



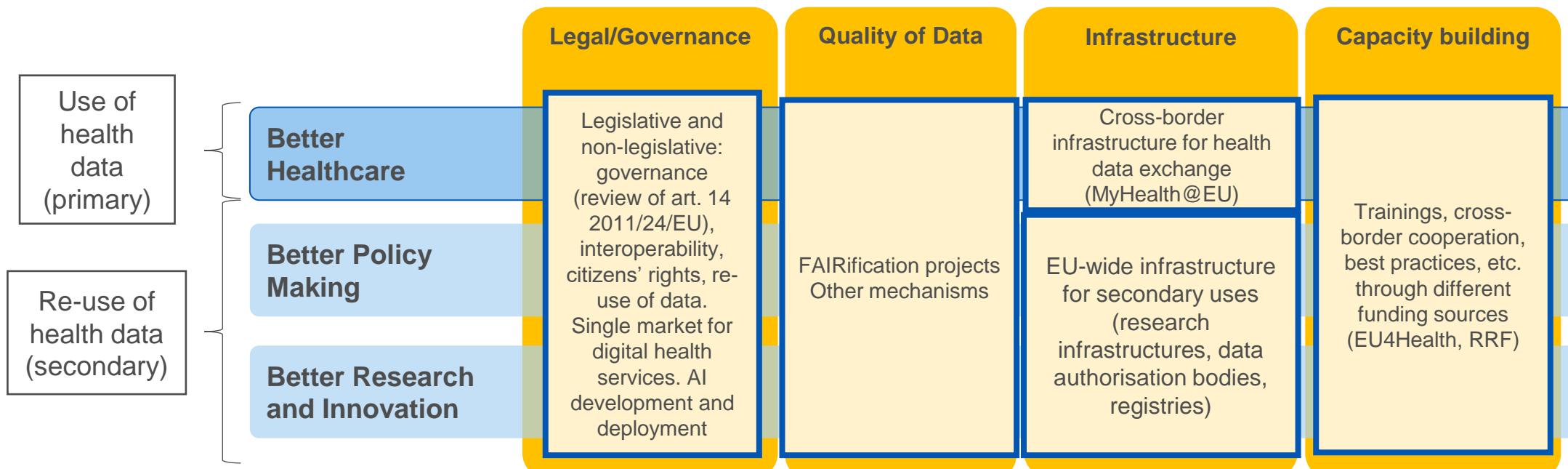
European Health Data Space



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



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

