

European Health Data Space

Harnessing the power of health data
for people, patients and innovation

EURORDIS

Stockholm, 25 May 2023

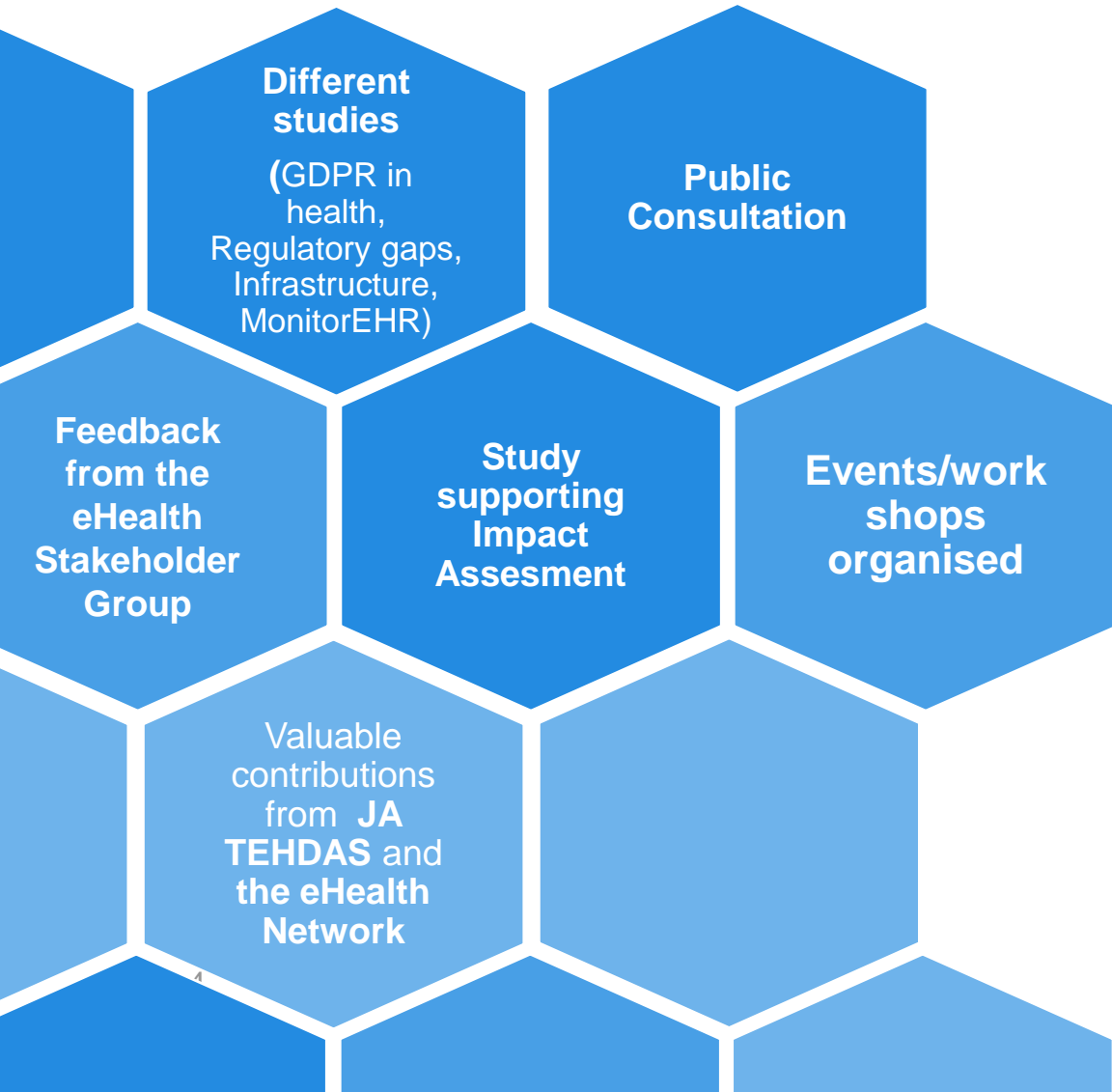


General overview

Why act now?

