European Health Data Space
Primary and secondary uses of health data

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

**Use of health data (primary)**

- Better Healthcare
- Better Policy Making
- Better Research and Innovation

**Re-use of health data (secondary)**

**Legal/Governance**

- Legislative and non-legislative: governance (review of art. 14 2011/24/EU), interoperability, citizens’ rights, re-use of data. Single market for digital health services. AI development and deployment

**Quality of Data**

- FAIRification projects Other mechanisms

**Infrastructure**

- Cross-border infrastructure for health data exchange (MyHealth@EU)
- EU-wide infrastructure for secondary uses (research infrastructures, data authorisation bodies, registries)

**Capacity building**

- Trainings, cross-border cooperation, best practices, etc. through different funding sources (EU4Health, RRF)
### European Health Data Space

#### Use of data for healthcare (primary)

**Sharing of health data for healthcare**

- **Problems**
  - Limited control of patients over their health data
  - Limited interoperability between health care providers

- **Areas of work**
  - Control of patients over their data
  - Interoperability
  - Role of e-health agencies
  - Reinforced EU governance (eHealth Network)
  - Reinforced MyHealth@EU

#### Single market for digital health products and services

- **Problems**
  - Uneven national legislative frameworks
  - Uneven quality framework
  - Uneven procedures for prescriptions, reimbursement, liability

- **Areas of work**
  - Eliminate barriers to free movement
  - Labelling
  - Interoperability
  - Reimbursement
  - Liability

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

- **Problems**
  - Low re-use of health data
  - Cumbersome cross-border access to health data
  - Fragmented digital infrastructures

- **Areas of work**
  - Governance and rules for access to health data
  - Data FAIR-ification
  - Digital infrastructure (EHDS2)

#### AI

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

- **Areas of work**
  - Support for development and rollout of AI
  - Data for AI
  - Support for regulators

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EHDS: articulation with EU regulatory framework

Cross-border healthcare Directive
GDPR
Data Governance Act
AI Act

EHDS
• Use of 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
Use of health data for healthcare, access to health data by citizens and healthcare professionals
Granting citizens and healthcare professionals access to health data across borders in an interoperable, digital format.
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.

The Commission set up **MyHealth@EU infrastructure** to facilitate cross-border exchange of health data (7 MS currently participate).
EHDS1: MyHealth@EU: cross-border exchange of patients’ data
7 MS live, 15 in 2021

MyHealth@EU
Cross-border exchange of health data
• Currently exchanging
  • Patient Summaries
  • ePrescription
• Number of MS is expanding
• Number of use cases to expand to
  • Lab results
  • Medical images
  • Discharge letters
• Patients to be given access to data
Digital health (tele-health and m-health)

- Example: Validation pyramid - mHealthBELGIUM

1. I am a CE certified medical device
2. I am safely connected
3. I show social-economic evidence and get reimbursed by RIZIV
Digital health

CEN standard for health apps approved

CEN/TC 251 Health informatics, ballot for ISO DTS 82304-2 ‘health and wellness apps – quality and reliability’ was approved

Call open for uptake of the standard under Horizon Europe

Draft standard on health wellness apps open for comments – Ehealth standards (ehealth-standards.eu)
Primary use of health data

• The legislative proposal will focus on a number of areas:
  • Expanding the rights of citizens to access and portability of health data
  • Strengthening the position of the eHN
  • Expanding the MyHealth@EU services
  • Promoting interoperability of health software solutions (including EHR, apps, medical devices)
Re-use of health data for research, innovation, policy making and regulatory decision
Secondary use in the EHDS

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

Health data from patients and healthcare professionals

Rules, protocols and governance

Granting researchers, policy-makers and industry access to health data across borders in an interoperable, digital format
EHDS2: access to data for research and policy making (secondary use of health data)

Digital infrastructure – by 2025

EHDS2 NODEs are the entry point for stakeholders into the EHDS

EHDS2 NODEs can be established by National or Trans-national stakeholders

EHDS2 NODEs follow common policies and interoperability specifications

DATA Holders make health data available for research and policy making

DATA Consumers use data for research or policy making

Findata, FR Data Hub, DK Data permit authority, DE Research Data Centre

EMA/Darwin, ECDC

ERNs, BBMRI, PHIRI, ELIXIR, eBrains
Secondary use of health data

• The legislative proposal will focus on a number of areas:
  • Expanding on the existing **infrastructure** in Member States (Data Permit Authorities)
  • Introduce a European infrastructure
  • Promoting **interoperability** and **data quality** transparency
  • Strengthening the **legal base** for the re-use of health data
EHDS legal proposal: next steps


- 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 (Q1 2022)
Thank you