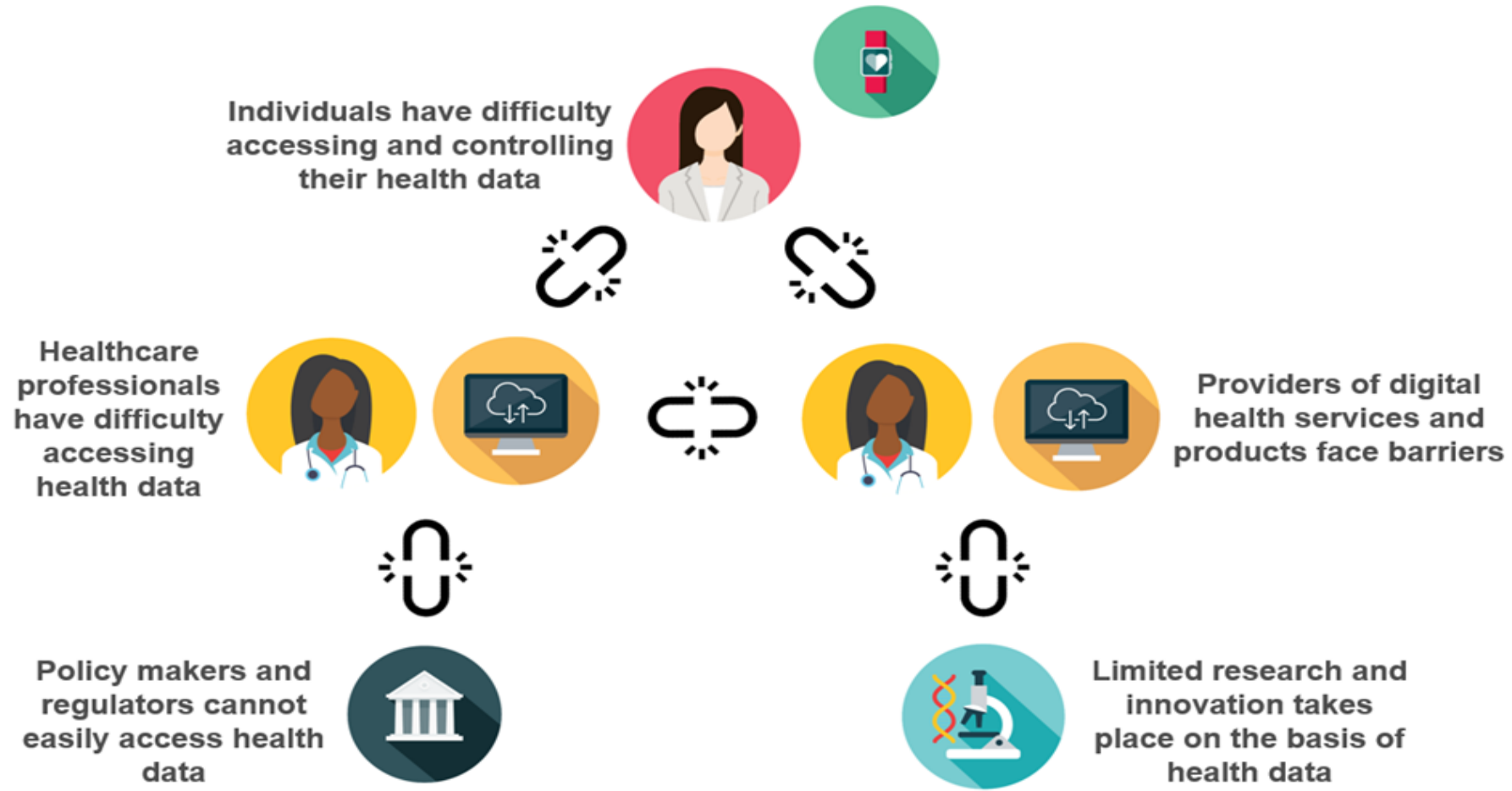


# European Health Data Space

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



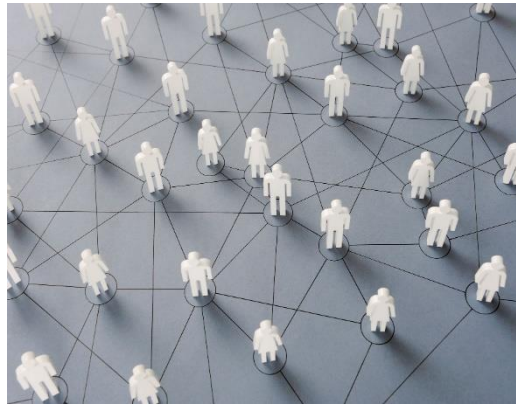
# Main challenges in harnessing the power of health data