- **The 2020 European Strategy for Data** announced the Commission's plans for European data spaces, including EHDS
- The COVID-19 pandemic has clearly demonstrated **the importance** of digital services in the health domain, and has triggered **an important acceleration in the uptake** of digital tools. The European Digital Covid Certificate – positioned the EU as a **global leader and standard setter in digital health**
- The challenge now is **to maintain this momentum** on the importance of health data

Preparatory process and consultation results



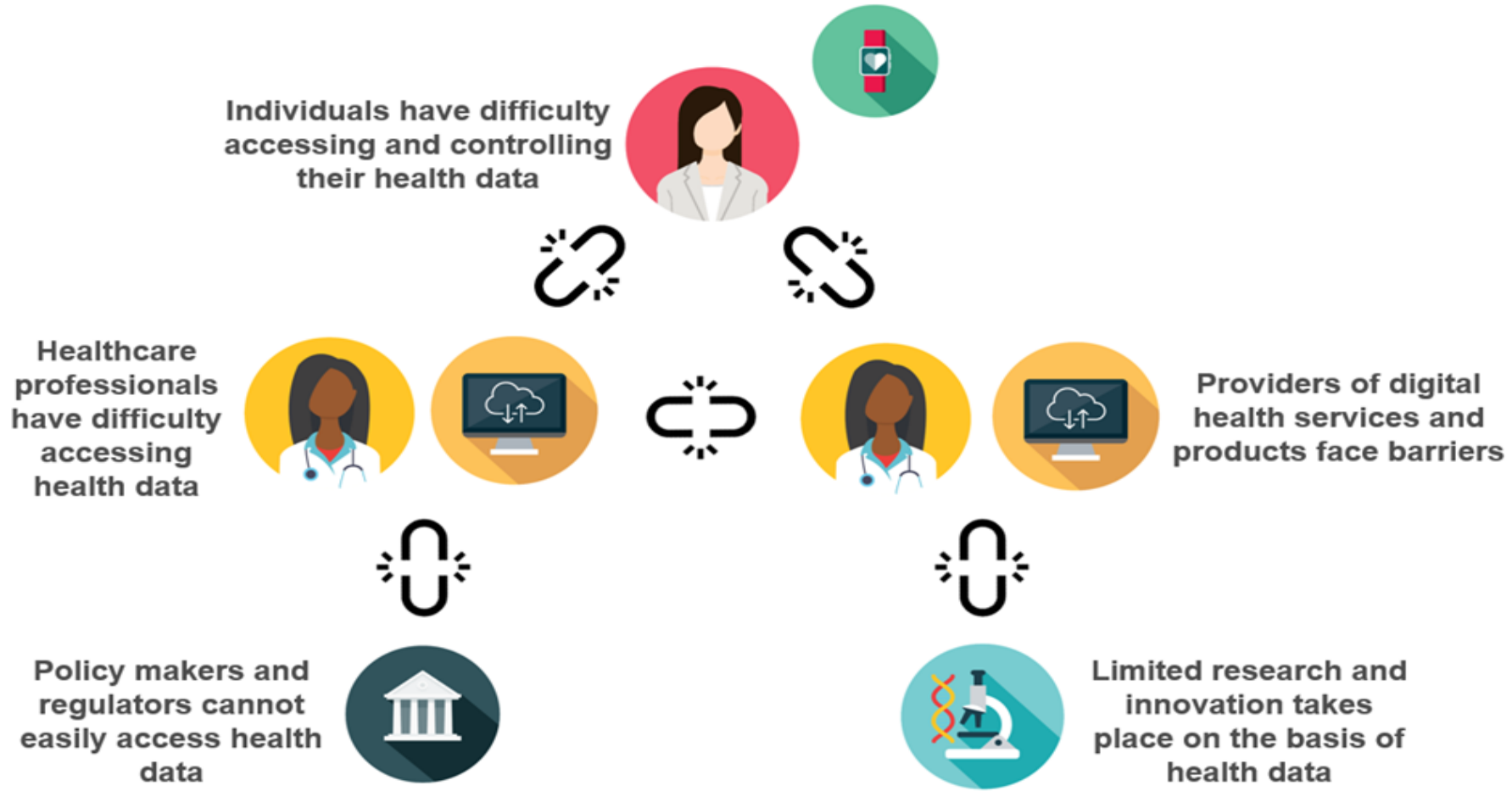
Online consultation on the EHDS (2021)

382 contributions

EU citizens, NGOs, academic/research institutions, companies/business organisations, business associations, public authorities, non-EU citizens, trade unions and consumer organisations.

Respondents came from **23 EU** Member States and 8 non-EU countries.

