

# European Health Data Space

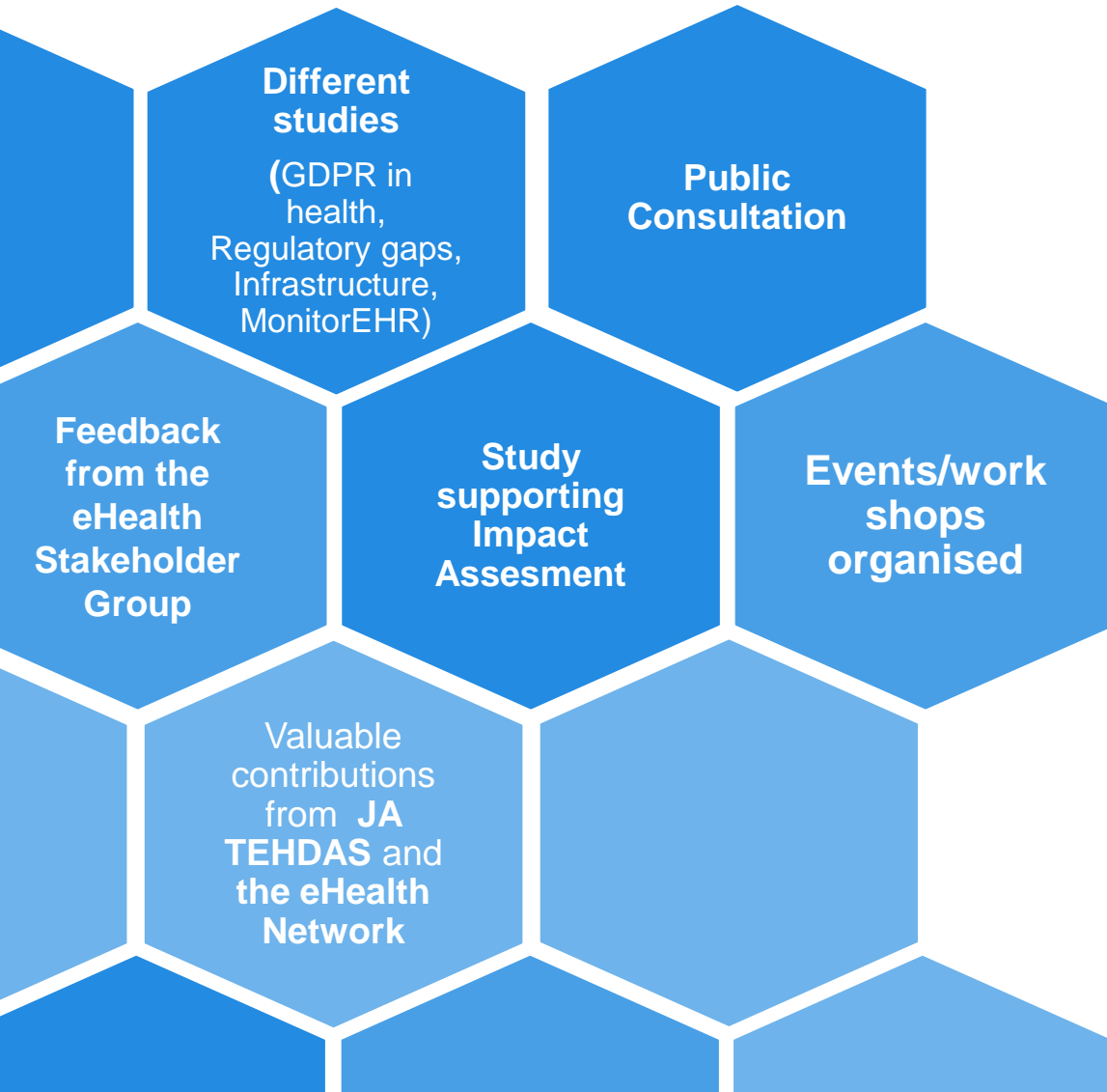
Harnessing the power of health data  
for people, patients and innovation



