

Towards the European Health Data Space

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TEHDAS coordinator



Agenda

European data policies and the European Health Data Space

Joint Action Towards the European Health Data Space (TEHDAS)



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

**GDPR
enters
in force
May 2018**

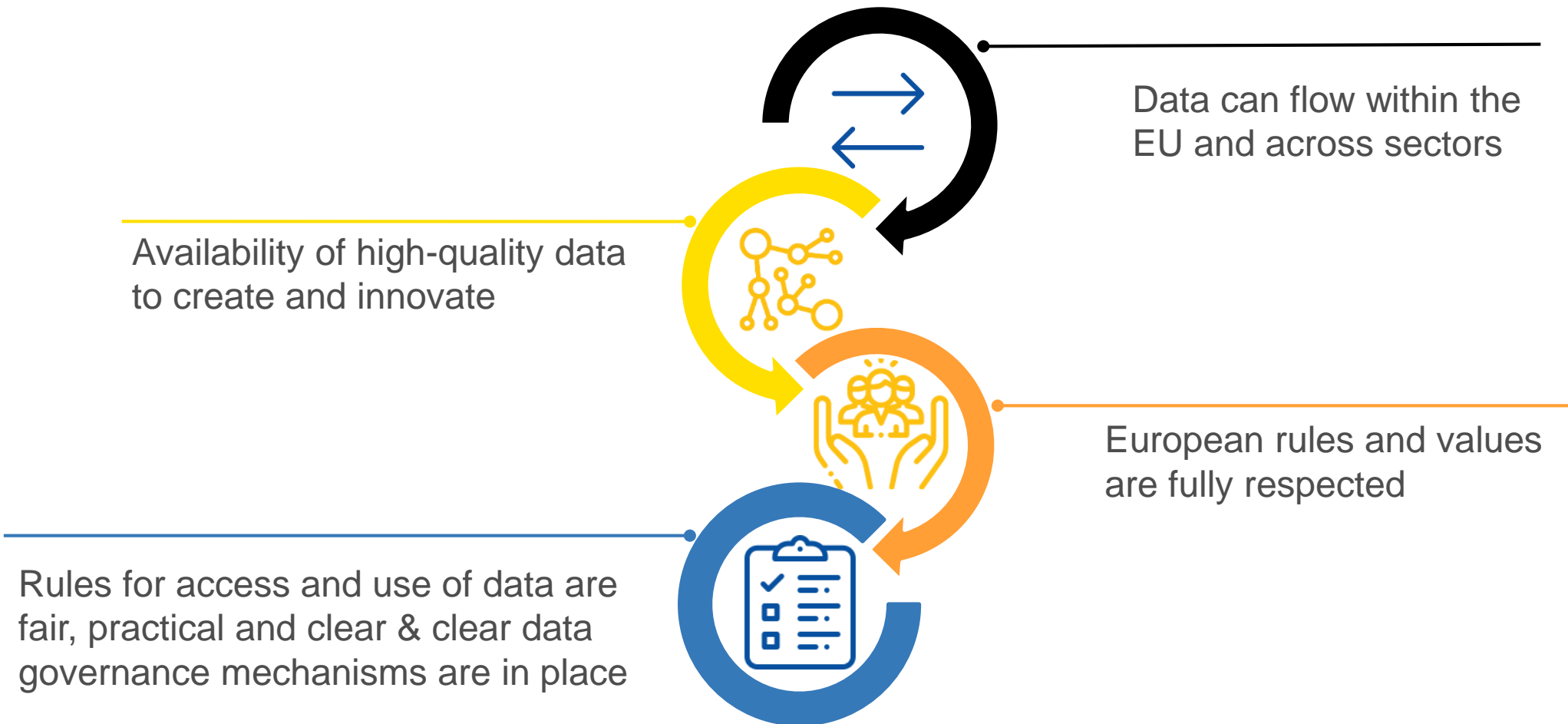


European Union Data related measures

