU

European Commission

Primary use of health data

- The legislative proposal will introduce:

  - Rights of individuals and healthcare professionals to access health data

  - Minimum, scalable requirements for specific health data categories in EHR systems through self-certification, registered in an EU database and voluntary labelling of wellness apps

  - Mandatory deployment of MyHealth@EU with a transition period for different services
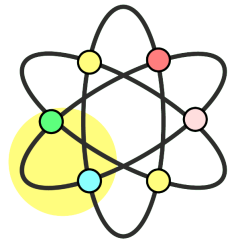
  - Designation of national digital health authorities, working in EU comitology towards binding Delegated and Implementing Acts

European Commission

Secondary use in the EHDS

Reuse of health data by researchers, policy-makers and industry

Health data from patients and healthcare professionals

Rules, protocols and governance

Granting researchers, policy-makers and industry access to health data across borders in an interoperable, digital format

European Commission

Secondary use of health data

The legislative proposal will introduce:

- A set of minimum health data categories available for secondary use that can be used for defined purposes (EU legal base) **+ prohibited purposes**

- Mandatory designation of national Health Data Access Bodies connected through a federated EU infrastructure, with duties for data holders

- Provisions on fees

- Provisions on dataset description and their quality and EU dataset catalogue

European Commission

HealthData@EU
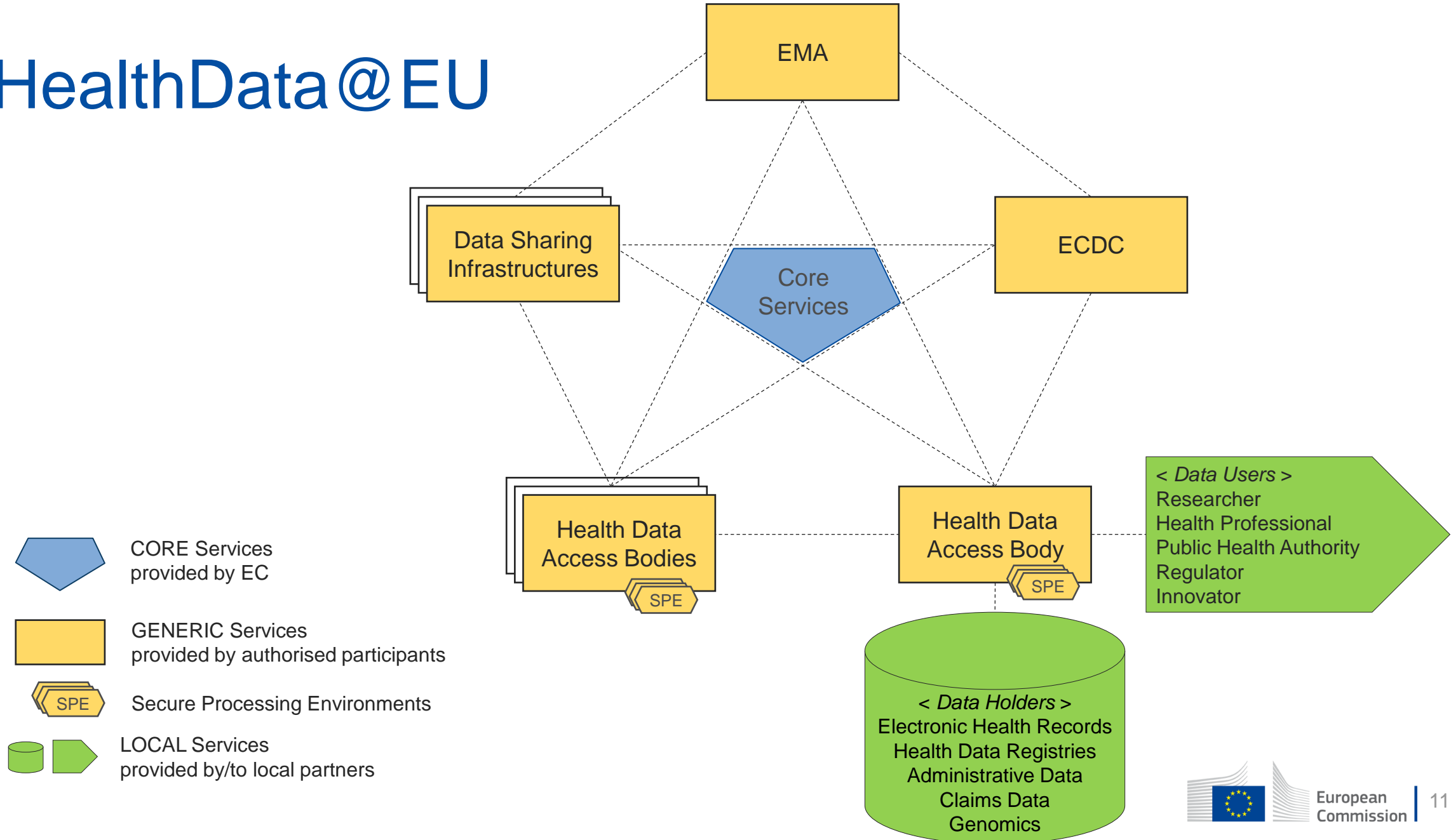
Entering into force

- The Regulation will start applying **one year** after its adoption following the negotiations between co-legislators.

- However, the proposal foresees **several transitional periods** for the application of different elements of the proposal, especially related to the primary use of health data (*1 year from the entry into application of the Regulation for patient summaries and ePrescriptions and 3 years for images and image reports, laboratory results and discharge reports*)

European Commission

Supporting studies and input

The EHDS proposal was drafted on the basis of input from:

- The Public Consultation

- Different studies (Nivel study, Regulatory gaps study, Impact Assessment, Infrastructure study, MonitorEHR study)

- Feedback from the eHealth Stakeholder Group

- Valuable contributions from TEHDAS and the eHN

Next steps

- The Regulation will be negotiated with the Council of the EU and European Parliament. Meanwhile, the role-out continues of MyHealth@EU, as well as a Joint Action on the primary use and a Pilot on the secondary use.

- More information can be found online: European Health Data Space (europa.eu)

- To get involved, please reach out to hugo.van-haastert@ec.europa.eu

Thank you!

Thank you

European Commission