# 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



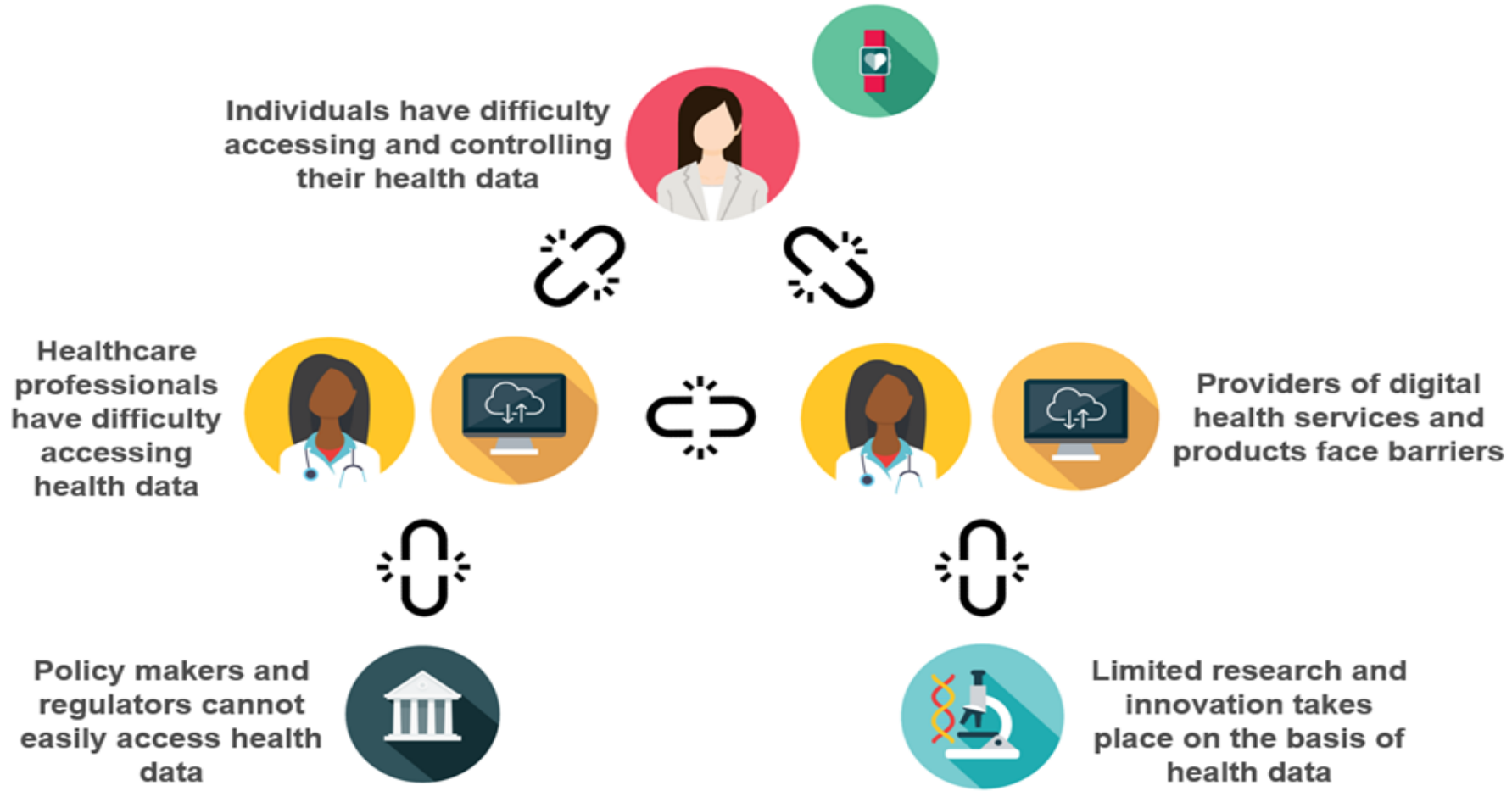
## Online consultation on the EHDS (3 May - 26 July 2021)

### 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.

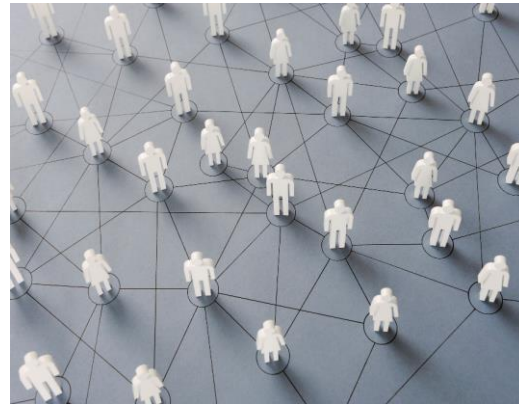
# Main challenges in harnessing the power of health data



