Towards the European Health Data Space

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European Union
Data related measures

Timeline:

- **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

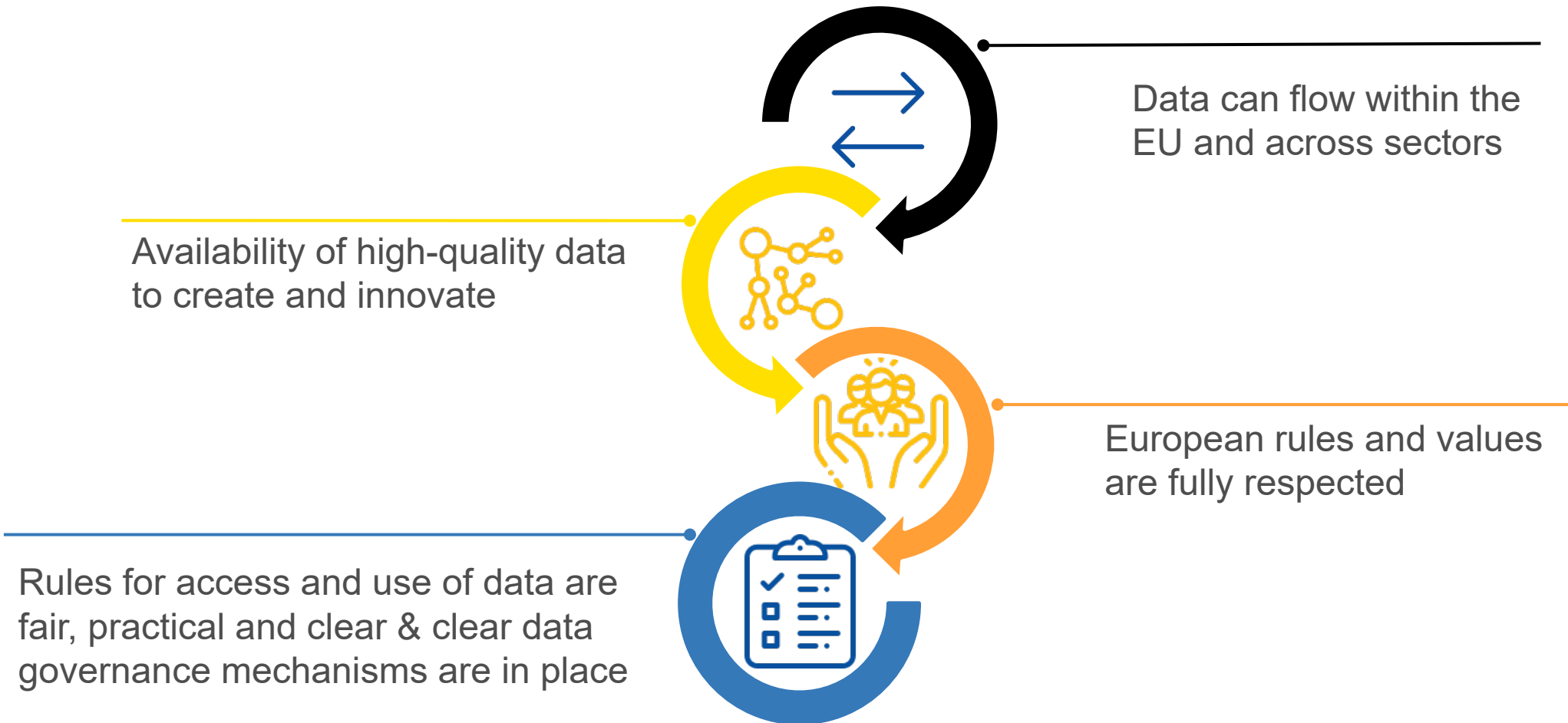GDPR enters in force May 2018

27.10.2021/22.3.2022

European Strategy for Data (2020)

A common European data space, a single market for data

Data can flow within the EU and across sectors

Availability of high-quality data to create and innovate

European rules and values are fully respected

Rules for access and use of data are fair, practical and clear & clear data governance mechanisms are in place

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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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) |