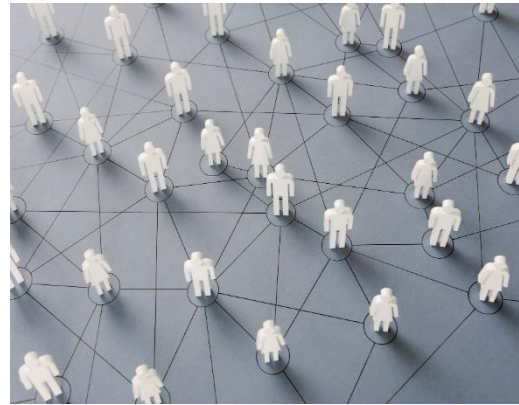
Main challenges in harnessing the power of health data



Proposal for a Regulation on the European Health Data Space

It 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

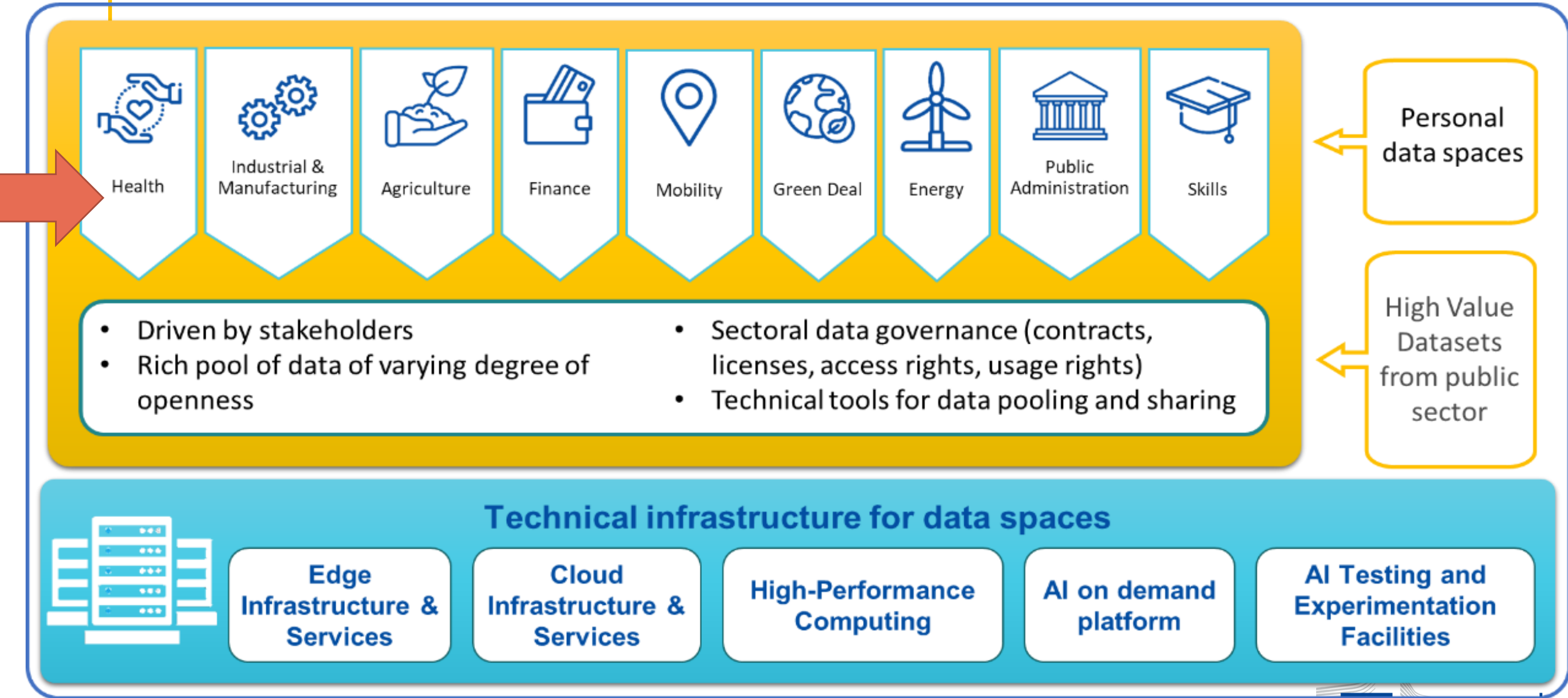


Ensure a consistent framework for the use of individuals' health data for research, innovation, policy-making and regulatory activities

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



EHDS – the first sector specific European Data Space



EHDS – links with other legal proposals and initiatives

GDPR

EHDS builds upon GDPR rights and further develops some of them

European Health Union

EHDS will boost the work of EU Cancer plan, HERA, Pharmaceutical Strategy for Europe

Data Governance Act, Data act

EHDS complements and provides more tailor-made rules for the health sector

EU cybersecurity framework (NIS directive)

EHDS complements and provides more tailor-made rules for the health sector

Artificial Intelligence Act

EHDS supports and complements training of AI, interoperability of AI and EHR systems and data quality

Medical Device Regulations

If manufacturers claim interoperability of devices with EHR systems –EHDS requirements apply

