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**

MEANS

Legal / Governance

Quality of data

Infrastructure

Capacity building/digitalisation (MFF)

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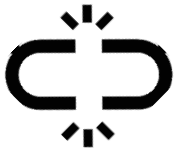
Main problems

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

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What are the objectives?

Empower individuals to control their health data

Foster a single market for digital health services and products

Ensure interoperability and security of health data and a level playing field for manufacturers

Unleash the power of the health data economy

Ensure a consistent and efficient framework for the reuse of health data for research, innovation, policy-making and regulatory activities

User perspectives

Empower citizens to have control over their health data

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

Enable healthcare professionals to have access to relevant health data

Health data from apps and medical devices

Health data in registries

Electronic health records

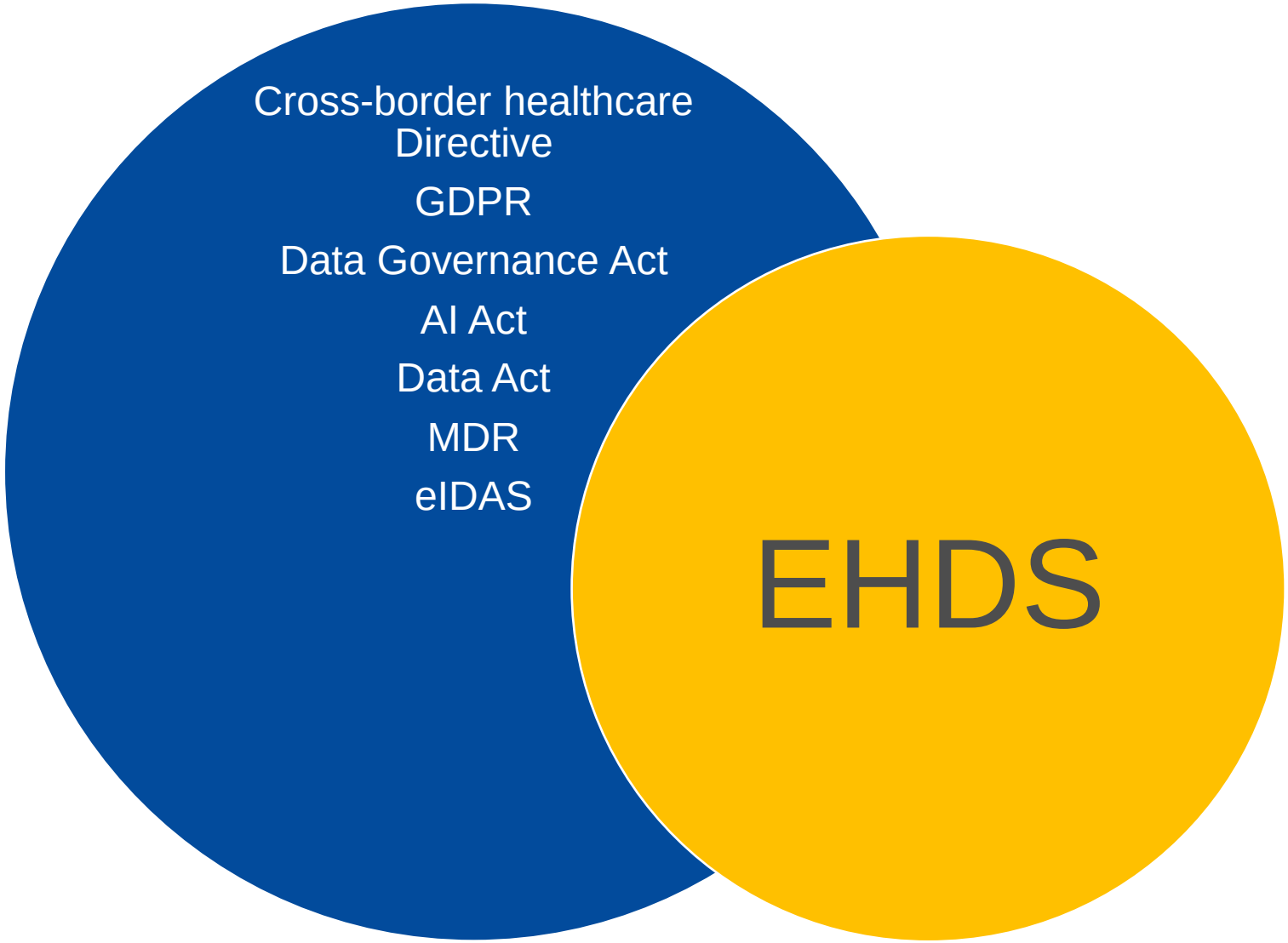
Assist policy makers and regulators in accessing relevant health data

