Towards a common
European Health Data Space

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Agenda

1. Digital transformation of health and care

2. A common European Health Data Space (EHDS)

   1. Primary and secondary uses of health data

   2. Digital health

   3. AI in health

3. What the future holds

Digital transformation of health and care

- Accessibility, affordability and availability of care

- Health challenges

  - Ageing population

  - Chronic diseases

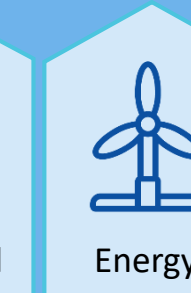 - Cancer (European Cancer Beating Plan)

*We need to make the most of the potential of e-health to provide **high-quality healthcare and reduce inequalities.** I want you to work on the creation of a **European Health Data Space** to **promote health-data exchange** and **support research** on **new preventive strategies**, as well as on **treatments, medicines, medical devices and outcomes**. As part of this, you should ensure **citizens have control** over their own **personal data**.*

Mission letter of Stella Kyriakides Commissioner for Health

European Commission

A common European Health Data Space (EHDS)

Common Data Spaces

Health | Industrial & Manufacturing | Agriculture | Finance | Mobility | Green Deal | Energy | Public Administration | Skills

Horizontal Framework

Data Governance Act

LEVERAGING THE POTENTIAL OF DATA FOR THE ECONOMY AND SOCIETY

Pillar 1: Re-use of sensitive data held by public sector bodies

Pillar 2: Framework for new **data intermediaries** in the Single Market: Data brokers

Pillar 3: Framework for **data altruism**

Pillar 4: Co-ordination and interoperability: European Data Innovation Board (expert group)

European Commission

A common European Health Data Space (EHDS)

- EHDS: Health Data + Digital Health + AI in health

  1. **Health data exchange** (governance, privacy, quality, portability and access to data, infrastructures, interoperability)

  2. A single market for **digital health services and products**

  3. Clear **rules** fit for **developing and deploying** data-intensive digital health services and products, including AI in health

- In combination with other horizontal initiatives

- Inception impact assessment available in *Have your say* (feedback period closed on 03/02)

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A common European Health Data Space (EHDS)

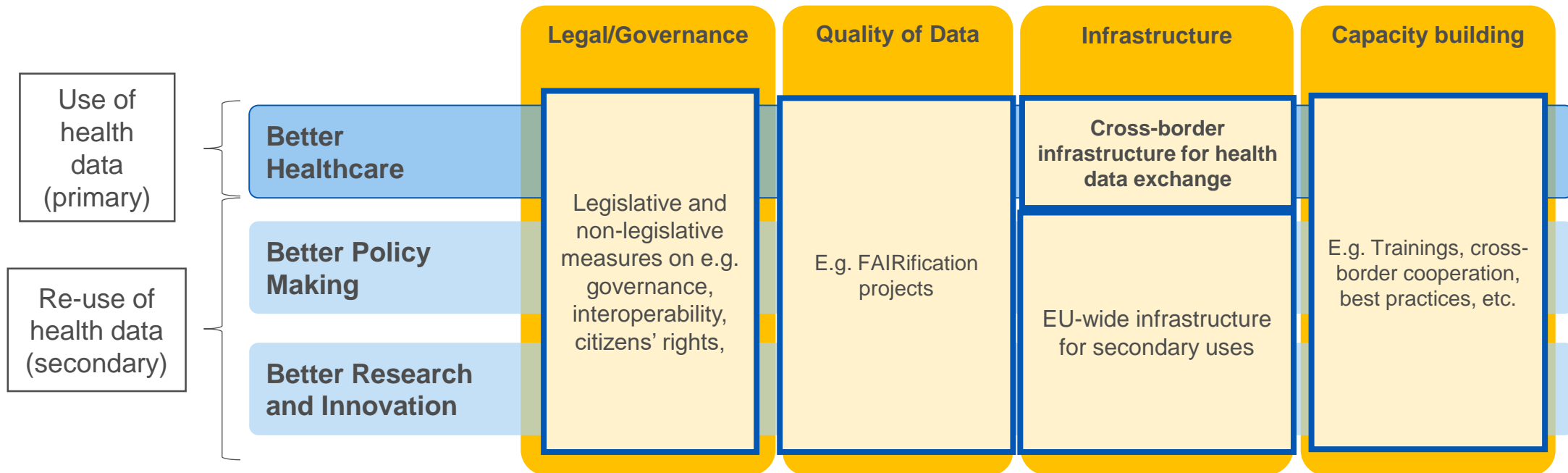| Access to health data for healthcare in cross-border context	Access to health data for secondary purposes (research, policy making)	Limited free movement of digital health services (e.g. tele-health, m-health)	Development and deployment of AI in health care
• Insufficient **health data exchange** negatively impacts on the provision of healthcare services (primary use of health data) • Exercising access and **control over their own health data** is often difficult for citizens	• Low **re-use of health data for research and policy making** • **Cross-border access rules to health data** for secondary purposes are unclear and cumbersome • **Fragmented infrastructures** for data use in research and policy making	• There is **fragmentation of digital standards and limited digital interoperability** between healthcare systems • Challenges related to **assessing of digital health products/services** (benefits, risks)	• **Knowledge gaps** and **difficult access** to health data for AI development • **Uncertainty** on AI liability in health