Legal basis and scope of health data

- **Legal basis - Article 16 TFEU and Article 114 TFEU**
- **Article 16-** EHDS is building upon GDPR, strengthening the rights to the protection of personal health data and building on possibilities of EU law for processive sensitive health and genetic data
- **Article 114** - EHDS aims to improve the functioning of the internal market and the free movement of goods and services to avoid legislative fragmentation in the internal market and different rules and practices across the EU
- **Full respect of Article 168 TFEU** – EHDS does not intervene in organisation and delivery of health services and medical care of Member States
- **Non-personal and personal health data** in scope

European Health Data Space (EHDS)

OBJECTIVES

Effective use of health data

SCOPE & EXPECTED IMPACT

Use of health data
(primary,
MyHealth@EU)

- Empower individuals to control their data
- Standardization and mandatory certification of EHR systems
- Voluntary labelling of wellness apps
- European Electronic Health Record Exchange Format

Single market for health data, data protection, free movement of people, digital goods and services

Re-use of health data
(secondary,
HealthData@EU)

- Health data access bodies
- Purposes for use and forbidden use
- Data permits, secure environments, no identification

Facilitated Research & Innovation

Better Policy Making

MEANS

Legal / Governance

Quality of data

Infrastructure

Capacity building/digitalisation (MFF)

Individuals: strengthened security

Primary use

Builds upon EU-cybersecurity legislation

Security/interoperability criteria for EHR systems + CE marking

Security audits for the MyHealth@EU (primary use) infrastructure

Strong authentication for patient and health professionals

Only persons entitled to access the data can get access to individual's data

Secondary use

Data processed in secure processing environments, compliant with high standards of privacy and (cyber)-security.