Facilitate access to health data for innovators in industry

Grant access to health data for researchers

Better health policy, greater opportunities for research and innovation

EHDS and other EU regulatory frameworks



The scope of EHDS

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

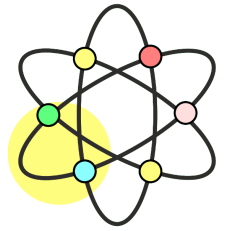
Access, share health data with health professionals nationally or cross-border, add information, rectify errors, restrict access, know what health professional accessed data, issue and accept health data in a common European format, strengthen interoperability.

Rules for electronic health record systems (EHR systems)

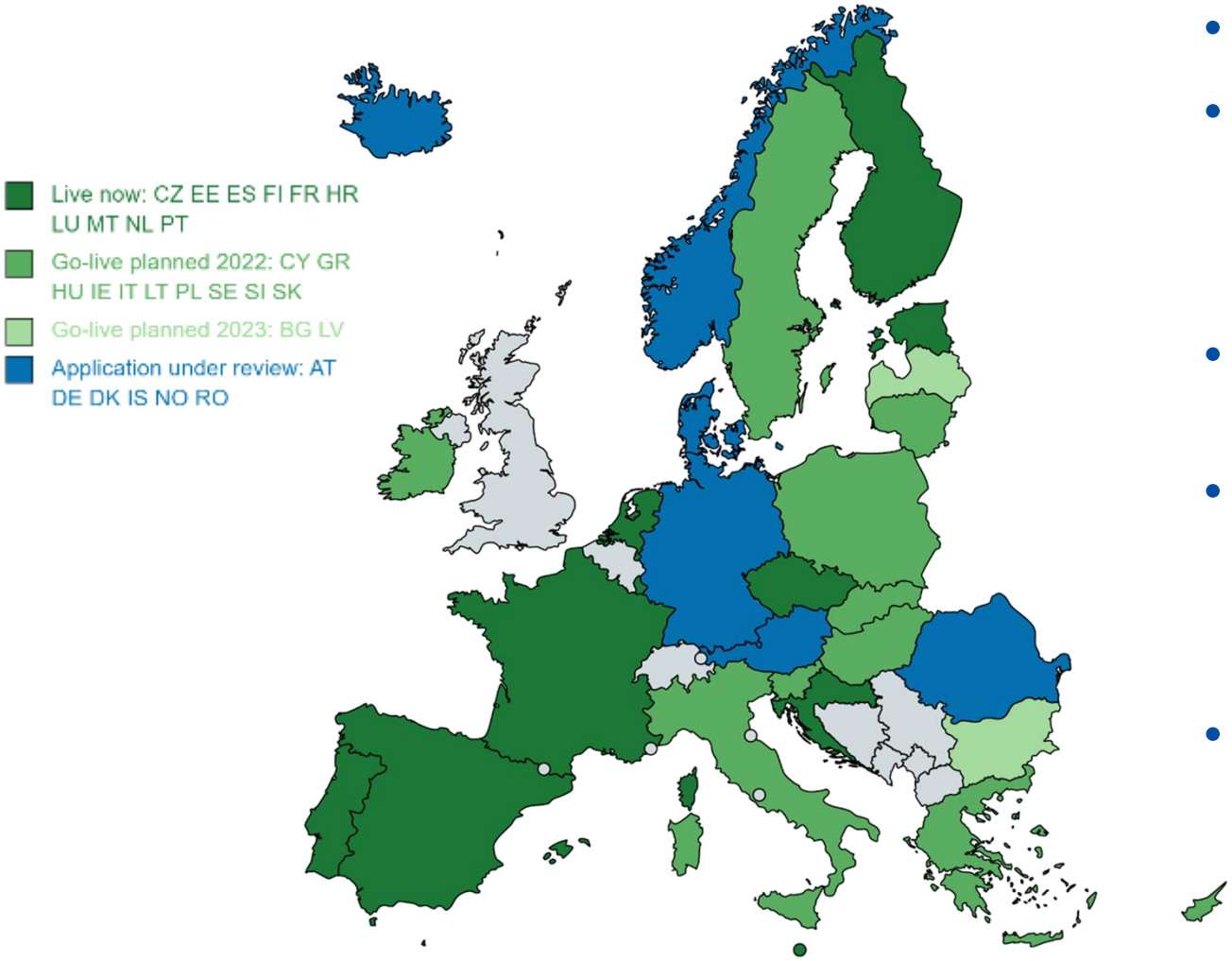
Rules and mechanisms supporting the secondary use of electronic health data

