

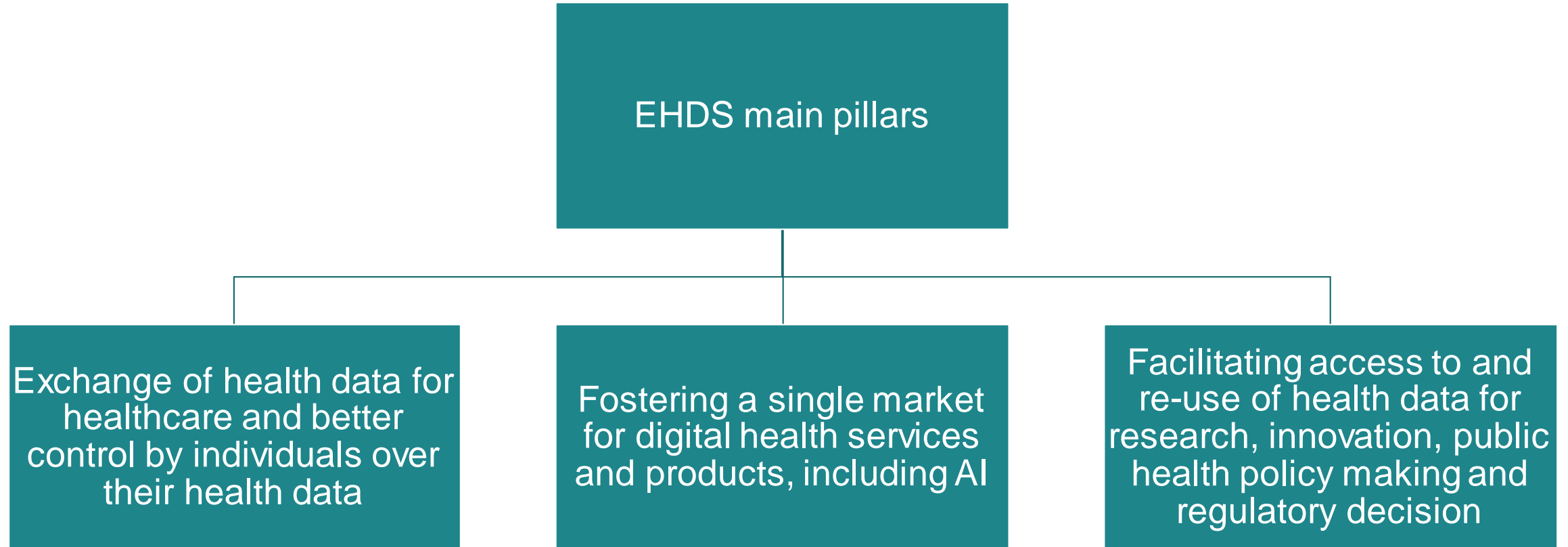


# Building the legislative proposal on the European Health Data Space

DG SANTE, European Commission  
Digital Health and European Reference Networks (B3)

