



# Importance of Data Standards in the European Health Data Space

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

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# Digital transformation of health and care

*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

- Health challenges
  - Accessibility, affordability and availability of care
  - Health threats (COVID-19)
  - Ageing population
  - Chronic diseases
  - Cancer (Europe's Cancer Beating Plan)
  - Mental health
  - *And so many other...*

# EHDS: Data ecosystem principles

- Embrace diversity (of data types and sources)
- Cross-health domain

# A common European Health Data Space (EHDS)

Common Data Spaces



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)**

# EHDS: Data ecosystem principles

- Embrace diversity (of data types and sources)
- Cross-health domain
- Cross-sector

# EHDS: Challenges

## Access to health data for healthcare in cross-border context

- 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

## Access to health data for secondary purposes (research, policy making, regulatory activities)

- 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

## Limited free movement of digital health services (e.g. tele-health, m-health)

- Low uptake of digital health services and products
- There is **fragmentation of digital standards and limited digital interoperability** between healthcare systems
- Challenges related to **assessing of digital health products/services**

## Development and deployment of AI in health

- **Difficult access** to health data for AI development
- **Complexity of AI** hampering deployment in health

# EHDS: Data ecosystem principles

- Embrace diversity (of data types and sources)
- Cross-health domain
- Cross-sector
- Privacy-preserving
- Extensibility

# MyHealth@EU:

Cross-border infrastructure for healthcare provision



My Health @ EU  
eHealth Digital Service Infrastructure  
A service provided by the European Union

## 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](#)





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## Patients access to ePrescriptions abroad

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



### 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](#)

# EHDS: Data ecosystem principles

- Embrace diversity (of data types and sources)
  - Cross-health domain
  - Cross-sector
  - Privacy-preserving
  - Extensibility
- Structured and unstructured data (diverse data models and formats)
  - Multiple controlled vocabularies

# EHDS: FAIR

## Findable

Data has rich meta-data  
and unique identifier

## Accessible

Data is available  
through standard protocols

**FAIR**

## Interoperable

Meta-data use a  
standard language

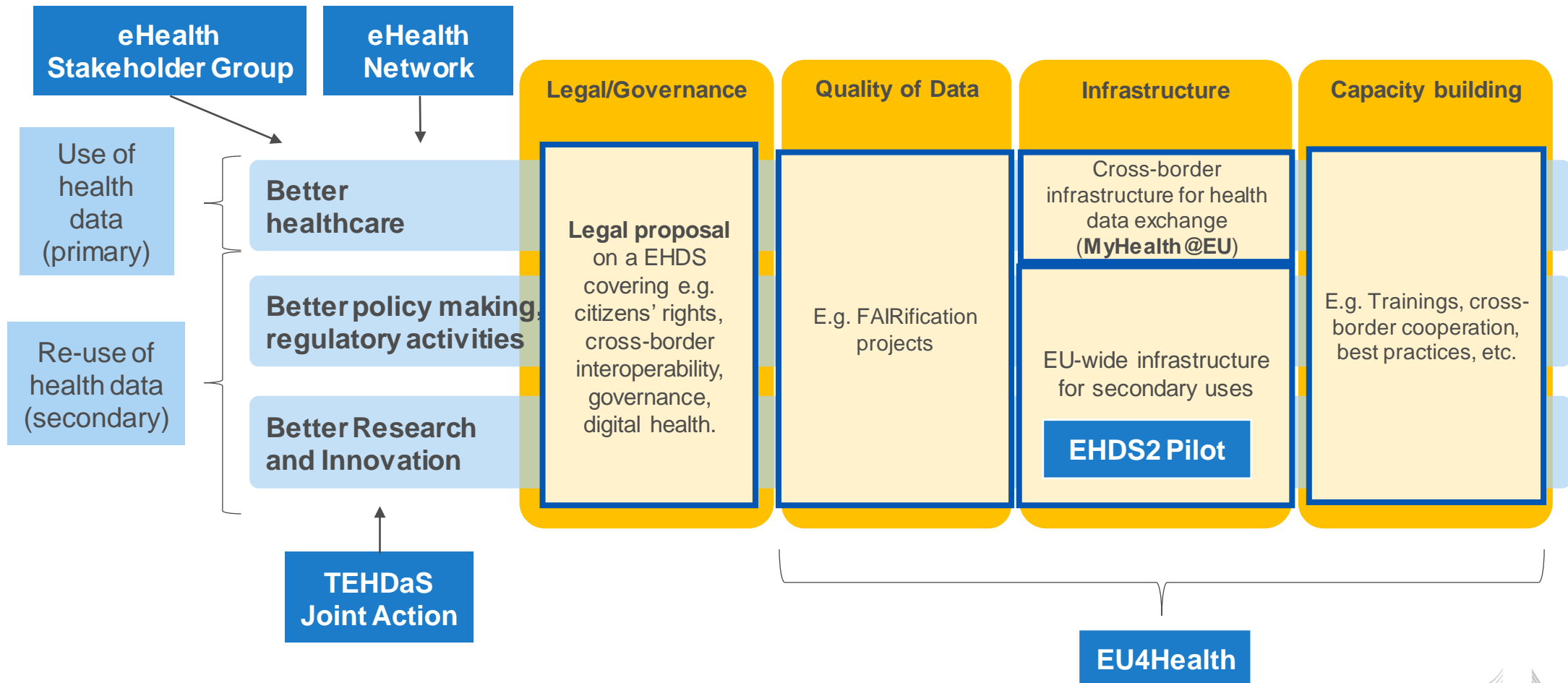
## Reusable

Data is well described and  
provides clear re-use conditions

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- FAIR

# EHDS initiative framework



# What the (short-term) future holds

- **Legislative proposal** on the European Health Data Space
  - Proposal on Data Governance Act already published
  - Inception impact assessment feedback (closed in Feb. 2021)
  - **Open public consultation open for input!** ([Have your say](#) until 26 July 2021)
- Cooperation with Member States and stakeholders in the **Towards a European Health Data Space (TEHDaS)** Joint Action
- Preparations for the **EHDS2 infrastructure pilot (architecture of standards)**

Questions?

Challenges?

Suggestions?

## Further information

eHealth Network

[https://ec.europa.eu/health/ehealth/policy/network\\_en](https://ec.europa.eu/health/ehealth/policy/network_en)

All events

[https://ec.europa.eu/health/ehealth/events\\_en#anchor0](https://ec.europa.eu/health/ehealth/events_en#anchor0)



# Thank you



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