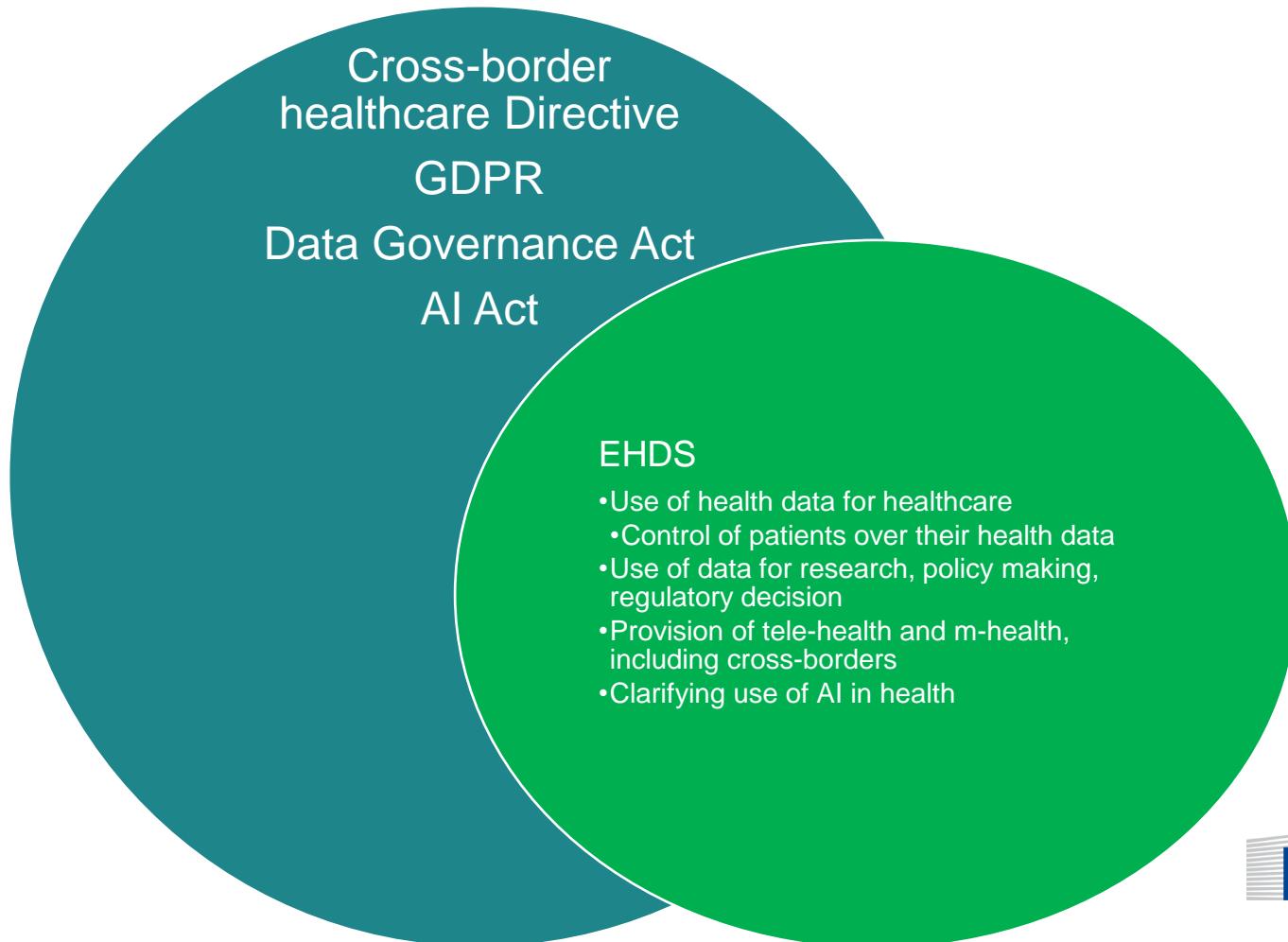
Problems

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

Areas of work

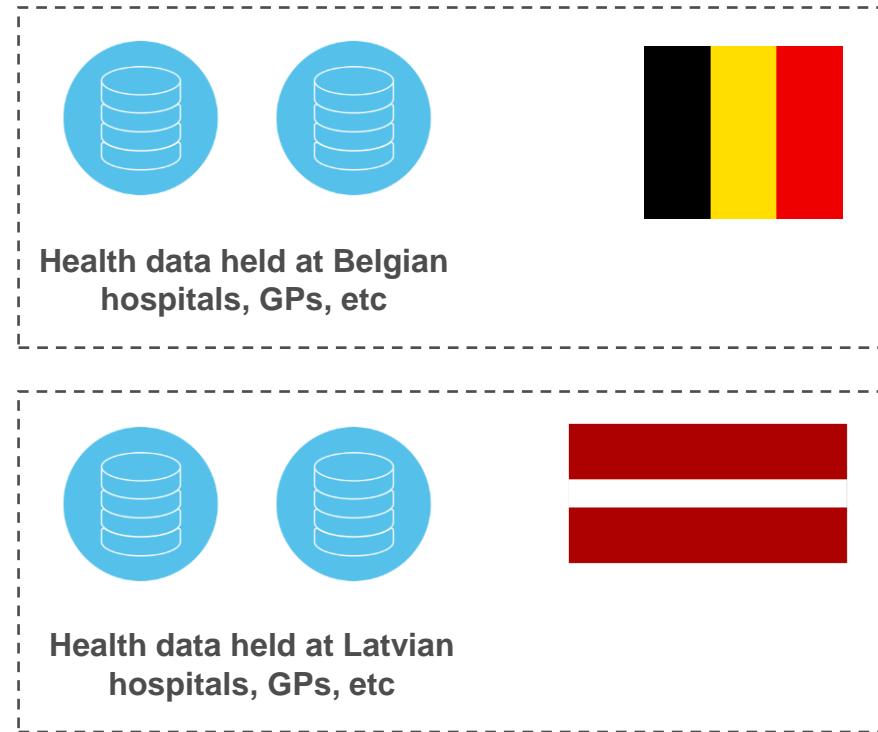
