

# European Health Data Space

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

December, 2022



# 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)

# 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**

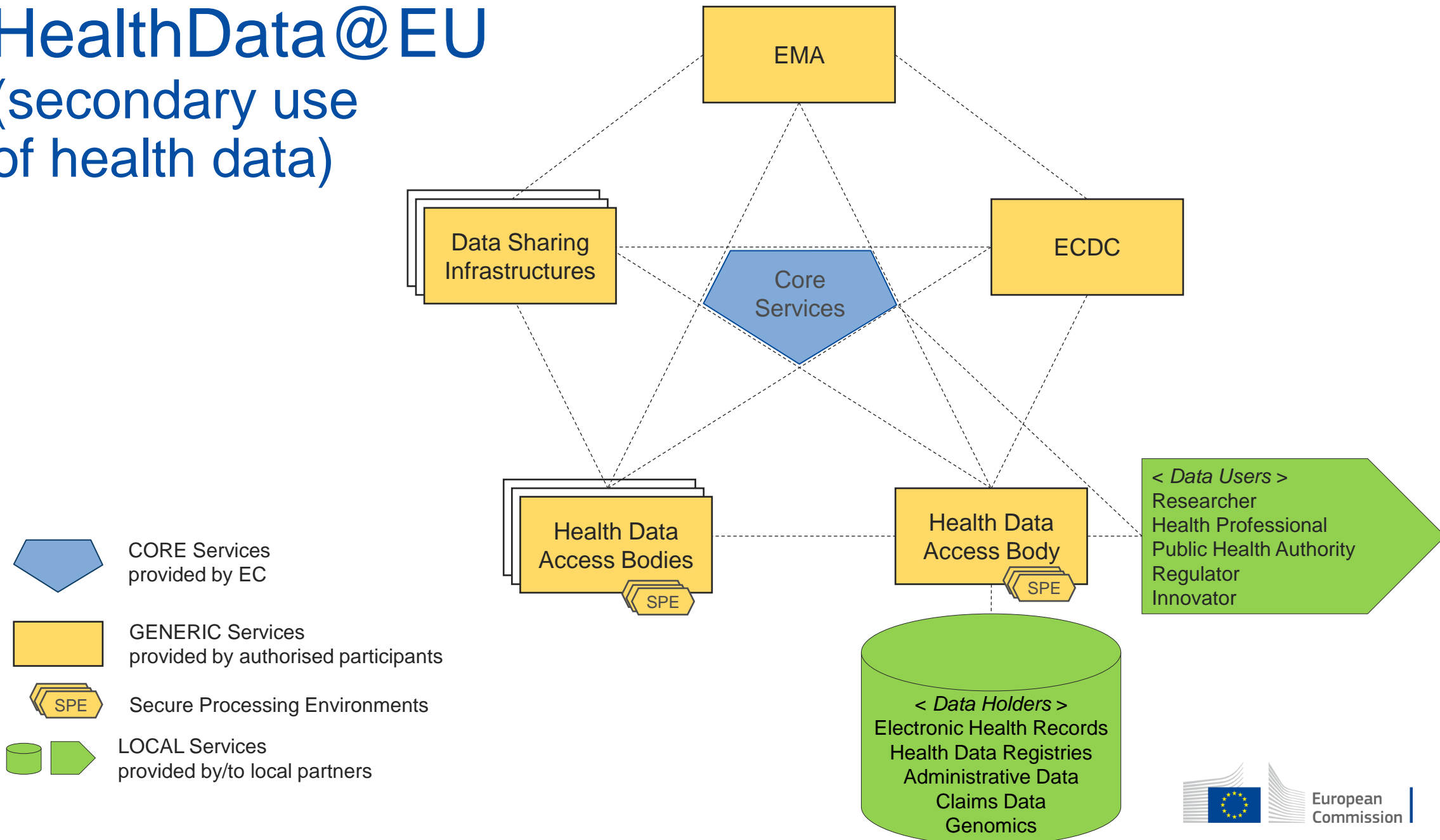


**Grant access to health data for researchers**

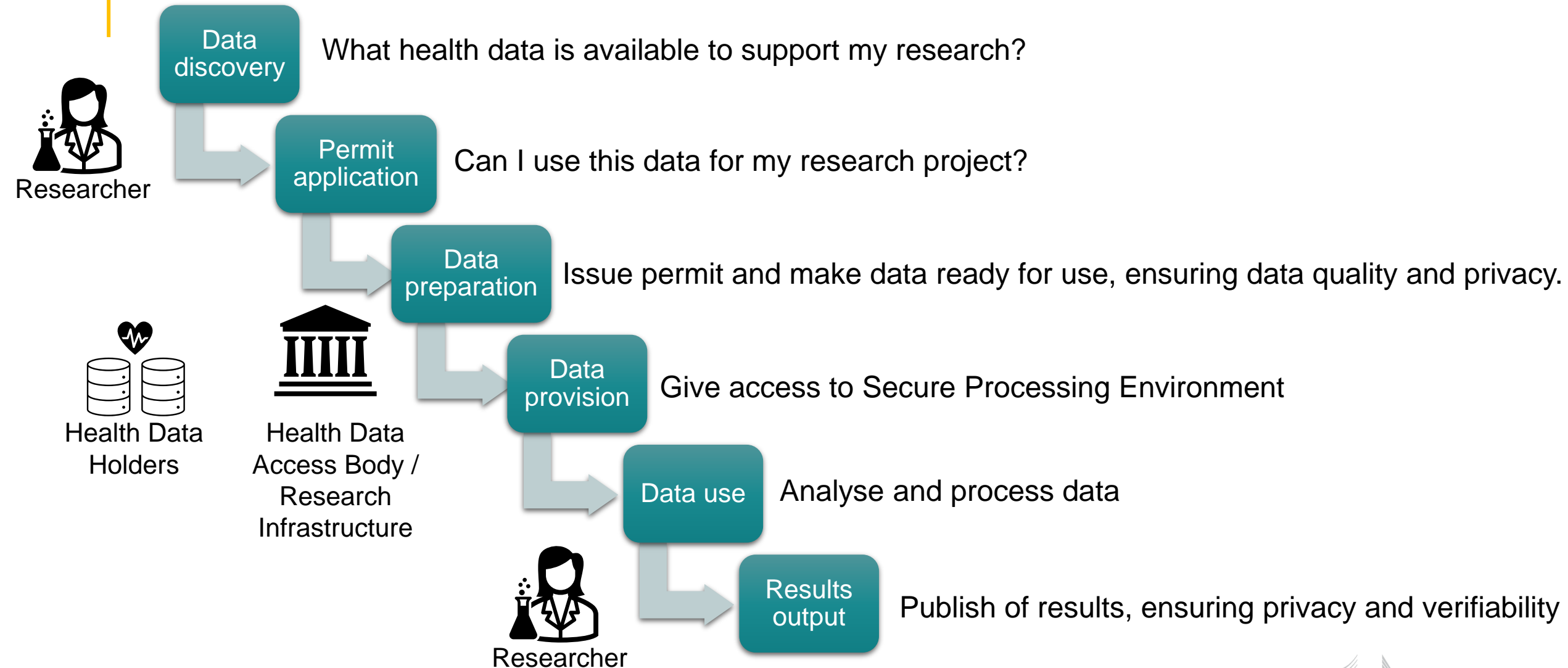
Better health policy, greater opportunities for research and innovation

# HealthData@EU

(secondary use of health data)



# Overview of a generic data access approval process



# EHDS2 - Infrastructure

## HealthData@EU Pilot

- Funded under EU4HEALTH
- Start: October 2022 (duration 2 years)
- Budget: EUR 5M (+ EUR 5M Central services)
- Objectives:
  - design, develop, deploy and operate a network of nodes federated by central services, enabling reuse of health data
  - investigate and establish the value of an infrastructure for the reuse of health data
  - assess the feasibility to scale towards a Union-wide infrastructure
  - validate the infrastructure through 5 complementary use cases

# Thank you



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