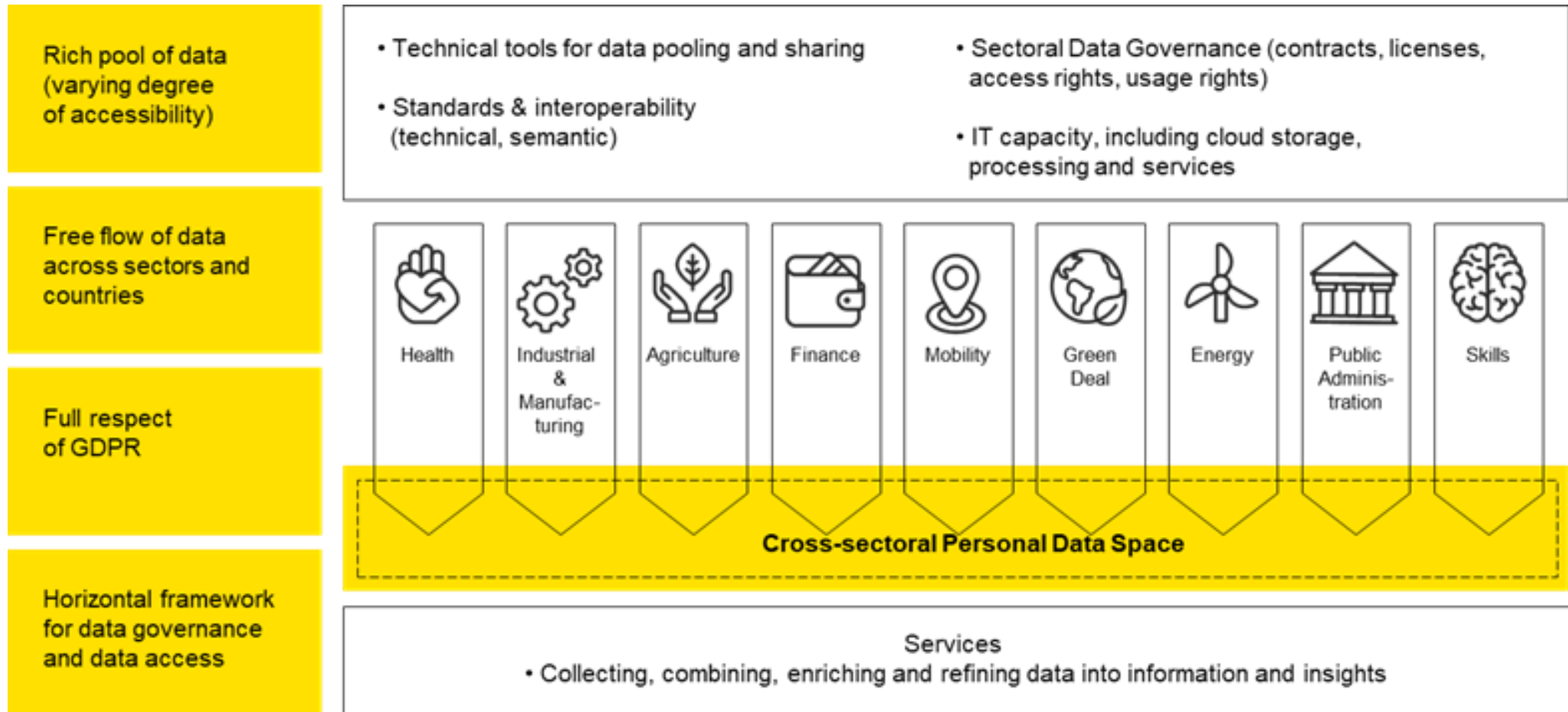
27.10.2021/22.3.2022

European Strategy for Data (2020)

A common European data space, a single market for data



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



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)

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

Agenda

European data policies and the European Health Data Space

Joint Action Towards the European Health Data Space (TEHDAS)



