

# Building the legislative proposal on the European Health Data Space

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

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#### Scope of EHDS work

EHDS main pillars

Exchange of health data for healthcare and better control by individuals over their health data

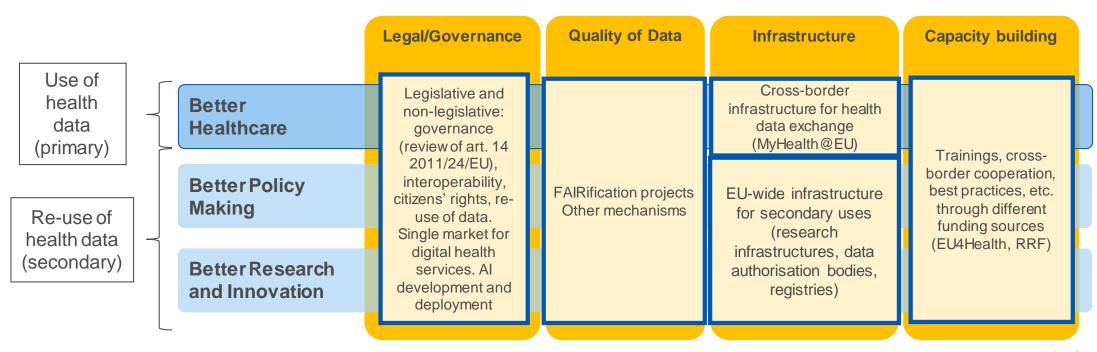
Fostering a single market for digital health services and products, including Al

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



### 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

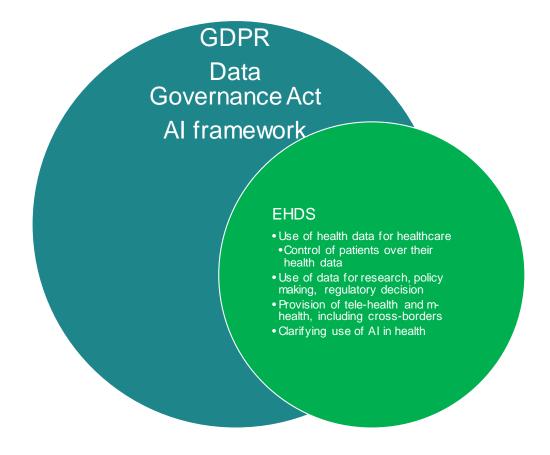
- Low re-use of health data
- Fragmented implementation of GDPR for processing in health and research
- Cumbersome cross-border access to health data, lack of coherent mechanisms and procedures across EU
- Fragmented digital infrastructures

#### 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

#### DGA

#### Access to data held by public sector

- Single Information Contact point
- National body with support function

#### Data intermediaries (B2B, C2B)

Notification to national authority

Trusted data altruism organisations

European Data Innovation Board

## EHDS

Specific governance mechanisms / support function for access to health data

Competent national health interoperability body

Sectoral bodies on data altruism/data permit authorities

National EU level body on secondary use of health data, represented in EDIB



## 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 mechansim for secondary use of health data

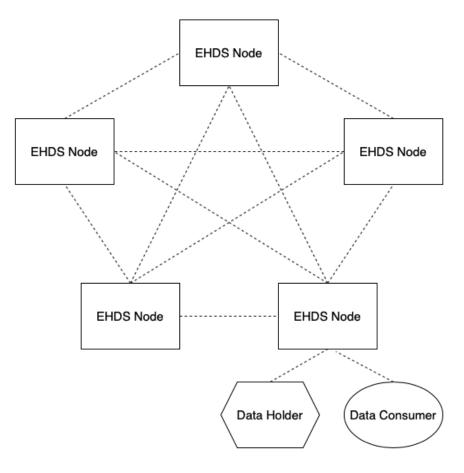
Role of an EU data permit authority

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

Inception Impact Assessment:

Public consultation (3 May – 26 July 2021)

### Impact Assessment (Q3 2021)

- Study on Assessment of the EU Member States' rules on health data in the light of GDPR (Q1 2021)
- •Study on regulatory gaps, including evaluation D. 2011/24/EU, digital health services, AI (Q2 2021)
- •Infrastructure study (Q3 2021)
- Studies to support the Impact Assessment (Q3 2021)
- •JA TEHDAS 2021

Consultation EDPS

Legal proposal (Q4 2021)