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

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



MyHealth@EU



- Currently 10 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

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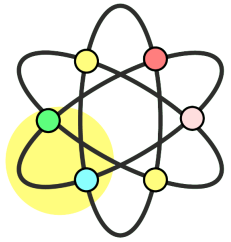
Primary use of health data

- The legislative proposal will introduce:

- Rights of individuals and healthcare professionals to access health data

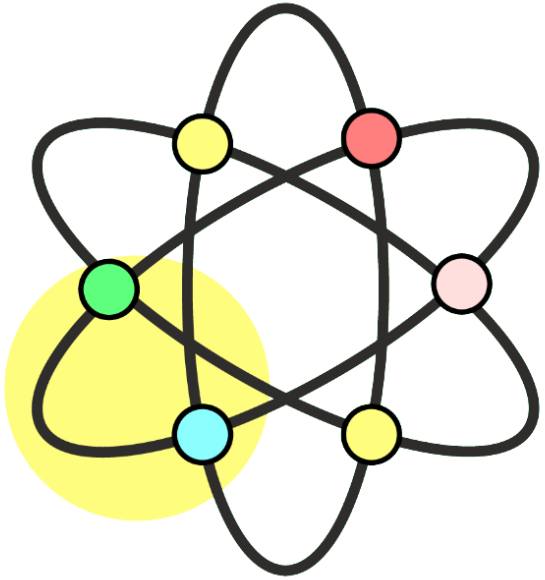
- Minimum requirements for specific health data categories in EHR systems through self-certification, registered in an EU database and voluntary labelling of wellness apps
- Mandatory deployment of MyHealth@EU with a transition period for different services



- Designation of national digital health authorities, working in EU comitology towards binding Delegated and Implementing Acts