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Primary and secondary uses of health data

	Legal/Governance	Quality of Data	Infrastructure	Capacity building
Better Healthcare	Legislative and non-legislative measures on e.g. governance, interoperability, citizens' rights,	E.g. FAIRification projects	**Cross-border infrastructure for health data exchange**	E.g. Trainings, cross-border cooperation, best practices, etc.
Better Policy Making			EU-wide infrastructure for secondary uses	
Better Research and Innovation				

Use of health data (primary)

Re-use of health data (secondary)

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MyHealth@EU: Cross-border infrastructure for healthcare provision

Doctor access to foreign citizen Patient Summary

Patient Summary

Used while traveling abroad and being in necessity of consulting a doctor in that country.

Provides information on important health related aspects such as your allergies, current medication, previous illness, surgeries.

Helps doctors to formulate an adequate treatment, avoid some possible risk (for instance in case of allergy) and overcome linguistic barriers.

eHealth Network Patient Summary guidelines, including minimum dataset

8

MyHealth@EU: Cross-border infrastructure for healthcare provision

Patients access to ePrescriptions abroad

Electronic prescription in Europe – a Finnish patient purchasing medication in a pharmacy aboard

ePrescription

allows citizens in Europe to retrieve their medication in a pharmacy located in another European country without having to bring the printed prescription and without being concerned about the language barrier.

eHealth Network ePrescriptions and eDispensation guidelines

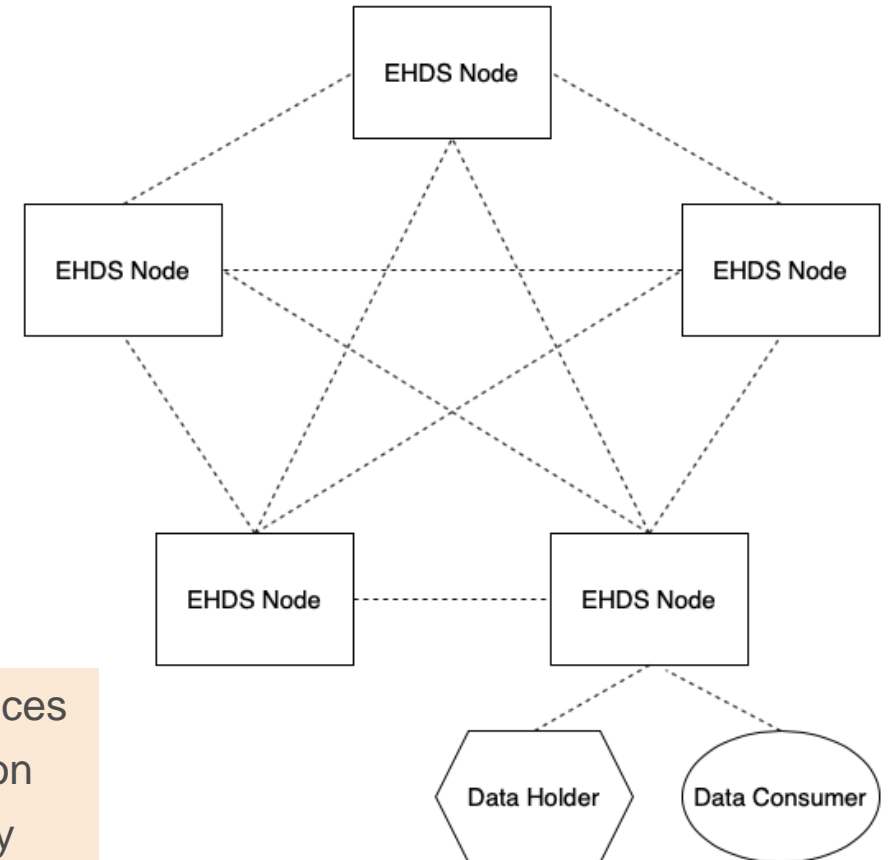# A pilot for the European Health Data Space infrastructure

- Demonstrate feasibility of connecting bodies and stakeholders dealing with secondary uses of health data

  - Data Permit Authorities: FR, FI, DK

  - Data-sharing infrastructures

  - Regulatory and public health bodies: EMA, ECDC

- Status: Design phase

- Timeline: start implementation in Q4 2021

EHDS NODES digital services
- Message exchange
- Backend integration
- Publish metadata (describing data sources)
- Access management

- **EHDS FEDERATION** digital services
  - Dynamic Service Location
  - Dataset lookup capability
  - Trust establishment
  - Service desk
  - Compliance check

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What the (short-term) future holds

- **Legislative proposal** on the European Health Data Space in 2021
  - Proposal on Data Governance Act (already published)
  - Inception impact assessment feedback closed in Q1 2021 (*Have your say*)
  - Open public consultation in Q1/Q2 2021

- Cooperation with Member State stakeholders in the **Towards a European Health Data Space (TEHDaS)** Joint Action

- Design and implementation of the **EHDS pilot**

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