# 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)



# 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)

# 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.*

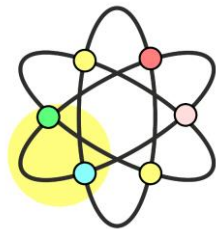


**Rules for electronic health record systems (EHR systems)**

**Rules and mechanisms supporting the secondary use of electronic health data**

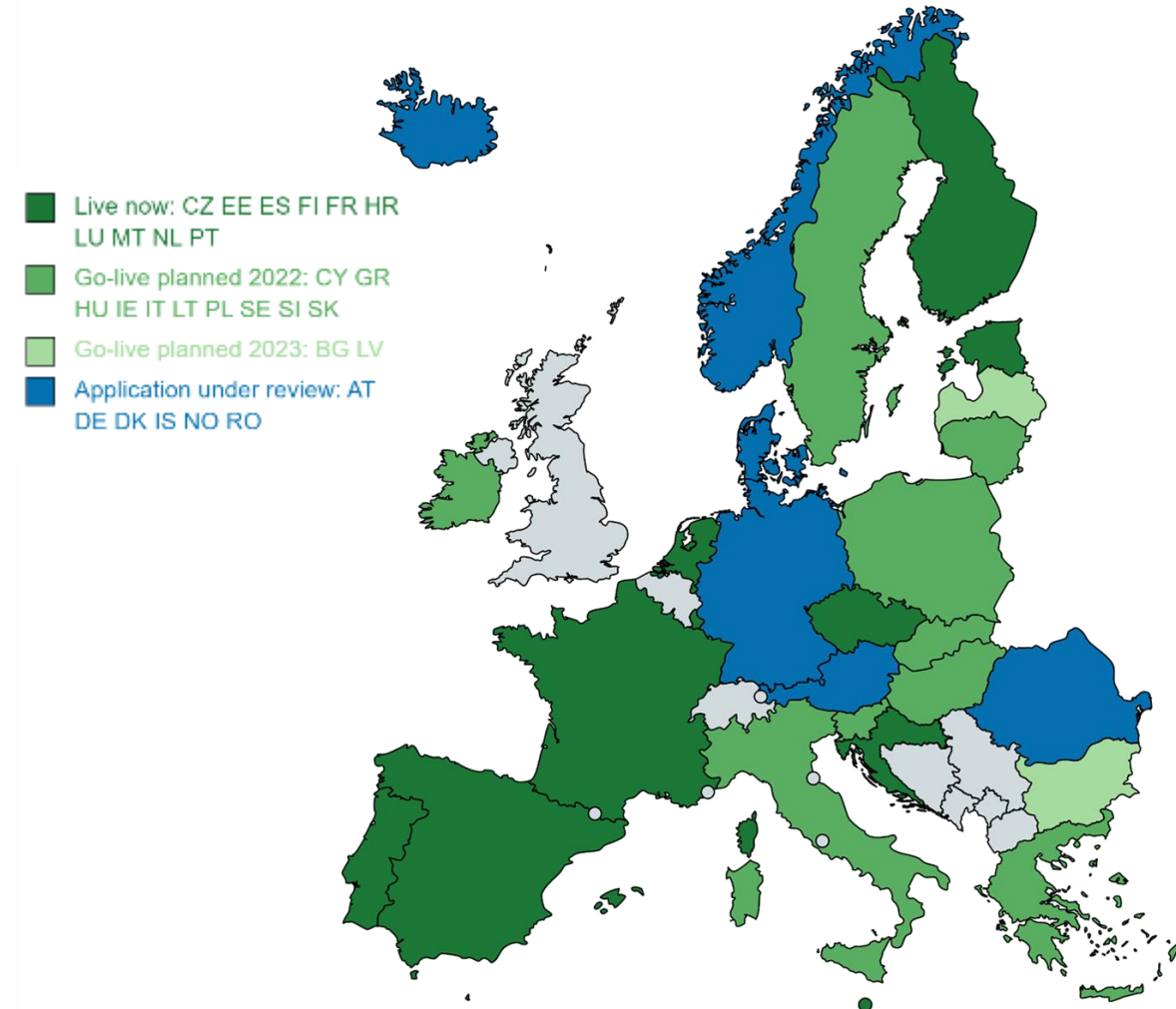
**Mandatory cross-border infrastructures for primary and secondary use of health data**

