

# Towards the European Health Data Space

13 October 2022

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Project Director

TEHDAS coordinator



Co-funded by  
The Health Programme  
of the European Union

# Agenda

European data policies and the European Health Data Space

Joint Action Towards the European Health Data Space (TEHDAS)



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2016

2017

2018

2019

2020

2021

2022

2023

**2016 - General Data Protection Regulation (GDPR)**

**2018 – Regulation on the free flow of non personal data**

**2018 - Digital Health Strategy**

**2019 - Open Data Directive**

**2019 - Cybersecurity Act**

**2020 - Data Strategy**

**2020 - Data Governance Act (DGA)**

**2021 – 2030 Digital Compass**

**2021 - Artificial Intelligence Act**

**2021 - Digital Services Act**

**2021 - Digital Markets Act**

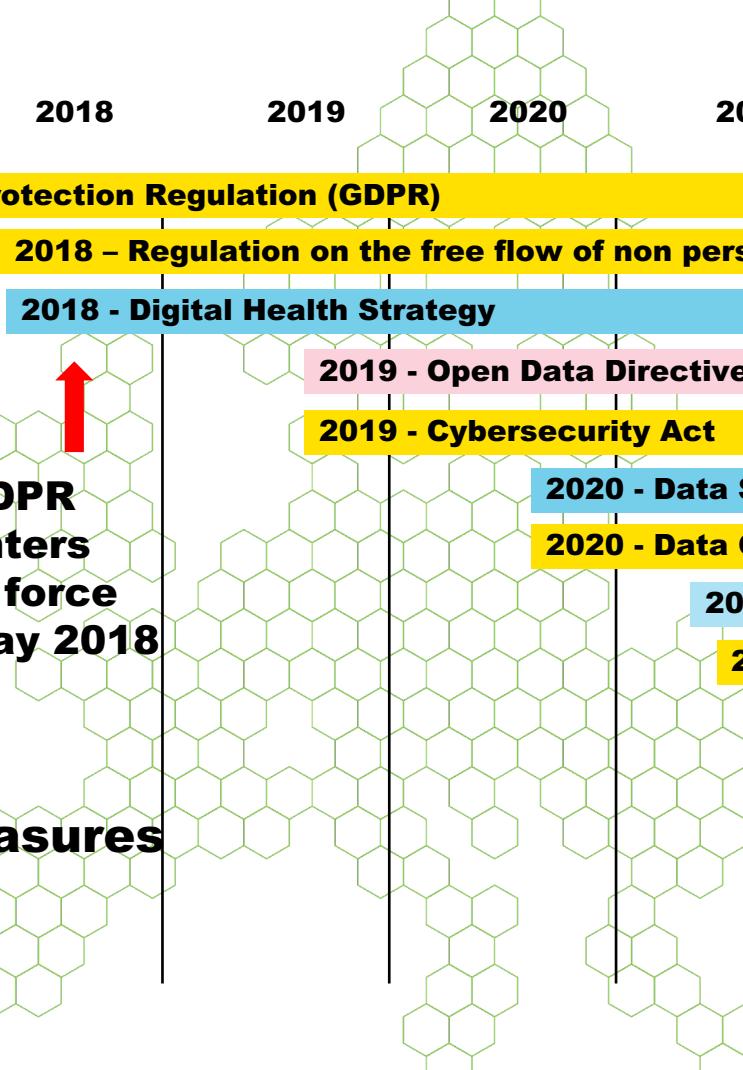
**2021 - Data Act**

**2022 – Chips Act**

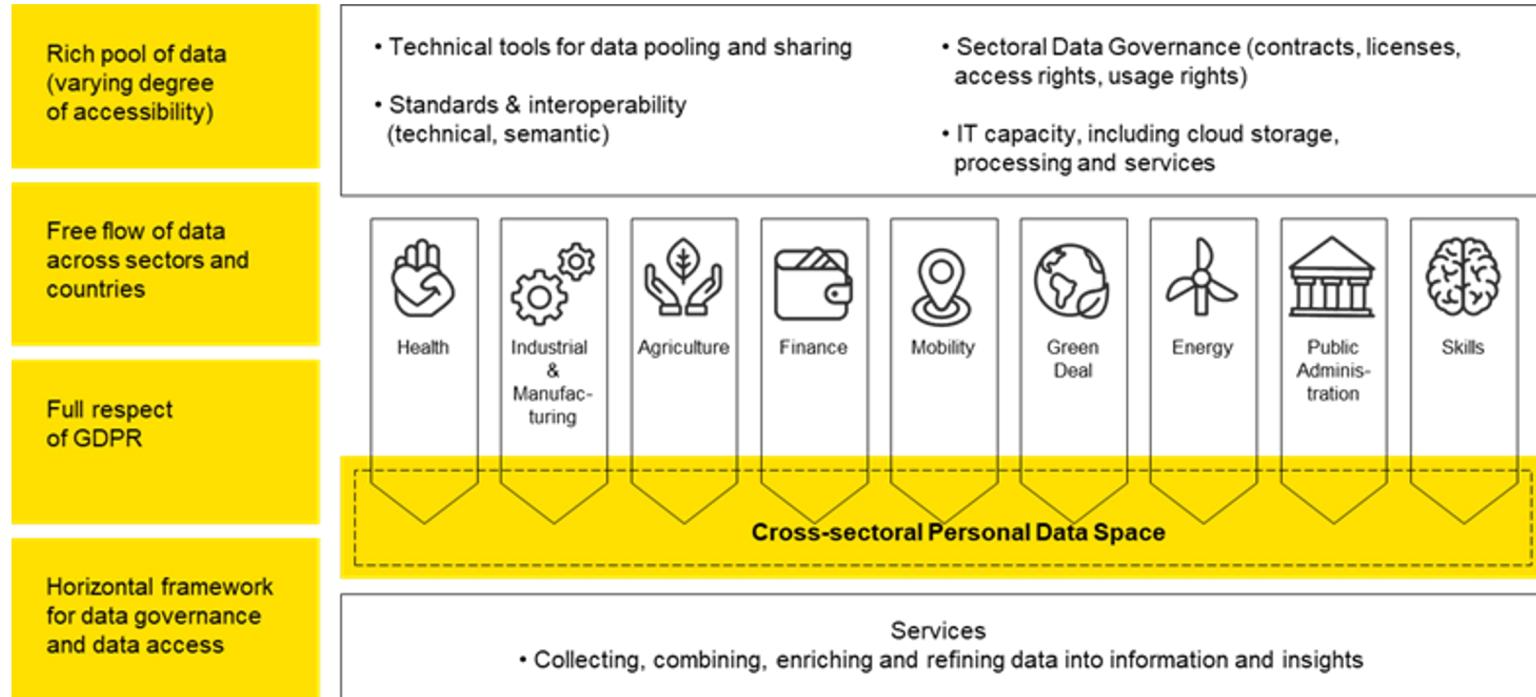
**2022 – EHDS**

## **European Union Data related measures**

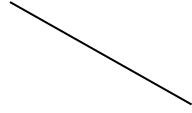
**GDPR  
enters  
in force  
May 2018**



# EU data strategy and Data Spaces



**The European Health Data Space is a health specific ecosystem comprised of rules, common standards and practices, infrastructures and a governance framework**



EHDS Proposal published 03/05/2022



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# EHDS proposal in a nutshell

- 1 Chapter 1: General provisions (Art. 1 -2)**
- 2 Chapter 2: Primary use of electronic health data (Art. 3 - 13)**
- 3 Chapter 3: EHR systems and wellness applications (Art. 14 - 32)**
- 4 Chapter 4: Secondary use of electronic health data (Art. 33 - 58)**
- 5 Chapter 5: Additional actions (Art. 59 - 63)**
- 6 Chapter 6: European governance and coordination (Art. 64 - 66)**
- 7-9 Chapter 7-9: Delegation, Miscellaneous, Deferred application (Art. 67 - 72)**