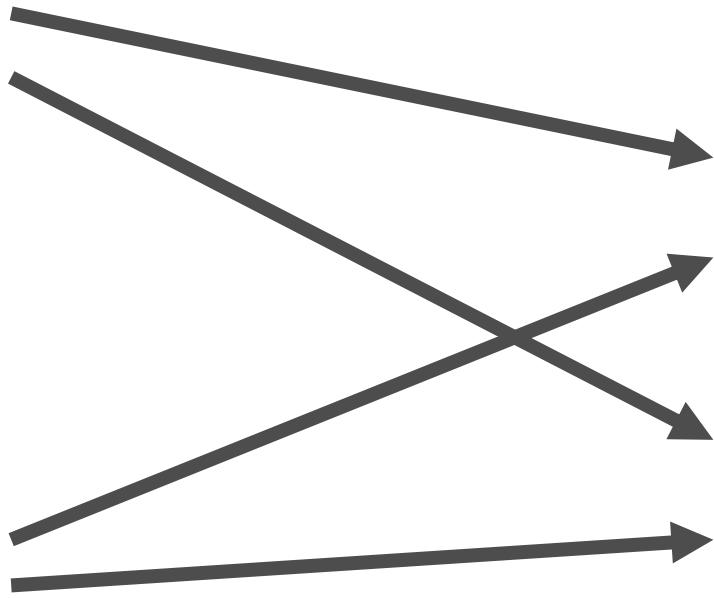
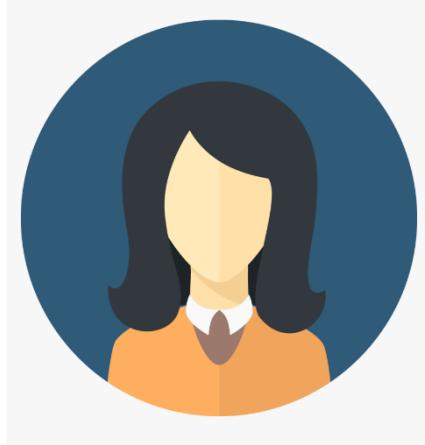
- Support for development and rollout of AI
- Data for AI
- Support for regulators