Secondary use in the EHDS

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



Rules, protocols and governance

Health data from patients and healthcare professionals

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

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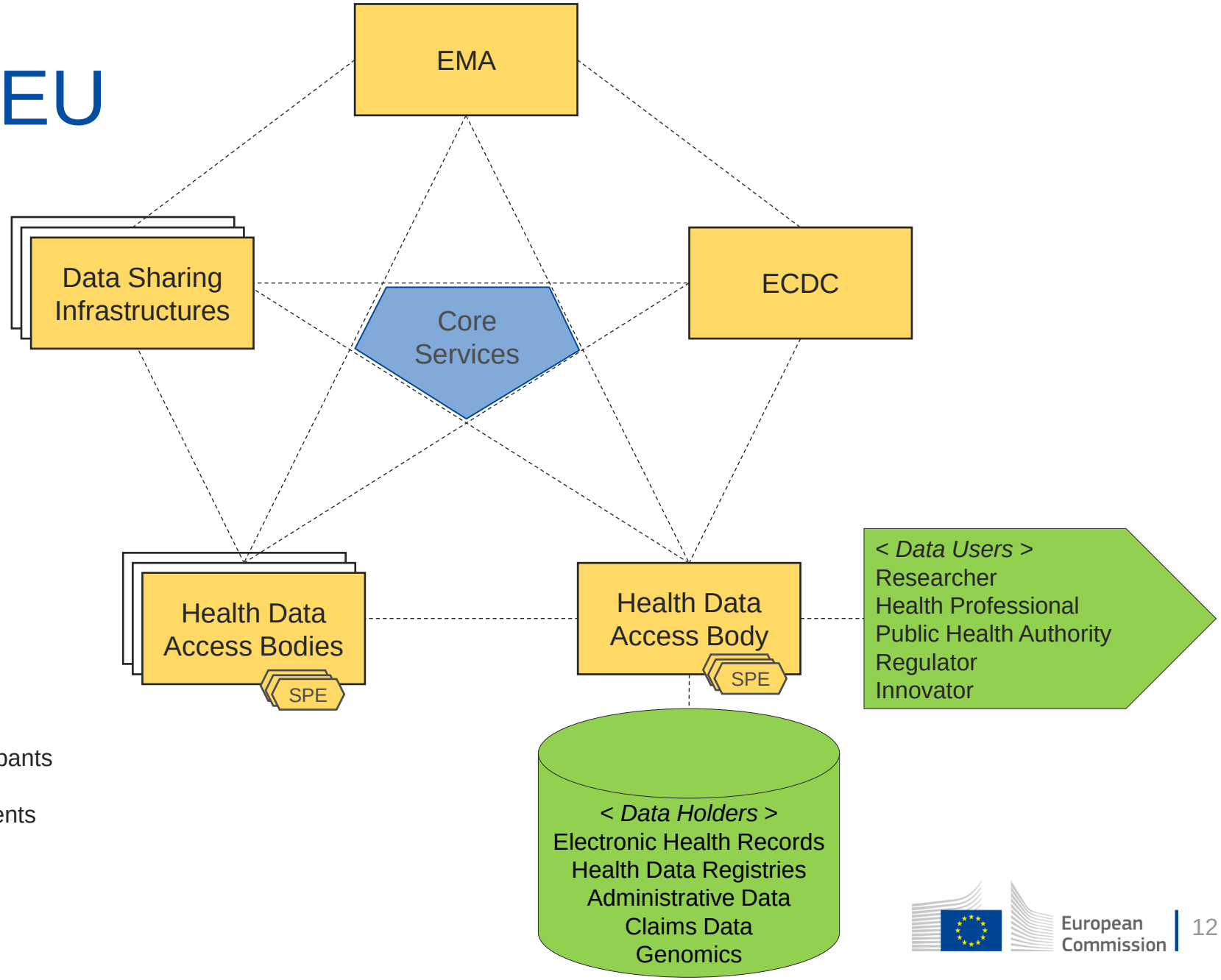
Secondary use of health data

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

HealthData@EU



Governance

- **Article 14** of Directive 2011/24/EU **is deleted** (Art. 71)
- **a new European Health Data Space Board (***high level representatives of digital health authorities (primary) and new health data access bodies (secondary) from all the Member States, the Commission, observers etc*). The Commission will chair these meetings. Among other tasks, it will assist Member States in coordinating practices, issue written contributions and to exchange best practices, facilitate cooperation of Member States etc

Governance

- **Comitology committee** – to provide an opinion on draft implementing acts (*now – more than 20 empowerments for implementing acts in the text*). They include one representative from every EU country and are chaired by the Commission.

- **Expert groups** - the Commission will prepare and adopt **binding** delegated acts (*now - more than 10 in the text)* after consulting experts groups, composed of representatives from each EU country.

- **Joint controllership groups -** for two cross-border digital infrastructures (one for primary and another one for secondary uses of health data). The composition, organisation, functioning and cooperation of the sub-groups shall be set out in the rules of procedure adopted by those groups.

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*)

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.
- 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