- MyHealth@EU
- HealthData@EU





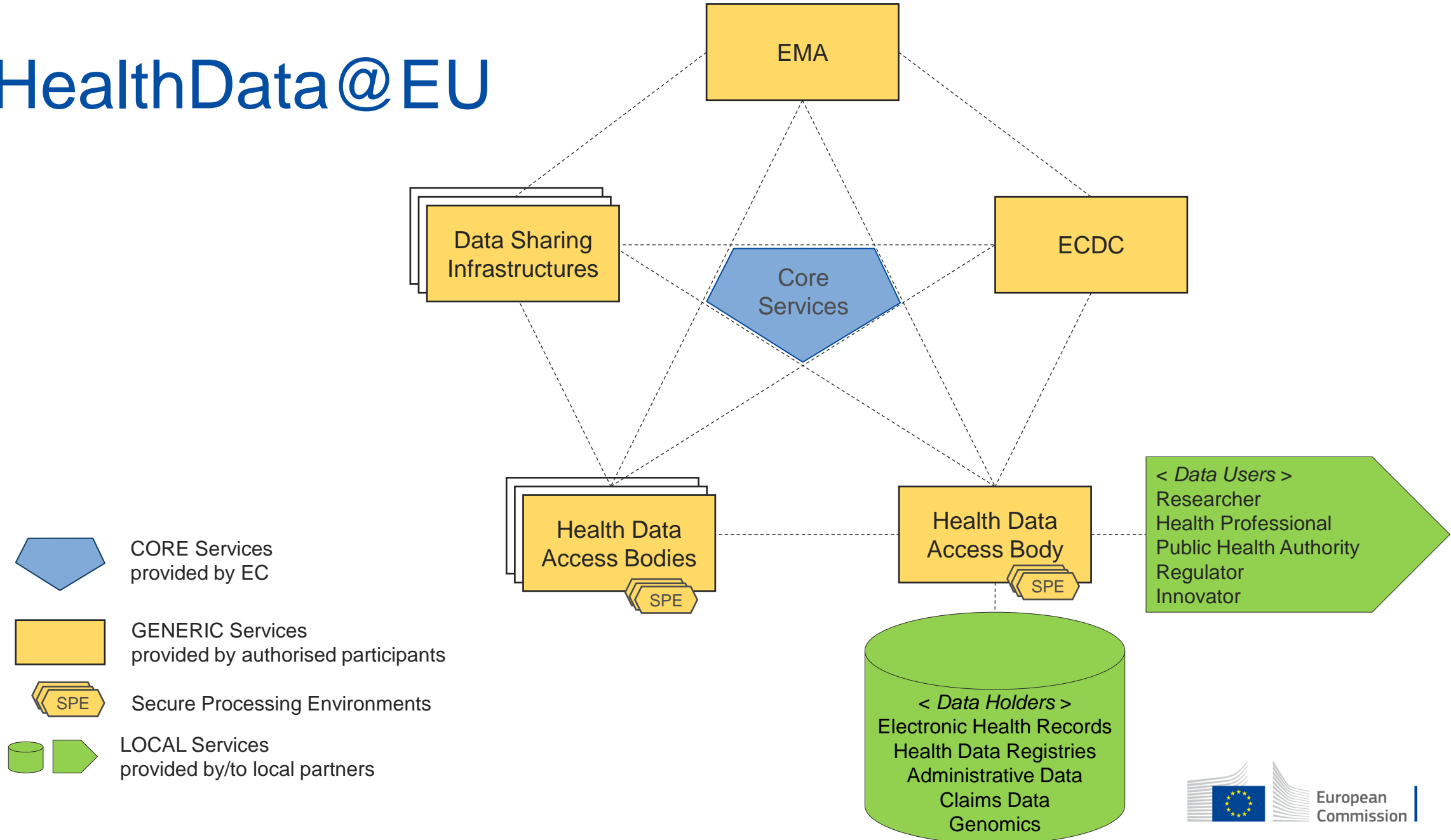
# MyHealth@EU



- Currently 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



# HealthData@EU



# 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

# 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

# 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

**Health data from apps and medical devices**



**Health data in registries**



**Electronic health records**



**Enable healthcare professionals to have access to relevant health data**

**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

# Thank you