EHDS: articulation with EU regulatory framework





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

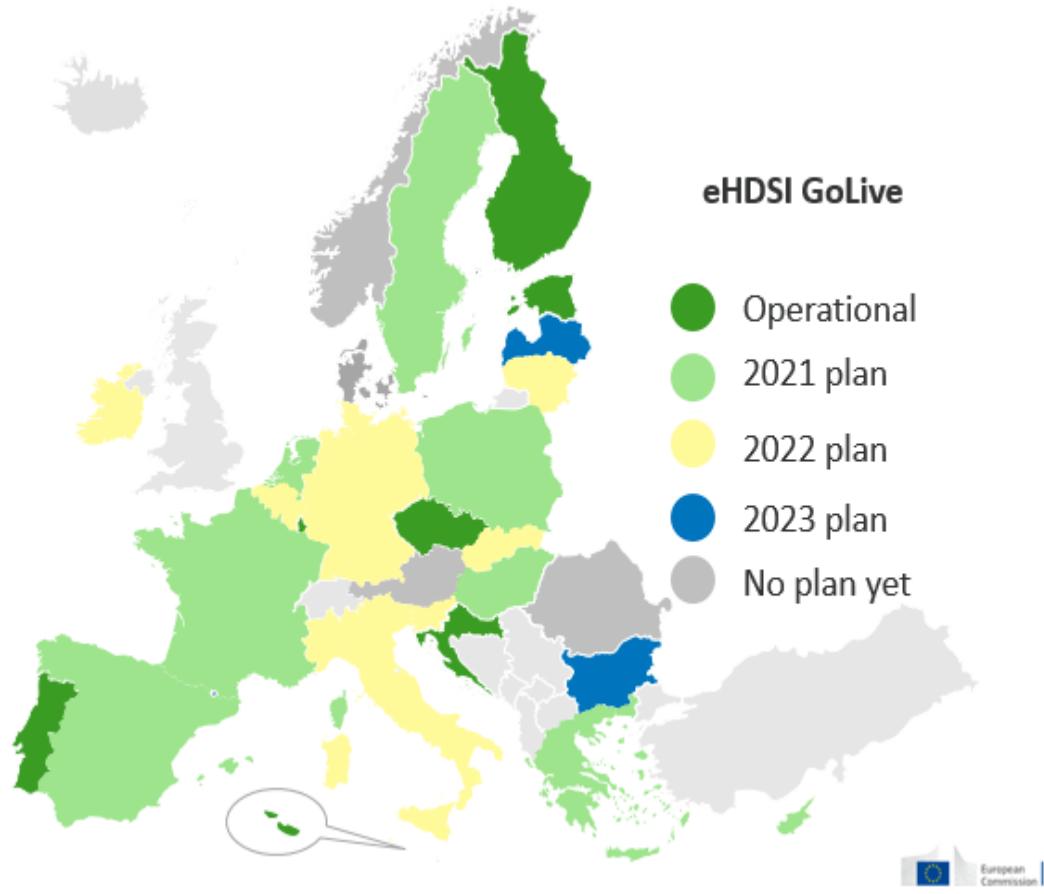
Member States organise health data access through different means. Some member states have patient or professional **portals** at the level of healthcare provider, region or nation, while others have apps or **personal data space** solutions. Also, registries of who should have **access** are also local,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