Joint Action Towards the European Health Data Space – TEHDAS

Joint Action

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

Participants

Nominated authorities from 25 European countries

Duration

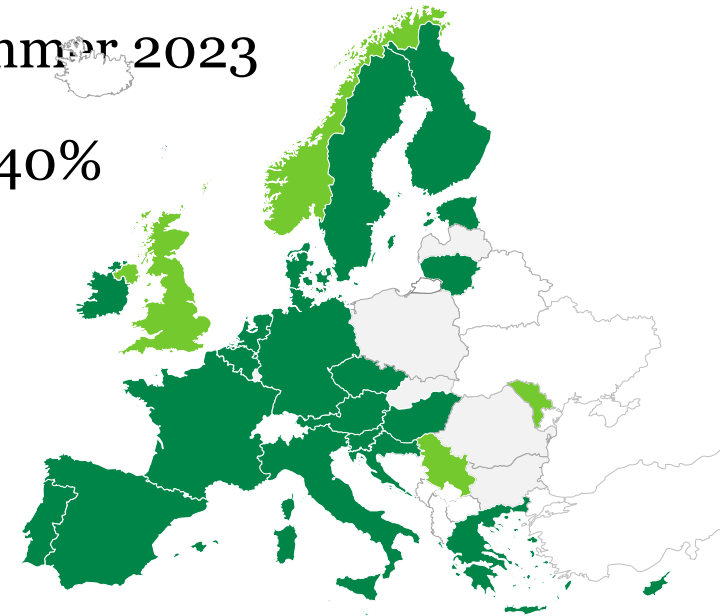
30 months from February 2021 – Summer 2023