No personal data can be downloaded

Users cannot identify individuals

Audits of participants in HealthData@EU

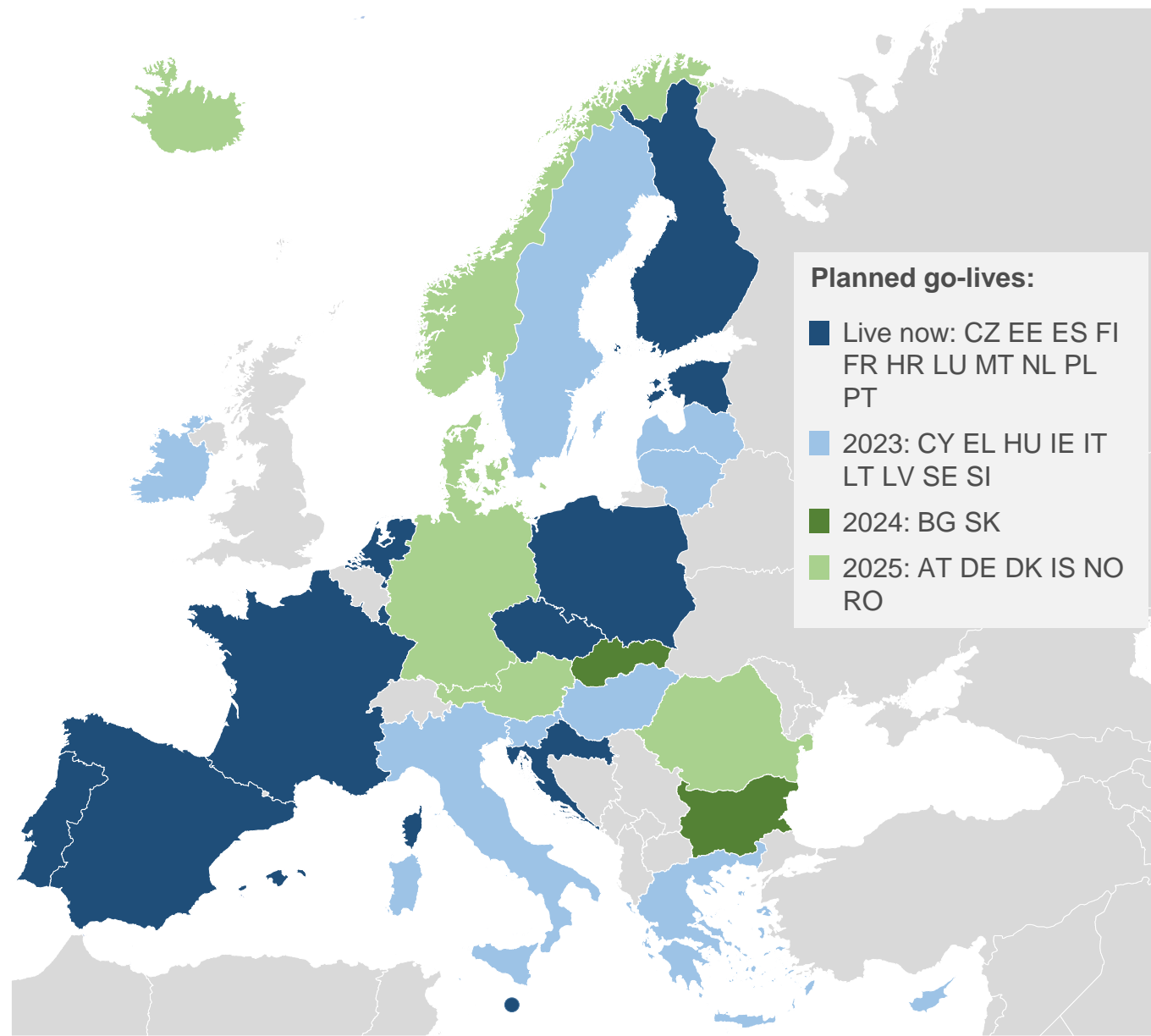
MyHealth@EU

Primary use of health data (for provision of health services)



MyHealth@EU

MyHealth@EU is the existing infrastructure that connects healthcare providers in 11 Member States. It allows them to exchange health data such as Patient Summaries and ePrescriptions. These services will be expanded to include lab results and other types of health data.



Some common goals of MyHealth@EU



To support continuity of care when people exercise their right of freedom of movement