European Commission

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
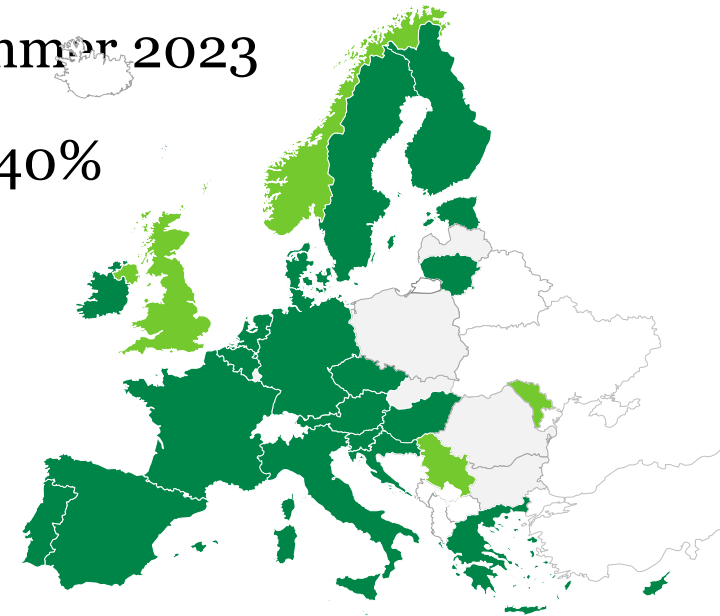Nominated authorities from 25 European countries

Duration
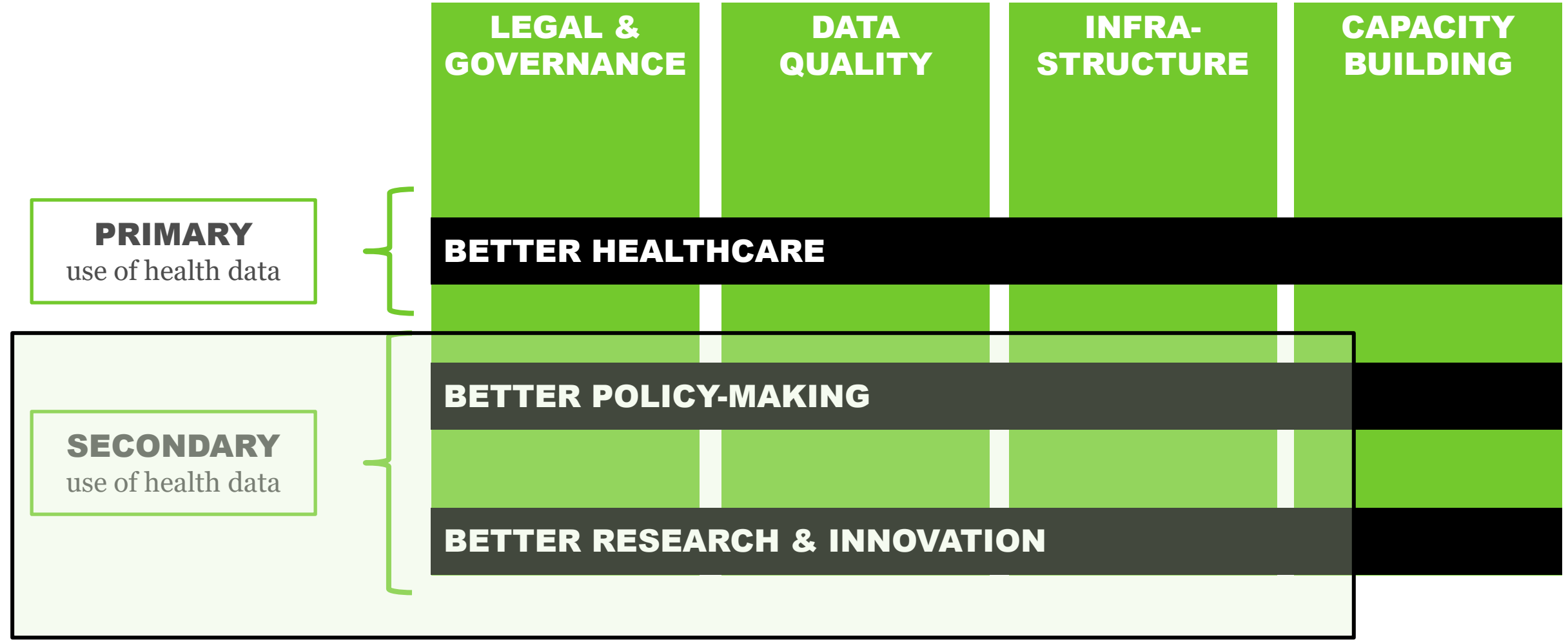30 months from February 2021 – Summer 2023