Co-funding

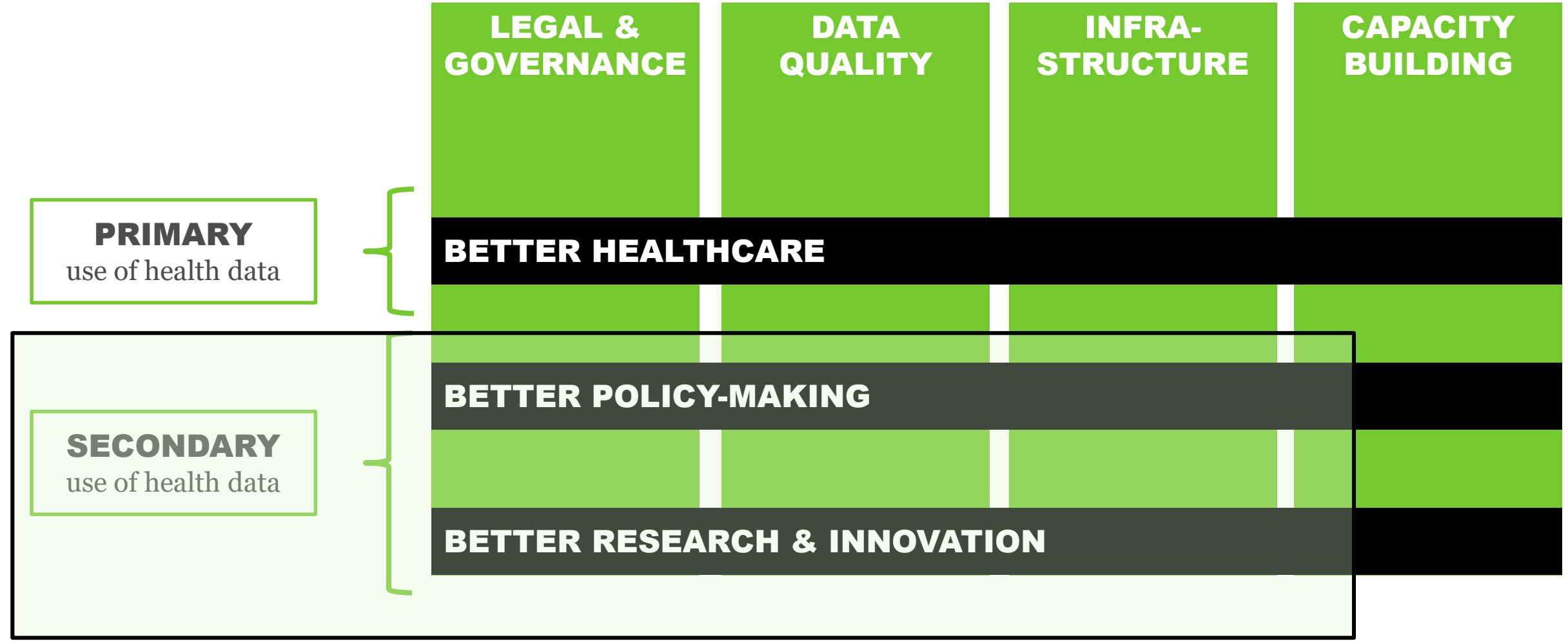
€4 million - EU 60%, Member States 40%

Project coordinator

Sitra, Finnish Innovation Fund



Four pillars of the European Health Data Space



The needs, expectations and views of stakeholders on economic sustainability



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

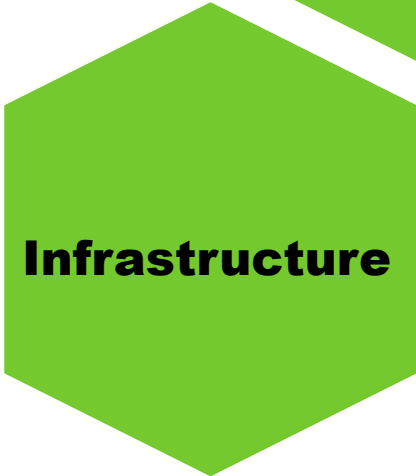


Secondary use of health data



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

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



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

Citizen perception of health data and data-sharing practices



A steady flow of outputs in 2021-2023

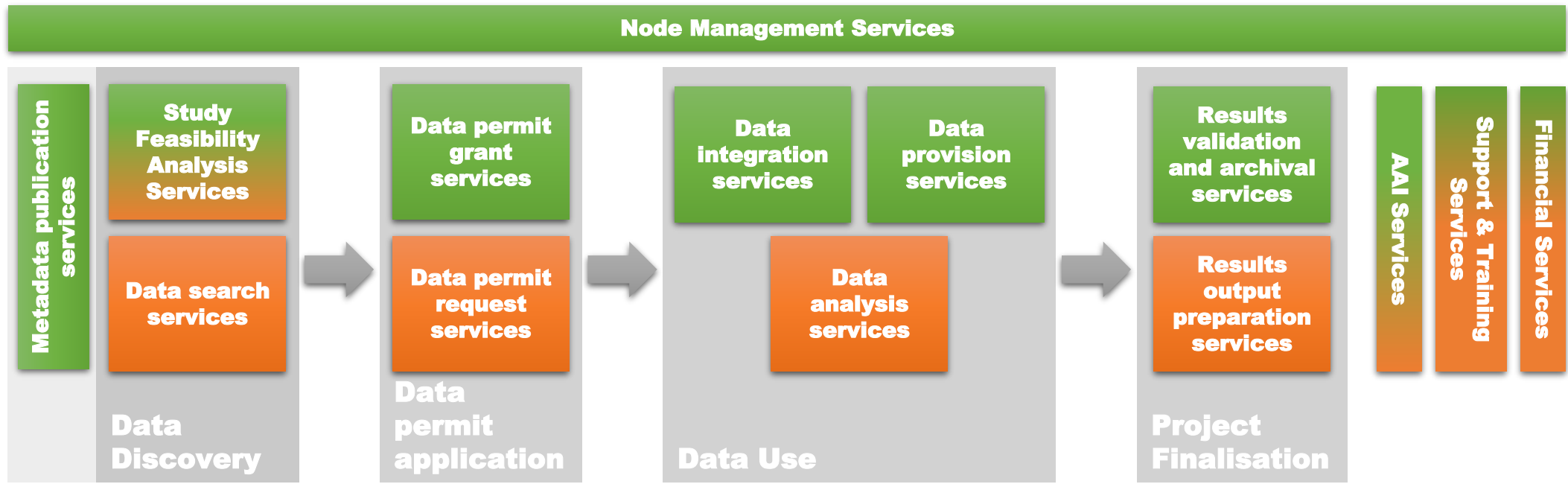


Barriers on cross-border sharing of health data for secondary use and options to overcome these