To provide appropriate and usable tools to health professionals and to patients



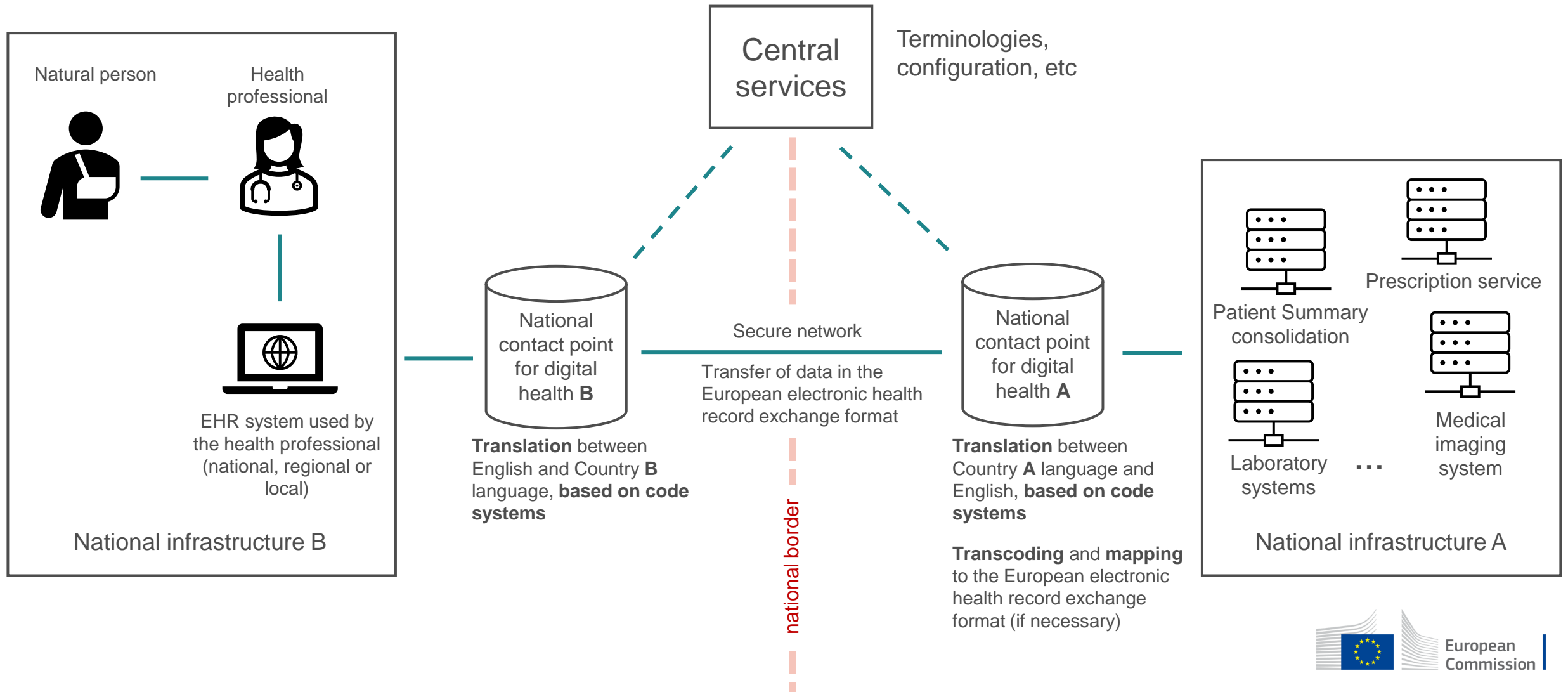
To ensure data protection and security



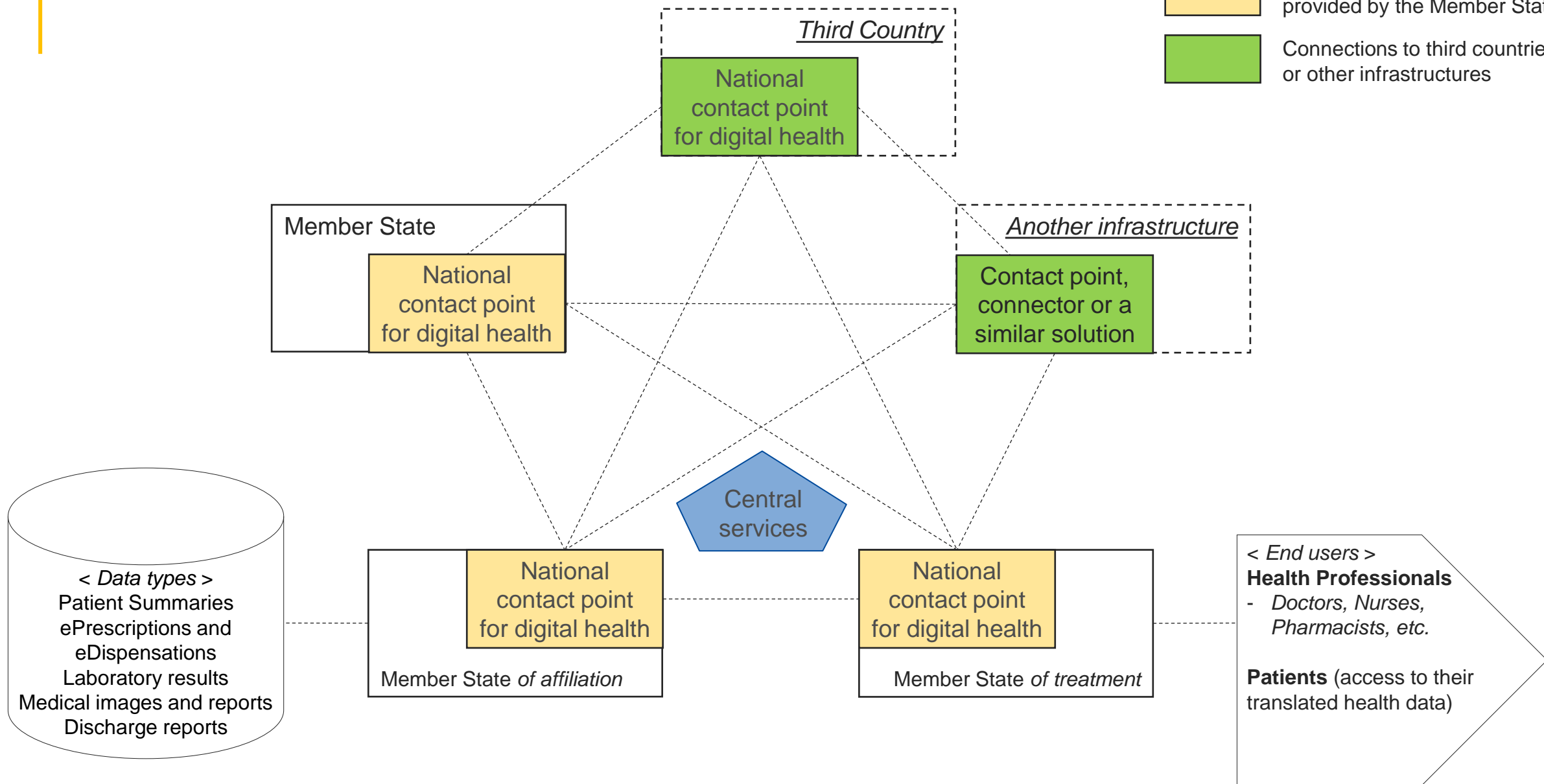
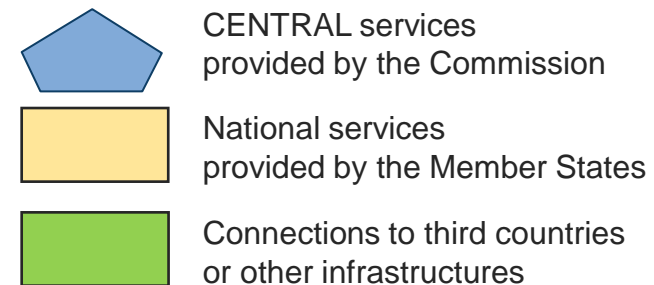
To ensure stability and further development of services, and make people aware of them

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

Entry into force of EHDS regulation

Mandatory participation in MyHealth@EU for all Member States with transitional periods for the different services