# 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
- European Electronic Health Record Exchange Format
- Standardization and mandatory certification of EHR systems
- Voluntary labelling of wellness apps

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)

# Primary use of health data: expected EHDS 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 of health data: expected EHDS 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

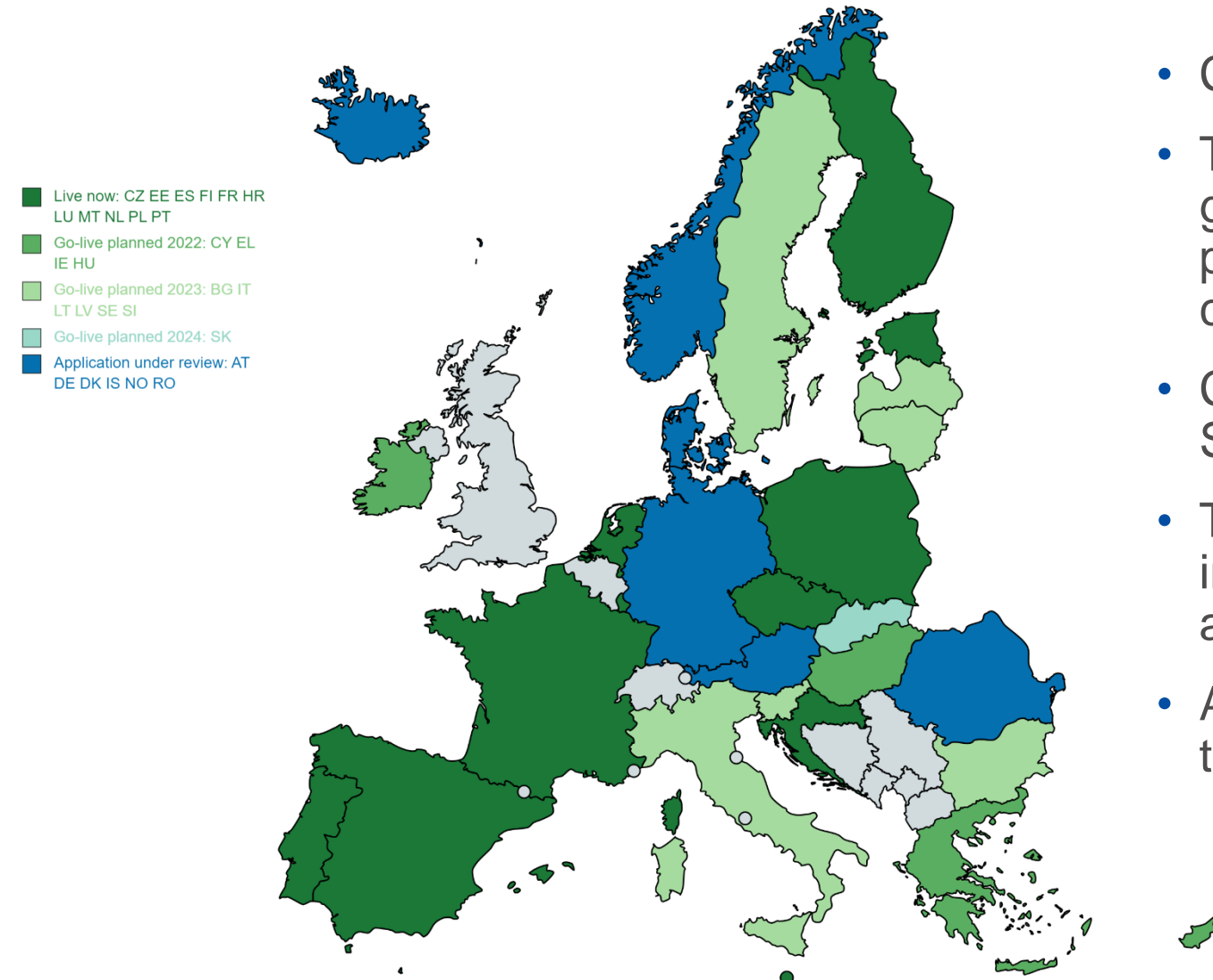


Make available health data for researchers