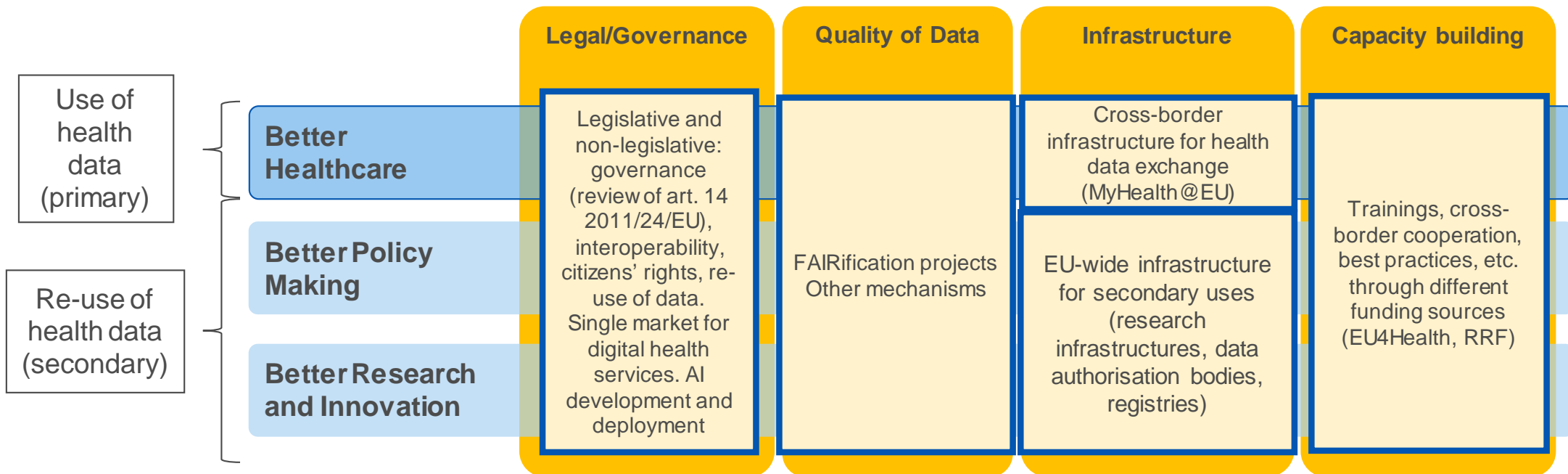
03/06/2021

# Scope of EHDS work



# Types of actions to support the EHDS

- Timely and simplified *exchange of* and *access to* health data for different use cases:
  - Healthcare provision, access and control of patient over their data, (cross-border) exchange of health data;
  - Digital health services (including telehealth and m-health);
  - Research (eg on cancer, rare diseases, COVID-19 etc), pharmacovigilance, public health, policy making



# Secondary use of health data

## Problems

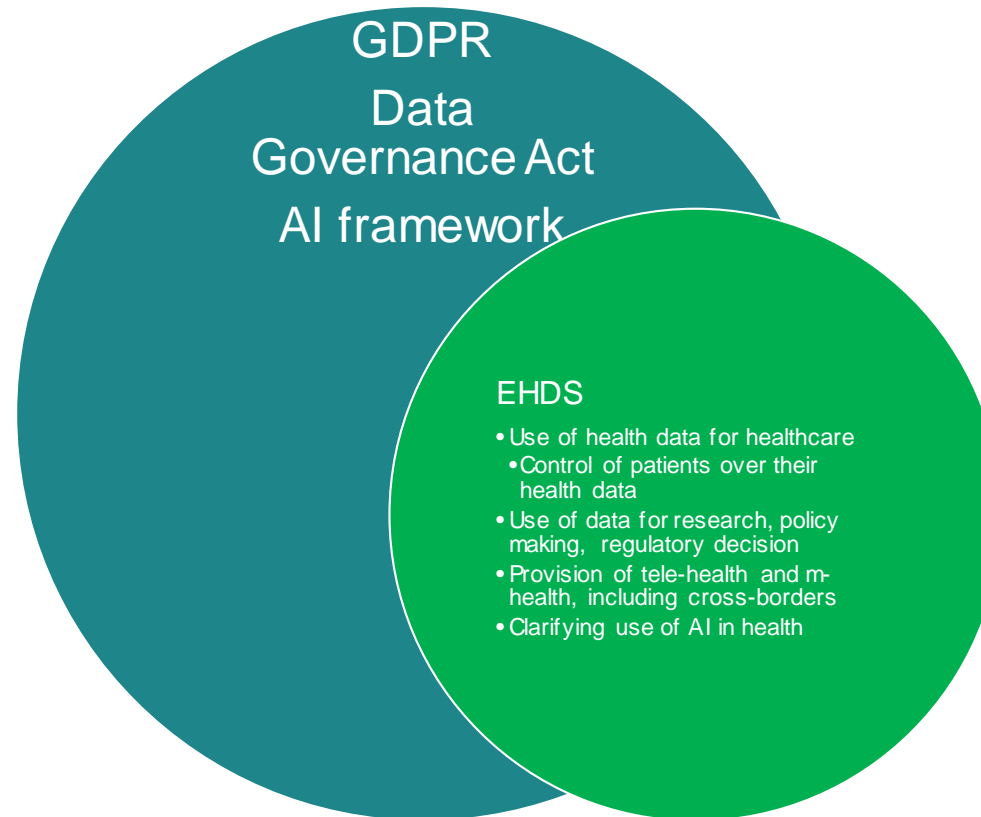
### *Results from Study on health data processing in light of GDPR*