Pilot on Patient Access

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



New services to be introduced

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

Enhancement of available services using EU DCC technology

New Member States joining MyHealth@EU

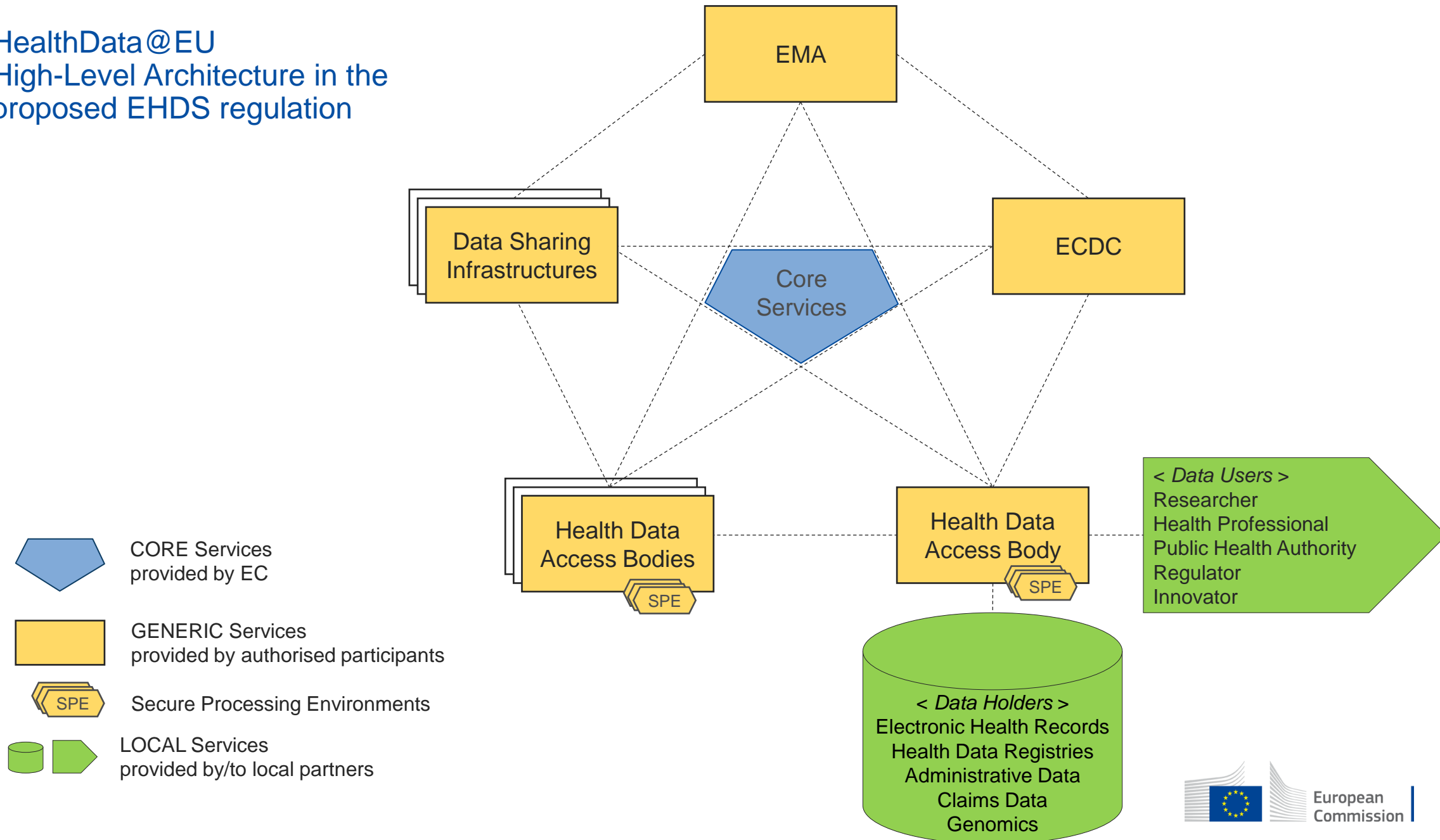
More Points of Care to be connected (2023 and beyond)