I show social-economic evidence and
get reimbursed by RIZIV

3

I am safely connected

2

I am a CE certified
medical device

1



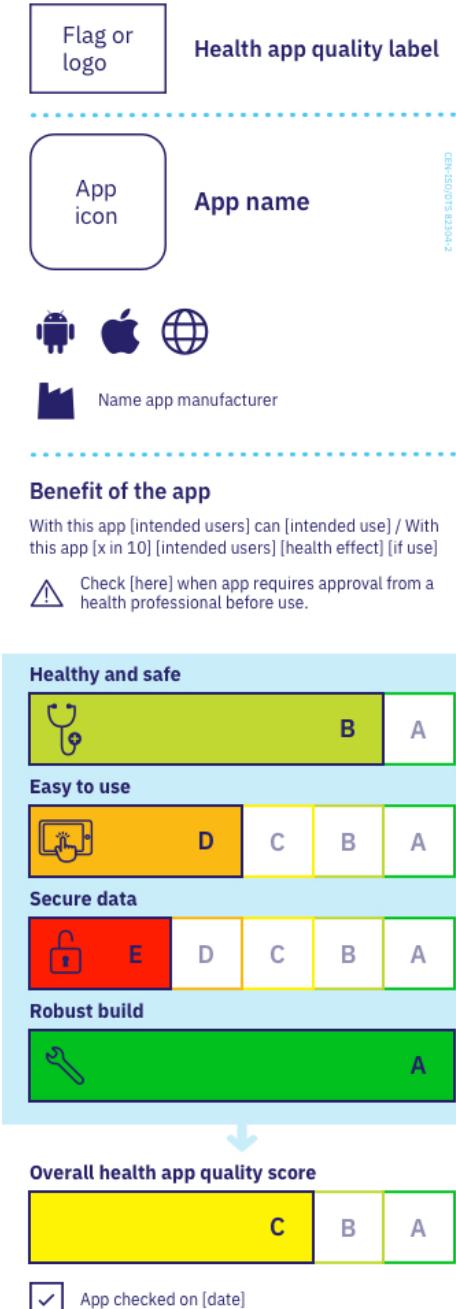
Digital health

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)

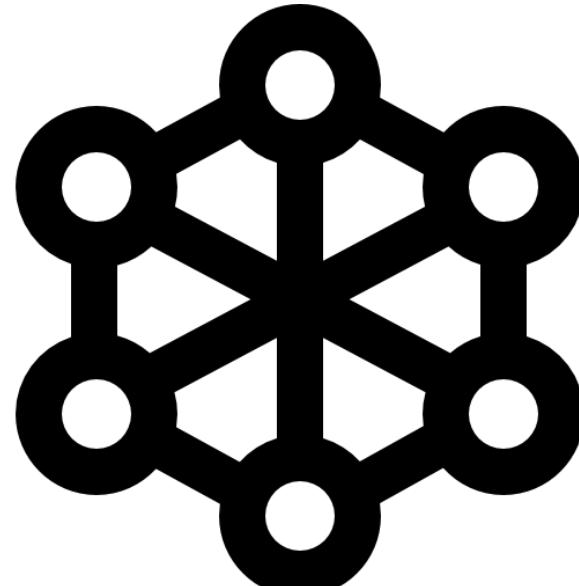


Re-use of health data for research,
innovation, policy making and
regulatory decision

Secondary use in the EHDS



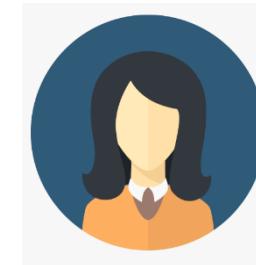
Reuse of health data by researchers, policy-makers and industry