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

Project coordinator
Sitra, Finnish Innovation Fund

Four pillars of the European Health Data Space

LEGAL & GOVERNANCE
DATA QUALITY
INFRA-STRUCTURE
CAPACITY BUILDING

PRIMARY use of health data

BETTER HEALTHCARE

SECONDARY use of health data

BETTER POLICY-MAKING

BETTER RESEARCH & INNOVATION

TEH DAS

The needs, expectations and views of stakeholders on economic sustainability

Sustainability

Governance

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

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

Data altruism

Secondary use of health data

Data quality

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

Citizen perception of health data and data-sharing practices

Citizen engagement
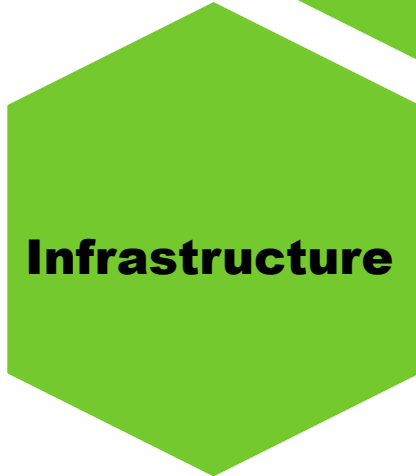
Infrastructure

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

A steady flow of outputs in 2021-2023

Why health is a specific case in data legislation?

1. Patient, consent, and the rights of data subjects i.e. citizens and patients.

2. Public health: Protection and promotion of public health.

3. Research and specific data types, such as genetic and biometric data.

4. Health data is highly sensitive data, and the need for safeguards.

5. Data and cyber security.

6. Health data in the private sector.

7. Semantic interoperability.

8. Fragmented regulatory framework at national level but the need for cross-border sharing.

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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

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# Identifying those data quality features that could be legally bound

- Metadata catalogs
- Regular audits
- Processing procedures

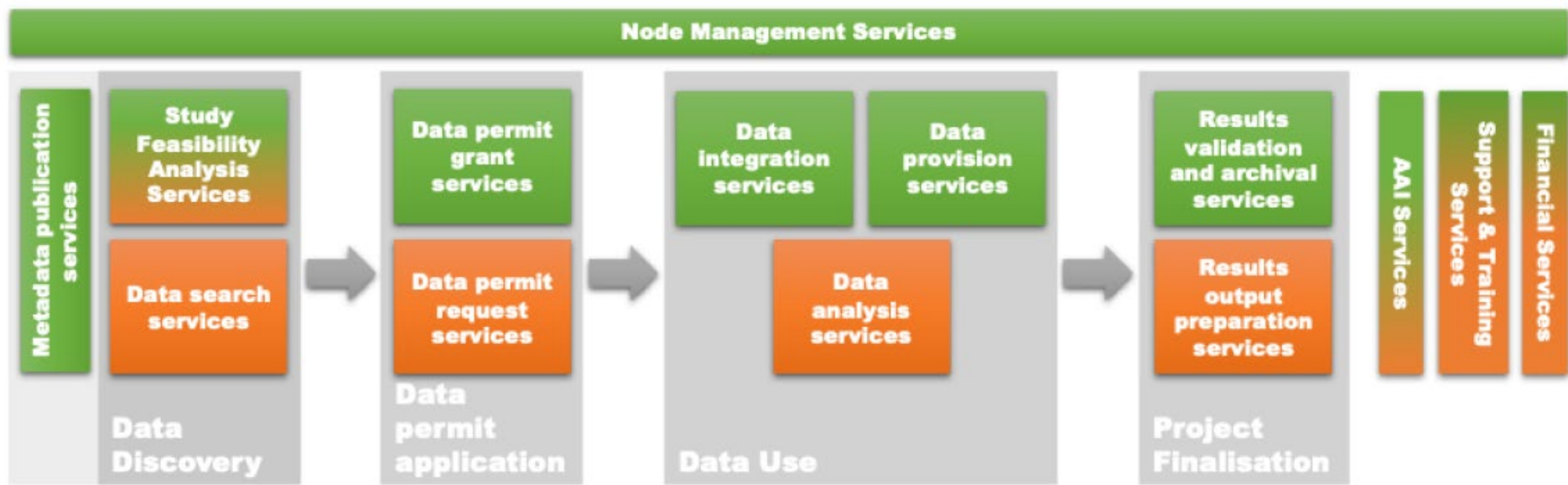# Identification of relevant standards

- 23 interoperability standards identified on 5 utilities
  – data discoverability (at data source and variable levels), 10 standards
  – development of common data models, 3 standards
  – communication across nodes, 6 standards
  – data provenance, 3 standards
  – taxonomy, 1 standard