Greater opportunities for research and innovation

# MyHealth@EU (primary use of health data)

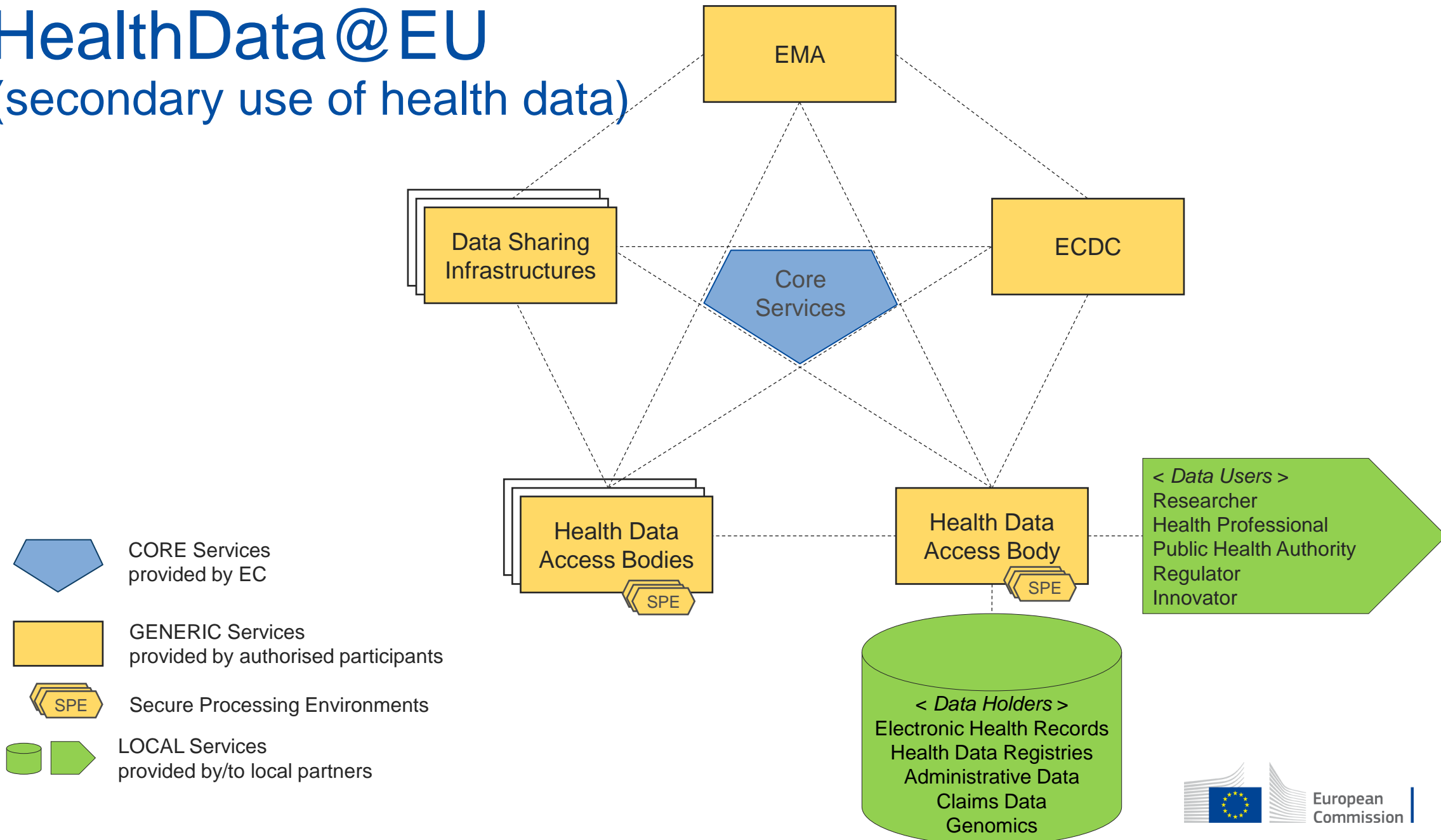


- Currently 11 Member States are live
- The number of connected Member States will grow rapidly in the years ahead - there are plans for most Member States and EEA countries to join **MyHealth@EU until 2025.**
- Currently there are 2 services: Patient Summary and ePrescription
- This is being expanded 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