HealthData@EU

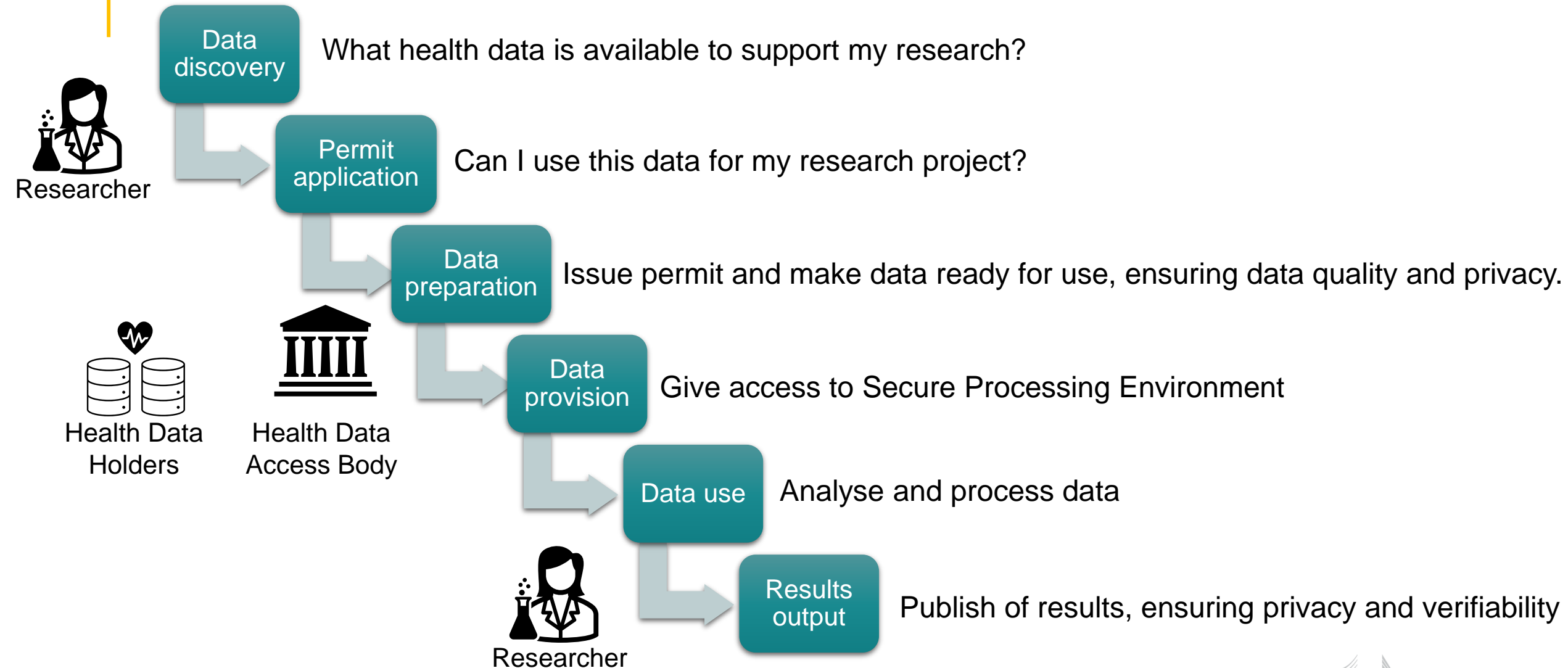
Secondary use of health data

HealthData@EU

High-Level Architecture in the proposed EHDS regulation



Overview of a generic data access approval process



Potential benefits

Primary use and benefits



Empower people...
... to have better control over their own health data
... to easily share with health professionals

Leading to...
... increased data sharing
... better health outcomes
... savings for patients and insurers by reducing unnecessary tests



Enable health professionals to have access to relevant health data
Translation functions as part of MyHealth@EU services

Better diagnosis and treatment
improved patient safety and continuity of care
Less manual data input



EU-wide standards for EHR systems

Easier market access in other Member States
Increased competition

Secondary use – expected benefits



Assist policy makers and regulators in accessing relevant health data



Better and faster decision-making
More resilient health systems
Safer medical technologies



Facilitate access to health data for innovators in industry



Greater opportunities for research and innovation
More innovative medical products



Make available health data for researchers



Greater opportunities for research and innovation

Growth potential of health data economy

EUR 5.5 billion over ten years for EU from better access and exchange of health data in healthcare

EUR 5.4 billion over ten years for EU from better use of health data for research, innovation and policy making

Other information

Funding

Overall funding for EHDS and its infrastructures

- Around € 800 mil

Earmarked funding: € 330 mil

- EU4Health: € 280 mil
- DEP: € 50 mil

Complementary funding: ≥ € 480 mil

- DEP: €140 mil
- CEF: €130 mil
- HE: € 210 mil

Funding for national investments

- RRF: € 12 bn
- ERDF
- InvestEU

Legislative process

- **Commission proposal** for EHDS Regulation: adopted on 3 May 2022 (COM(2022)197)
- **Council:** started examination under the FR Presidency (05/2022); Progress Report under the CZ Presidency (12/2022); work continues under the SE Presidency (1st half 2023).
- **European Parliament:** shared competence of ENVI and LIBE committees.