# 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

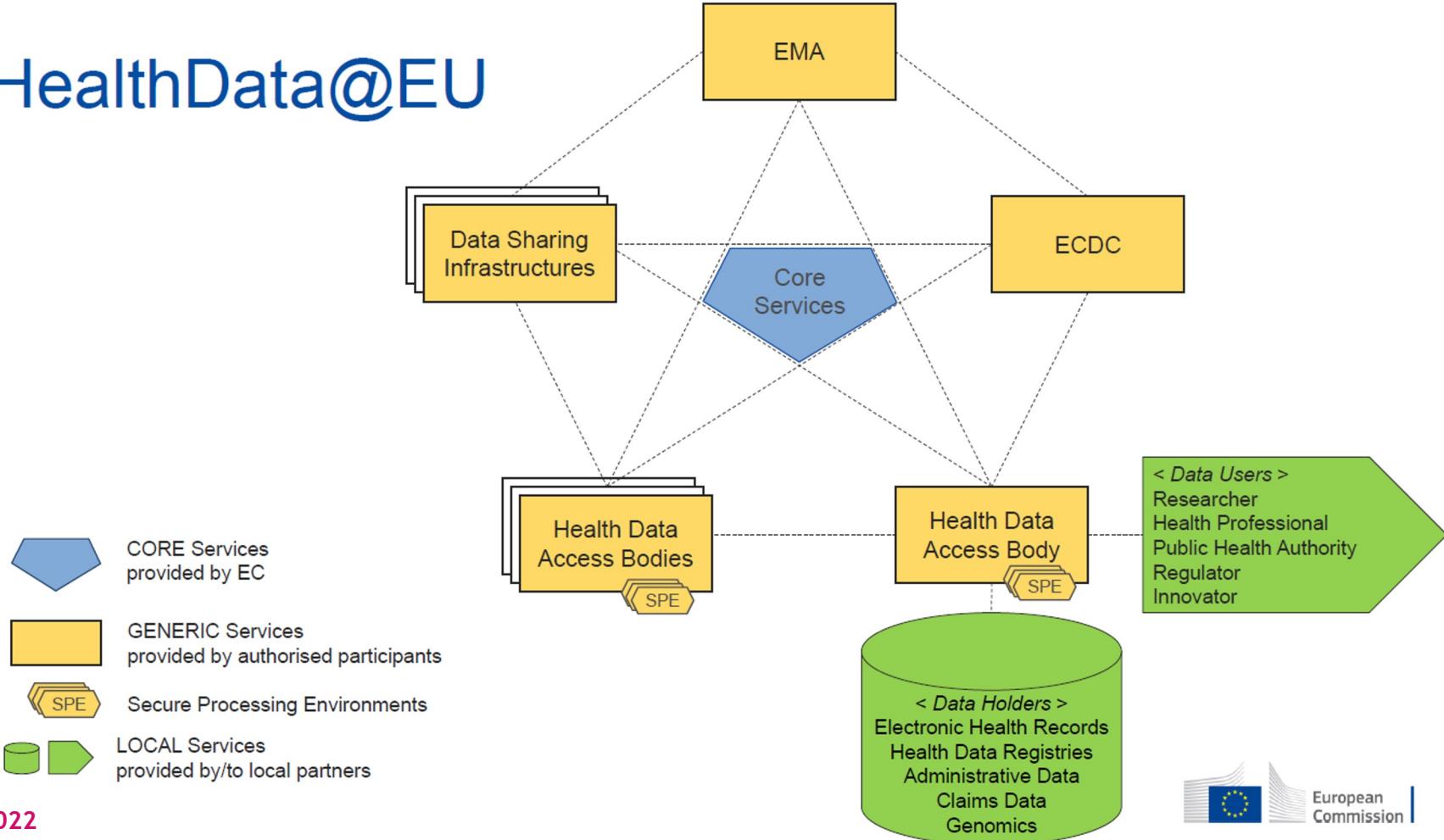
Legal / Governance

Quality of data

Infrastructure

Capacity building/digitalisation (MFF)

# HealthData@EU



# Funding

Overall funding for EHDS and its infrastructures	Earmarked funding: € 330 mil	Complementary funding: $\geq$ € 480 mil	Funding for national investments
<ul style="list-style-type: none"><li>Around € 800 mil</li></ul>	<ul style="list-style-type: none"><li>EU4Health: € 280 mil</li><li>DEP: € 50 mil</li></ul>	<ul style="list-style-type: none"><li>DEP: €140 mil</li><li>CEF: €130 mil</li><li>HE: € 210 mil</li></ul>	<ul style="list-style-type: none"><li>RRF: € 12 bn</li><li>ERDF</li><li>InvestEU</li></ul>