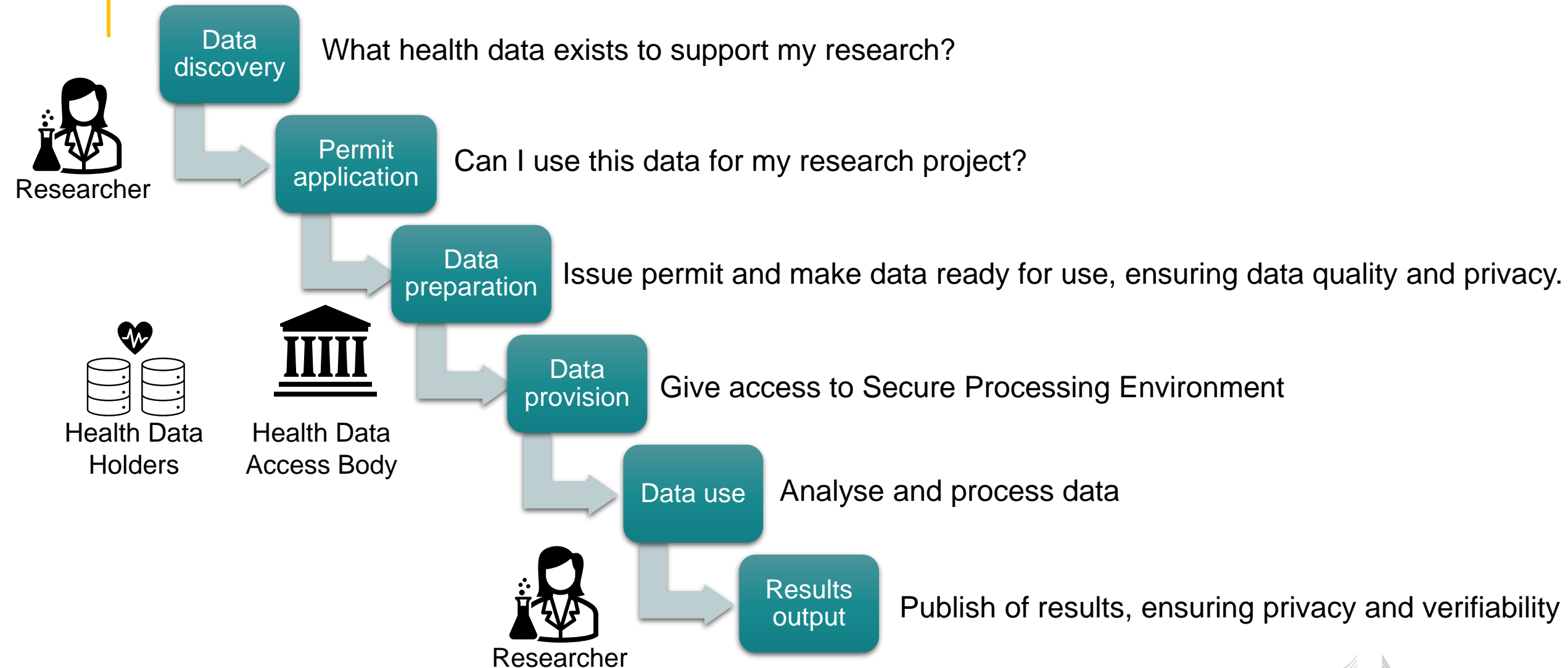
# HealthData@EU

(secondary use of health data)