Rules, protocols and governance



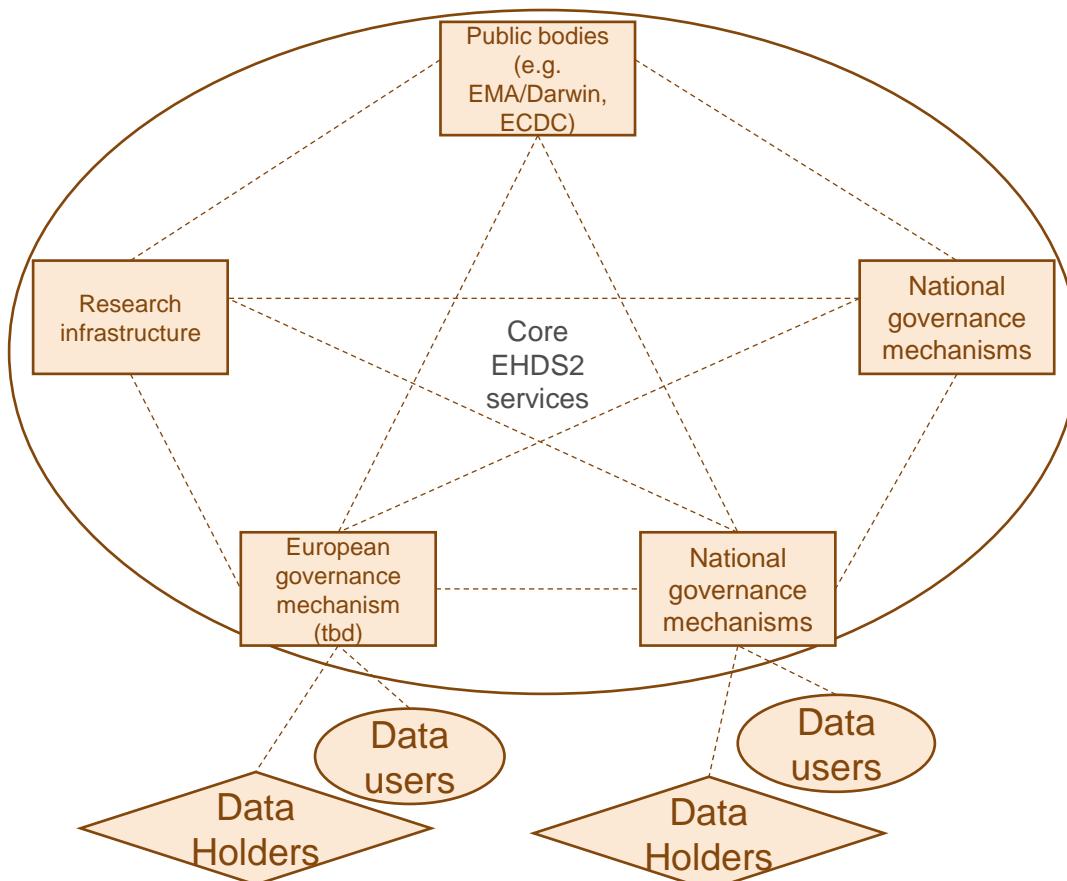
Health data from patients and healthcare professionals



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

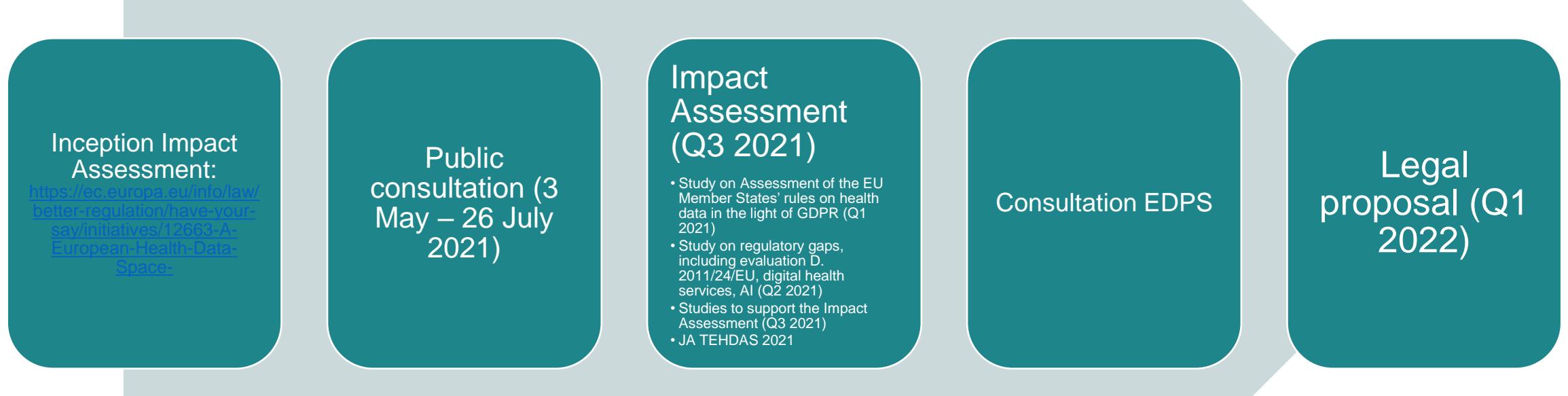
ERNs, BBMRI, PHIRI, ELIXIR, eBrains



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



Thank you



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