# Agenda

European data policies and the European Health Data Space

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# Joint Action Towards the European Health Data Space - TEHDAS

## Joint Action

Supports the Members States and the Commission  
Develops and promotes concepts for sharing of data in secondary use

## Participants

Nominated authorities from 25 European countries

## Duration

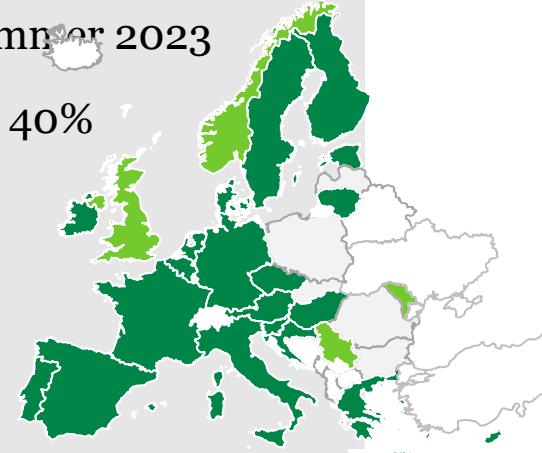
30 months from February 2021 – Summer 2023

## Co-funding

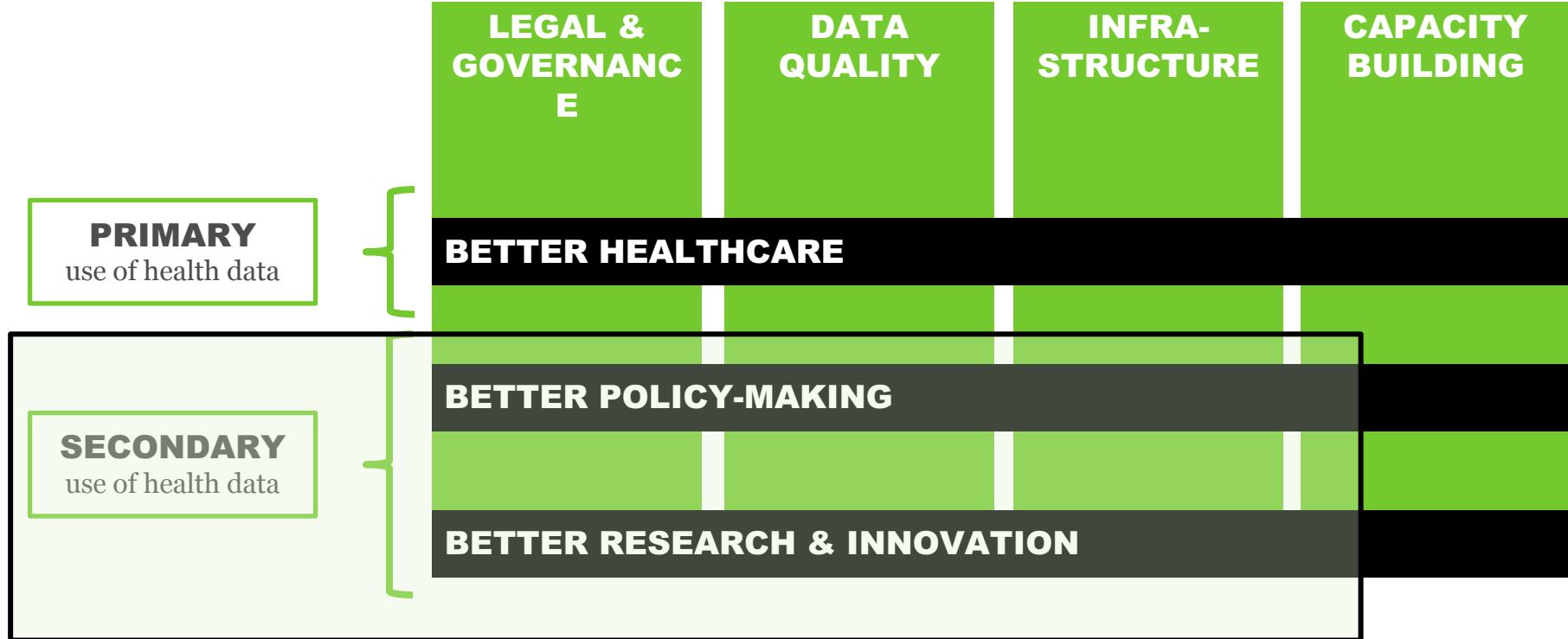
€4 million - EU 60%, Member States 40%