# Overview of a generic data access approval process for secondary use under EHDS proposal



# Pilot project to build and operate a first version of HealthData@EU



17 partners, 9 countries  
2 years (2022-2024)  
5 million euros of EU fundings

Create and test a beta version of the European Health Data Space

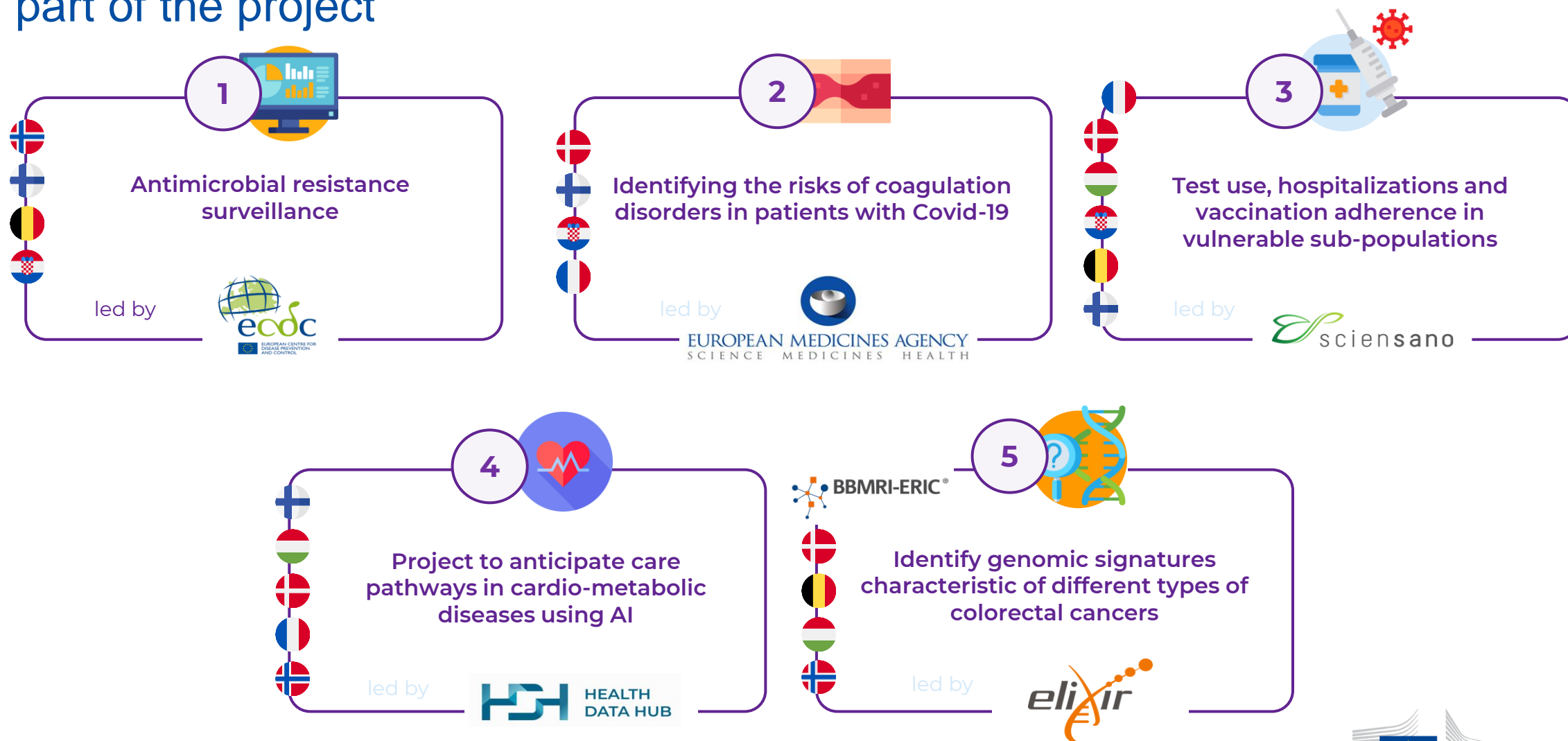
Build a network of data platforms on a European scale...

...tested by concrete cross-border use cases



European Commission

# 5 cross-border use cases proposing complementary research questions will show the added value of HealthData@EU and drive the work developed as part of the project



# EHDS: 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

# **EHDS unlocks new opportunities for ERN registries data**

- **The EHDS will complement and build on the existing activities related to ERN registries, not replace them**
  - ERNs expected to continue their essential work in managing data on rare diseases and registries
- **The EHDS presents a unique opportunity for ERN registries to enhance the impact of their data**
  - It enables more extensive use of ERN registries data for research, innovation, policy-making, regulatory purposes, improvement of patient treatments and advancements of personalized medicine
- **The EHDS introduces an opportunity to standardise electronic health data for their secondary use across borders**
  - By establishing minimum specifications for datasets, the EHDS fosters a harmonised approach to collecting data with high societal impact

# Thank you



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