- Low re-use of health data
- Fragmented implementation of GDPR for processing in health and research
- Cumbersome cross-border access to health data, lack of coherent mechanisms and procedures across EU
- Fragmented digital infrastructures

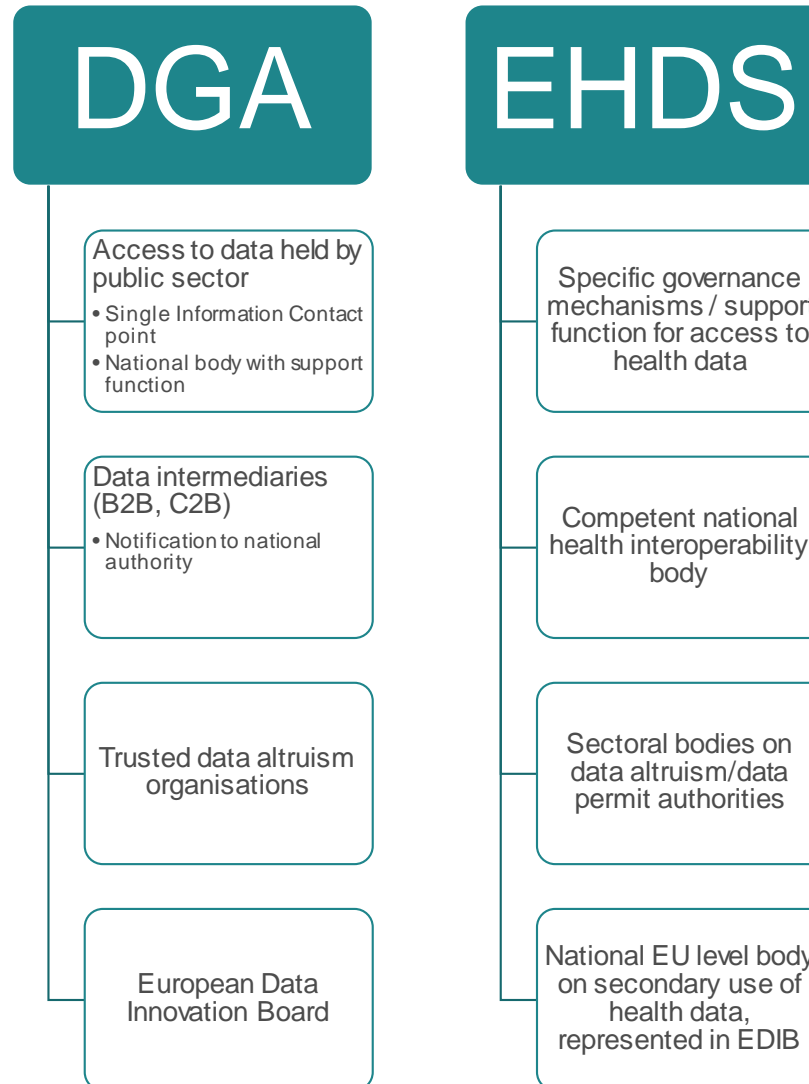
## Areas of work

- Governance and rules for facilitating access to health data for re-use
- Data quality and interoperability (Data FAIR-ification, etc)
- Digital infrastructure (EHDS2)

# EHDS: articulation with EU regulatory framework



# Legislation: Data Governance Act - EHDS



# Feedback from stakeholders on Inception Impact Assessment (Dec 2020 – Feb 2021)

Facilitating access to and re-use of health data for research, innovation, policy making and regulatory-decision