## Project coordinator

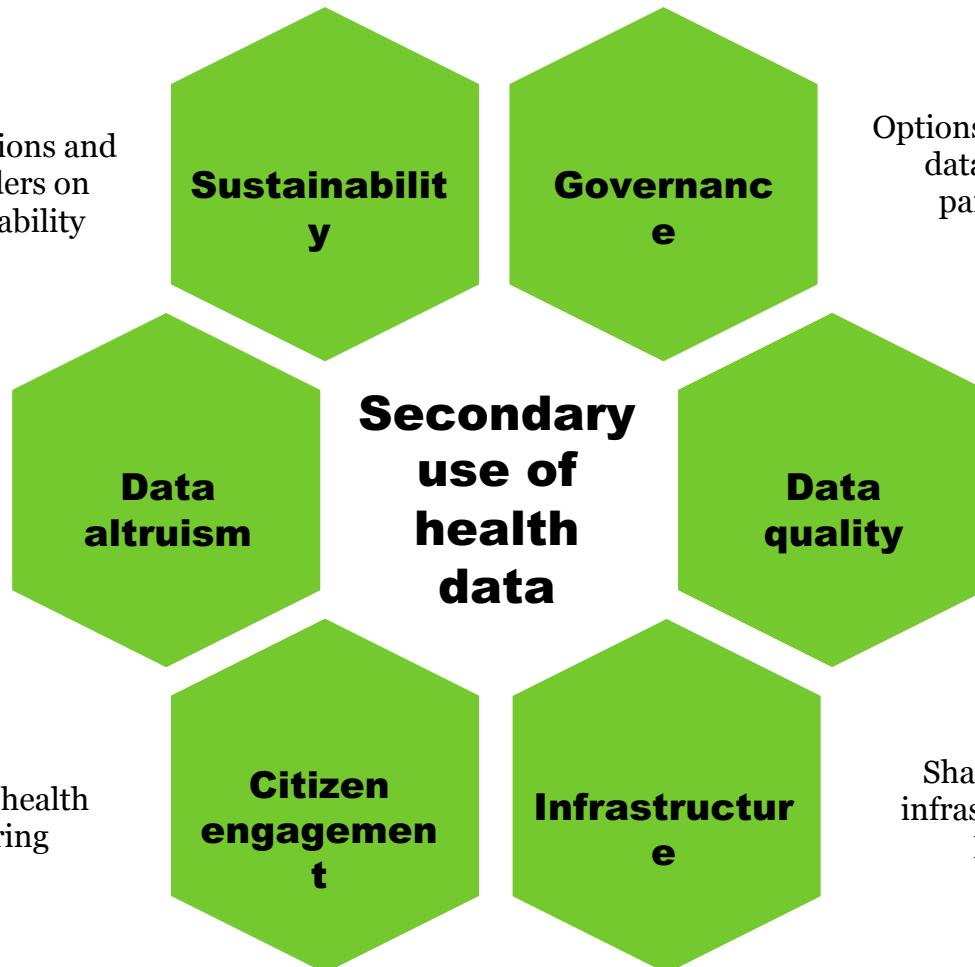
Sitra, Finnish Innovation Fund



# Four pillars of the European Health Data Space



The needs, expectations and views of stakeholders on economic sustainability



Definitions, good practices and use cases of GDPR-compliant data altruism

Citizen perception of health data and data-sharing practices

Options for governance models for data-sharing at EU level, in particular networking for secondary use

Availability of comparable high-quality health data for research and innovation

Shared European data infrastructures across the EU (cf. eHDSI)



