

## European Health Data Space



# Towards a European Health Data Space (EHDS)

#### **OBJECTIVES**

Timely and simplified exchange of and access to health data

#### **SCOPE & EXPECTED IMPACT**

Use of health data (primary, EHDS1)

 Individuals to access and control their data & exchange of health data (incl. cross-border), irrespective of source (electronic health records, tele-health, m-health, wellness apps) Single market for data, data protection, free movement of people, digital goods and services

Re-use of health data (secondary, EHDS2)

- · Research, innovation
- Policy (incl. e.g. public health, HTA) & Regulatory decisions

Facilitated Research & Innovation

**Better Policy Making** 

#### **MEANS**

**Legal / Governance** 

**Quality of data** 

Infrastructure

Capacity building/digitalisation (MFF)



## EHDS: What are the problems?

## Use of health data for healthcare (primary)

Sharing of health data for healthcare

- Limited control to and access to patients
- Repeated tests and high costs
- Insufficient exchange of health data
- Limited interoperability between health care providers

Single market for digital health products and services

- Uneven national legislative frameworks
- Uneven quality / interoperability frameworks
- Uneven procedures for prescriptions, reimbursement, liability

## Re-use of health data (secondary)

Access to health data for research, innovation, public health policy making

- Low re-use of health data
- Cumbersome crossborder access to health data
- Fragmented digital infrastructures

Artificial Intelligence

- Limited provision of data for training of Al
- Difficulties for regulators to evaluate
- Al algorithms
- Uncertainty on Al liability in health

## EHDS: Articulation with EU regulatory framework

Cross-border healthcare
Directive
GDPR

Data Governance Act

Al regulation

#### **EHDS**

- health data for healthcare
- Control of patients over their health data
- Use of data for research, policy making, regulatory decision
- Provision of tele-health and m-health, including cross-borders
- Clarifying use of AI in health





# 1a. Use of data for healthcare

Primary use of health data (EHDS 1/MyHealth@EU)



#### Access to health data in digital format

Today, a large number of EU citizens and healthcare professionals cannot access health data in a **digital format**. Data are often available in paper, or only a limited set of data categories are available in digital format.

#### Interoperable health data

Health data is collected in such a way, that **the format is different** everywhere. This makes it impossible to understand the meaning of health data in different contexts. Therefore, interoperability standards are required to **promote wider use and understanding**.

#### **Tools and infrastructure**

Member States organise health data access through different means. Some member states have patient or professional **portals** at the level of healthcare provider, region or nation, while others have apps or **personal data space** solutions. Also, registries of who should have **access** are also local, regional or national solutions.

# **EHDS1: rules: Commission Recommendation on a Electronic Health Record Exchange Format**

Common technical specifications (baseline)



## Initial health information domains:

- patient summaries
- ePrescriptions
- laboratory reports
- medical images and reports
- hospital discharge reports



## Interoperability specifications

- HL7 CDA
- DICOM
- IHE profiles



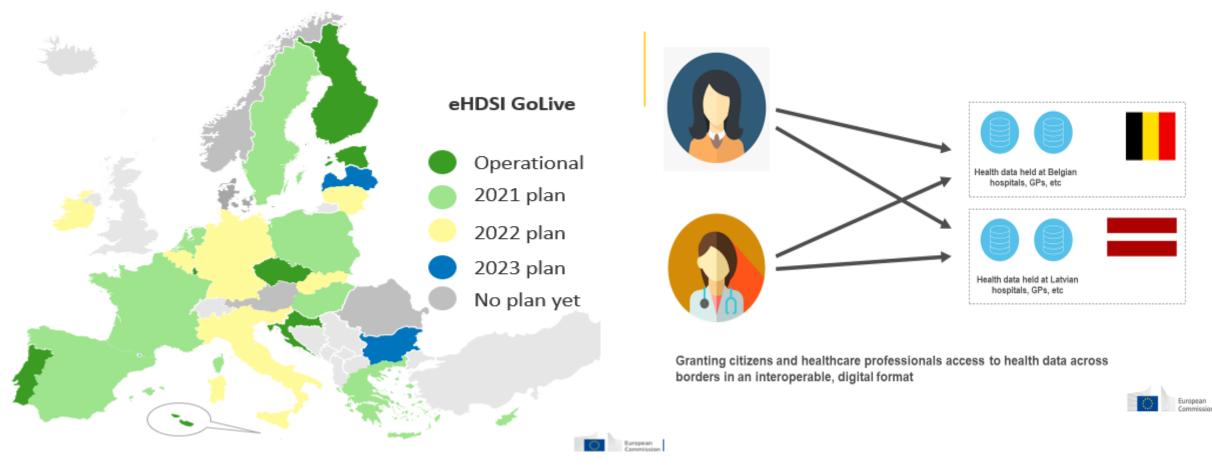
## Incremental and selective approach

 adopting, refining, and maintaining the specifications of the European EHR exchange format



## EHDS1: MyHealth@EU: cross-border exchange of patients' data

patient summaries and ePrescriptions: 8 MS live, more MS in 2021 > 2021: images, laboratory results, discharge reports; access of patients to their health data







# 2. Use of data for research, policy making and Al

Secondary use of health data

## Secondary use of data in the EHDS

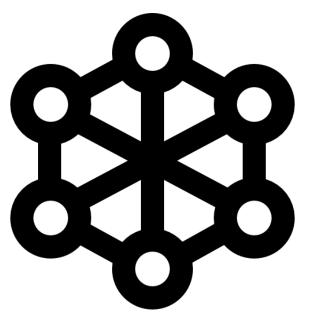


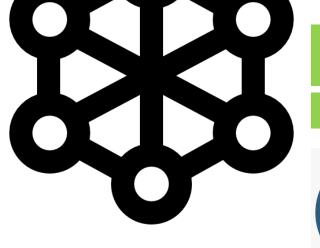


Reuse of health data by researchers, policy-makers and industry









Rules, protocols, infrastructure and governance



**Health data from patients** and healthcare professionals

Other research data



Granting researchers, policy-makers and industry access to health data across borders in an interoperable, digital format



## Pilot project EHDS2: motivation



#### **Targets**

2021: Pilot infrastructure

2025: EU-wide infrastructure



**Testbed (proof of concept)** 

Governance

IT and data infrastructure



#### **Demonstrator**

Cross-country ecosystem
Secondary use of health data

**EU4HEALTH** 



## EHDS: next steps

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)
- Studies to support the Impact Assessment (Q3 2021)
- JA TEHDAS 2021

Consultation EDPS

Legal proposal (first part 2022



## Budget

#### National level investments

- National funds
- RRF
- ERDF
- ESF+
- InvestEU

### **EU** level investments

- EU4Health
- DEP
- Horizon Europe

# Thank you



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