- 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

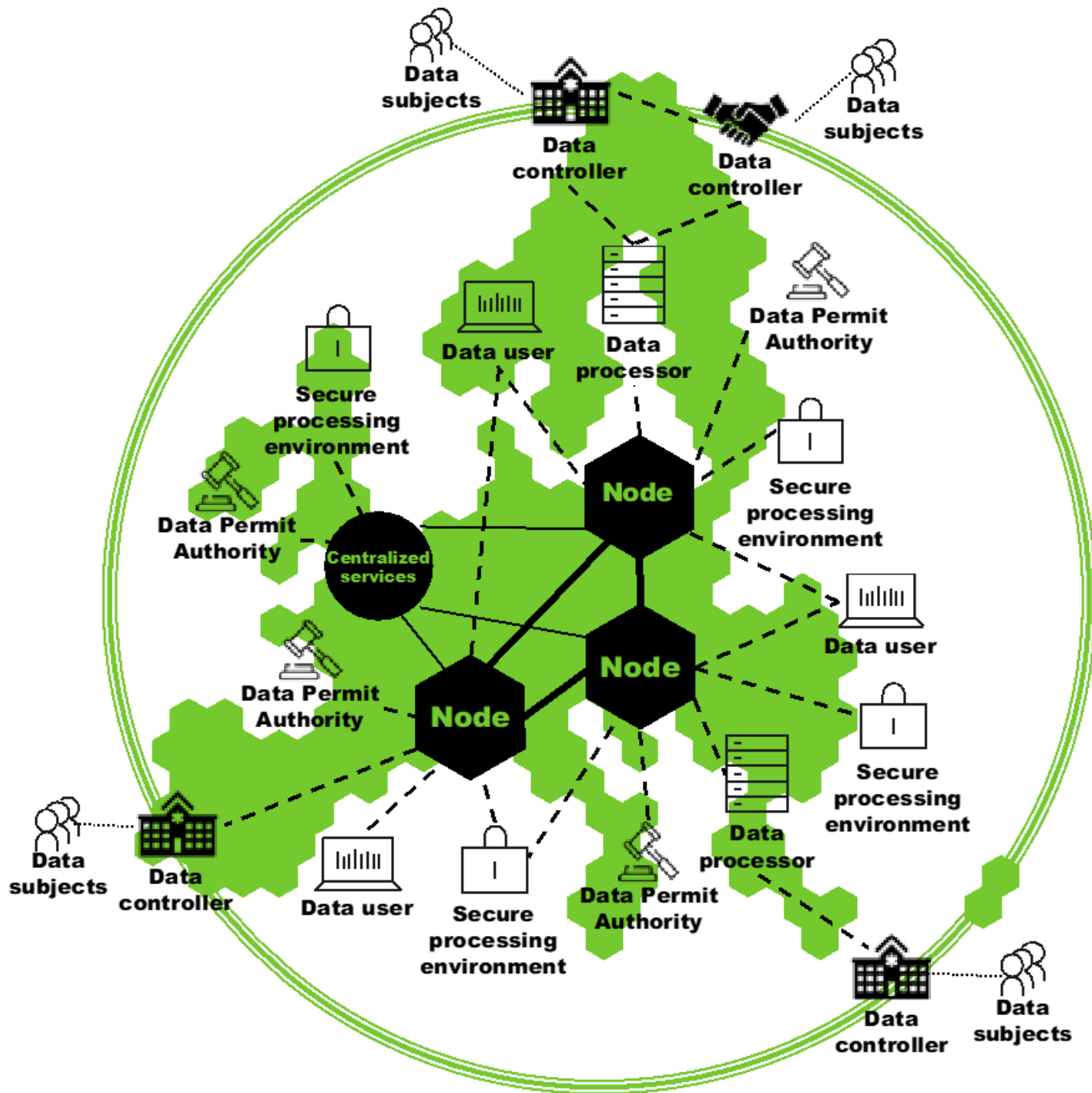


Infrastructure services



Services with data user interaction

Overall architecture



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**RISE TO
SHINE!**