# A steady flow of outputs in 2021-2023

 <p>Milestone 5.4 <b>Description of steps in access to individual-level data for non-EU researchers in a selected cross-border partnership: secondary use of health data from centralised systems and decentralised systems</b></p> <p>8 April 2022</p> <p>This project has been co-funded by the European Union's Health Programme (2014-2020) under Grant Agreement no 101035467.</p>	 <p>Milestone 5.5 <b>Guidelines for a peer-to-peer cross-border partnership: secondary use of health data through European cross-border sharing mechanisms</b></p> <p>31 March 2022</p> <p>This project has been co-funded by the European Union's Health Programme (2014-2020) under Grant Agreement no 101035467.</p>	 <p>Deliverable 5.1 <b>Report on secondary use of health data through European cross-border sharing mechanisms</b></p> <p>26 February 2022</p> <p>This project has been co-funded by the European Union's Health Programme (2014-2020) under Grant Agreement no 101035467.</p>	 <p>Milestone 5.6 <b>Potential health data mechanisms for Europe Data Space</b></p> <p>1 September 2022</p> <p>This project has been co-funded by the European Union's Health Programme (2014-2020) under Grant Agreement no 101035467.</p>	 <p>Summary of Milestones 5.1 &amp; 5.2 <b>Summary of results: case studies on barriers to cross-border sharing of health data for secondary use</b></p> <p>28 September 2021</p> <p>Authors: Linda Abbott, Shirley Cosgrave, Ilaria Richards, Flavia Soares, Carla Pinto, Penelope E. M. G. de Bruin</p> <p>This project has been co-funded by the European Union's Health Programme (2014-2020) under Grant Agreement no 101035467.</p>	 <p>Milestone 5.7 <b>Towards European Health Data Space: Why health is a special case for data governance</b></p> <p>23 June 2021</p> <p>This project has been co-funded by the European Union's Health Programme (2014-2020) under Grant Agreement no 101035467.</p>
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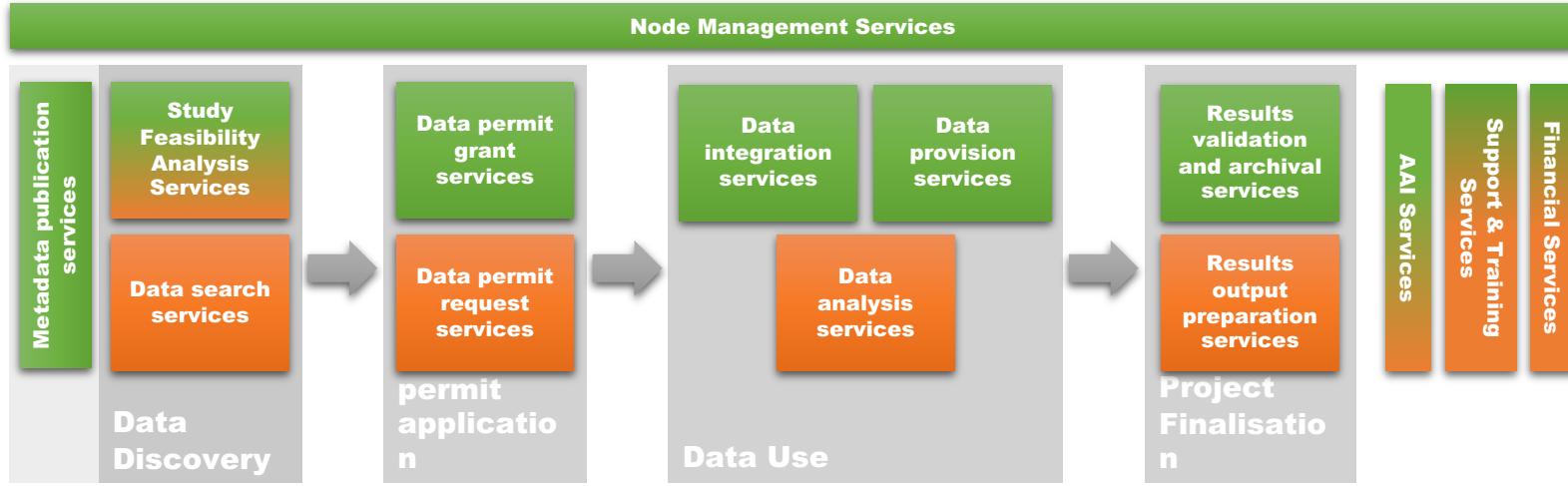


# Barriers on cross-border sharing of health data for secondary use and options to overcome these

- 47 papers reviewed by 4 reviewers to identify barriers
- from 89 barriers 20 went through detailed analysis and 11 barriers were prioritized
- 23 European countries provided 113 case studies to give real-life examples of the 11 barriers on impact, issues and solution
- 6 were legal
- 3 were data/semantic related
- 1 infrastructure
- 1 trust