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Overall architecture
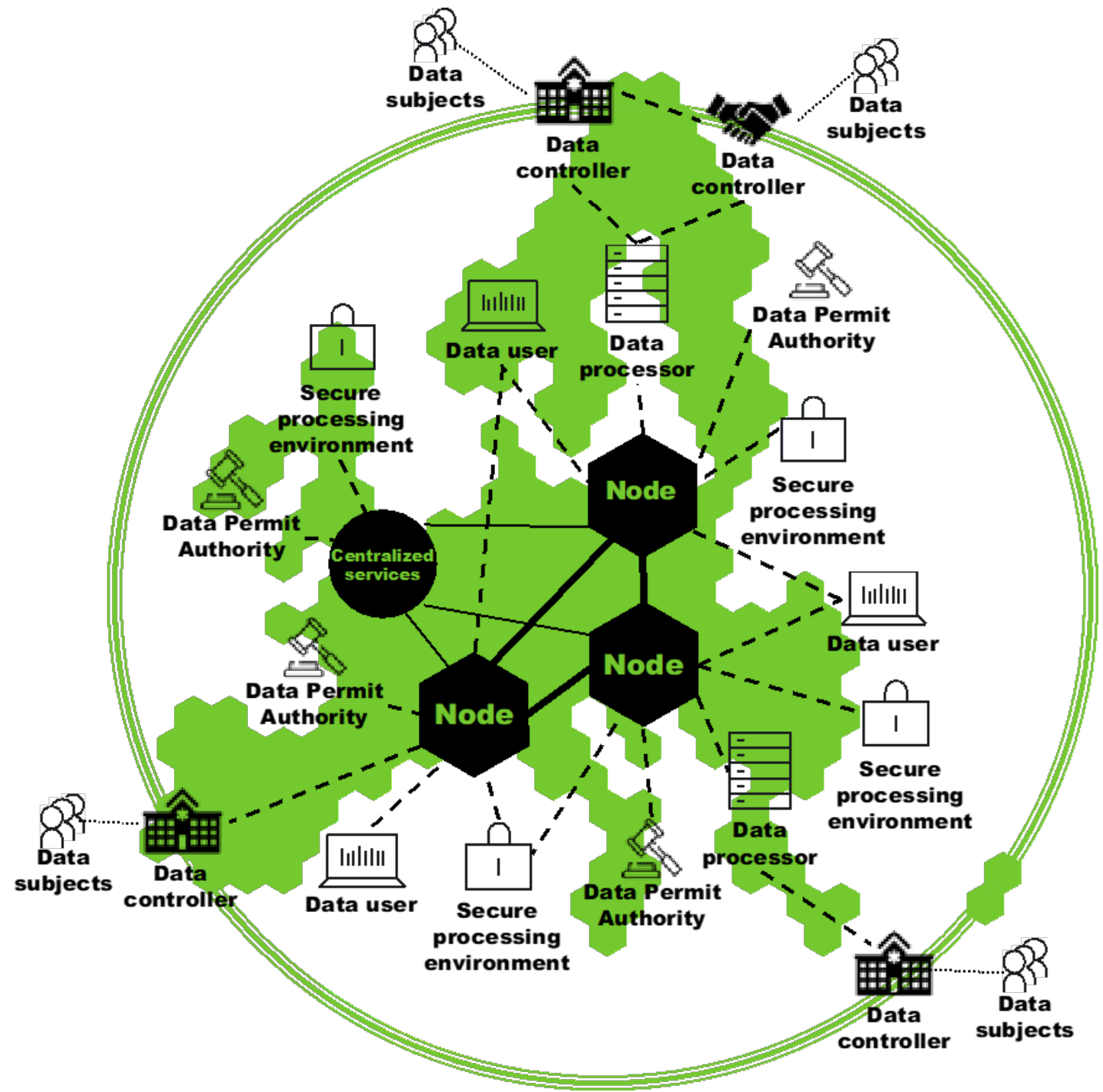
Steps to access the data – user journey

Next steps