- Strong and trusted **governance framework**, fully compliant with the **GDPR and ethical requirements**, transparency and security, patient centric
- **Establish governance** mechanisms at **national** level and **EU** level
- Coherence with **Data Governance Act**
- Appropriate **data quality** and **interoperability** standards
- Use of secure federated cloud **infrastructures**
- Ensure broad **engagement** with the **public**

# Public Consultation 3 May 2021 – 26 July 2021 : Policy options explored for secondary use of health data

## Governance mechanisms at national level

Voluntary data permit body

Mandatory data permit body

Data altruism managed by public body or private body

## Content of rules for access in line with GDPR and ethics

Health data categories

Format of data (anonymised, pseudonymised, fully identifiable datasets)

Eligibility, conditions and safeguards

Security

## How to facilitate access to health data from private stakeholders

By data holder

By data permit body

Incentives

## At EU level

Governance mechanism for secondary use of health data

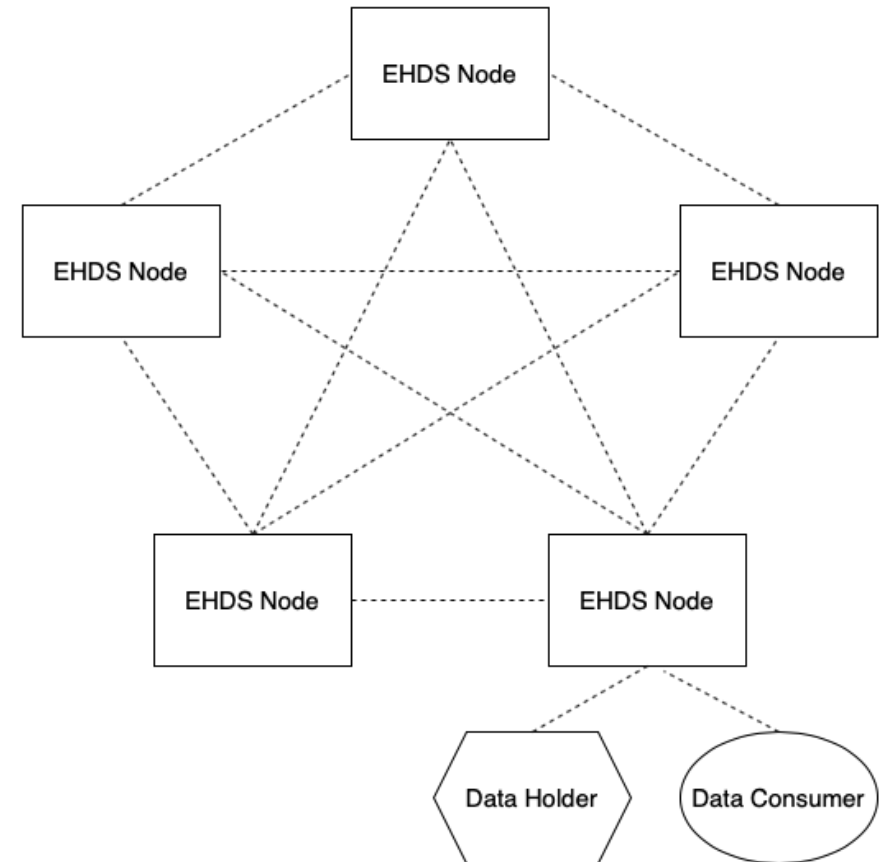
Role of an EU data permit authority

Common standards and specifications for cross-border infrastructure



# Infrastructure: A pilot for the EHDS2

- Demonstrate feasibility of connecting bodies and stakeholders dealing with secondary uses of health data
  - Data Permit Authorities
  - Data-sharing infrastructures
  - Regulatory and public health bodies
- Status: Design phase
- Tentative timeline: start implementation in Q4 2021



# EHDS: better regulation process