# User's Journey Services



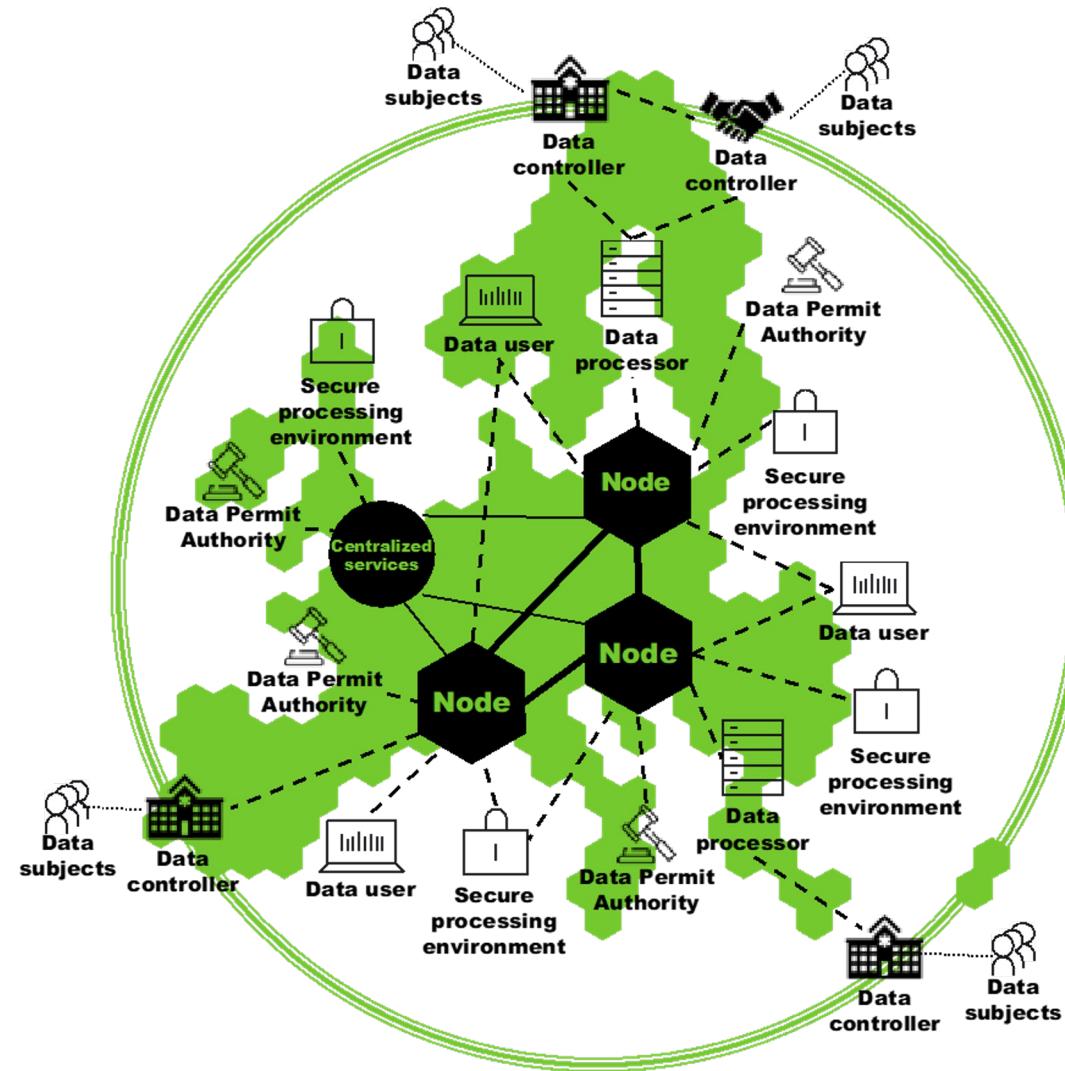
**Infrastructure**  
services

**Services with data user**  
interaction



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# Overall architecture



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SHINE!**

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## Audience Q&A Session

- ⓘ Start presenting to display the audience questions on this slide.