



# Health Data, new challenges and solutions

A photograph of the European Union flag, showing the blue field with twelve gold stars, waving in the wind. The background is a blurred green landscape.

Ornella Martinello,  
Policy coordinator, European Commission  
WINTER SCHOOL ProMIS, 25 February 2022

# Europe's digital decade

Europe's digital infrastructure has brought major advantages throughout the pandemic. It has shown that **up-to-date, robust health data are key for an efficient public health response, for the development of effective treatments and vaccines and responding to crises.**

However, the pandemic also showed the need to further accelerate the digital transformation.

In March 2021, the Commission presented a new vision for **Europe's digital transformation** by 2030, and proposed in September 2021 a governance framework to achieve the 2030 digital targets.



- At least 20% of each recovery and resilience plan to be spent on digital



- EUR 1 billion to be invested annually in artificial intelligence from the Digital Europe and the Horizon Europe programmes



- **e-Health:** 100% of citizens having access to medical records by 2030



# Europe's digital decade

- The [European strategy for data](#) aims to make the EU a leader in a data-driven society. Creating a **single market for data** will allow it to flow freely within the EU and across sectors for the benefit of businesses, researchers and public administrations
- The [Data Governance Act](#) will increase trust in data sharing, strengthen mechanisms to increase data availability and overcome technical obstacles to the reuse of data. It will also support the set-up and development of common European data spaces in strategic domains, involving both private and public players, in sectors such as health, environment, energy, agriculture, mobility, finance, manufacturing, public administration and skills.
- With the [European data act](#) proposed in February 2022, the Commission aims to make more data available for use, and set up rules on who can use and access what data for which purposes across all economic sectors in the EU.
- The Commission proposed an AI Act aiming to turn the EU into the global hub for excellent and trustworthy **artificial intelligence**.
- The Commission proposed a framework for a trusted and secure **European digital identity**, available to all EU citizens, residents and businesses.

# Europe's digital decade

## Digital Rights and Principles



### People at the centre

Digital technologies should **protect people's rights, support democracy, and ensure that all digital players act responsibly and safely**. The EU promotes these values across the world.



### Freedom of choice

People should benefit from a **fair online environment, be safe from illegal and harmful content**, and be empowered when they interact with new and evolving technologies like artificial intelligence.



### Safety and security

The digital environment should be **safe and secure**. All users, from childhood to old age, should be empowered and protected.



### Solidarity and inclusion

Technology should **unite, not divide, people**. Everyone should have access to the internet, to digital skills, to digital public services and to fair working conditions.



### Participation

Citizens should be able to **engage in the democratic process** at all levels and have **control over their own data**.



### Sustainability

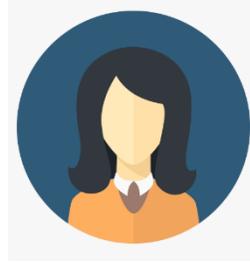
Digital devices should support **sustainability** and the **green transition**. People need to know about the environmental impact and energy consumption of their devices.



# Main challenges to the access and (re)use of health data in the EU

Health data refers to personal information that relates to the health status of an individual, or to non-personal information related to health, such as statistics, anonymous or aggregated data. This includes both medical data (doctor referrals and prescriptions, medical examination reports, laboratory tests, radiographs, etc.), but also administrative and financial information about health (including invoices for healthcare services and medical certificates for sick leave management etc.).

Individuals have difficulty accessing and controlling their health data

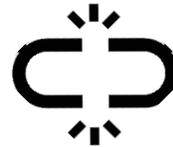


Fragmented implementation of the GDPR at national level



Providers of digital health services and products face barriers

Healthcare professionals have difficulty accessing health data



Fragmentation of standards and specifications for storing and sharing data



Policy makers and regulators cannot easily access health data



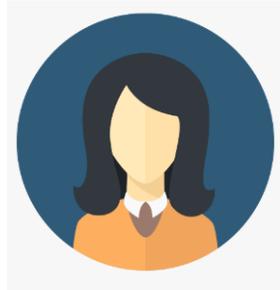
Limited innovation takes place on the basis of health data

# The solution: the establishment of a European Health Data Space

- A health specific data environment which comprises rules, common standards and practices, infrastructures and a governance framework for the use and reuse of electronic health data.
- Data-driven innovation will bring benefits for companies and individuals by making our lives and work more efficient through:
  - more efficient, higher quality, safer and more personalised care and improved health care delivery (**primary use**)
  - Better research, better policies, more innovation, speeding up the development of new medical products and treatments (**secondary use**)
- Improving personalised treatments, providing better healthcare, and helping cure rare or chronic diseases, saving approximately €120 billion a year in the EU health sector and providing a more effective and quicker response to the global COVID-19 health crisis.

# What are the objectives?

Empower citizens to control their health data



Foster a single market for digital health services and products



Ensure interoperability and security of health data  
Level playing field for manufacturers



Unleash the health data economy



Ensure a consistent and efficient framework for the reuse of health data for research, innovation, policy-making and regulatory activities

# European Health Data Space (EHDS)

## OBJECTIVES

Timely and simplified *exchange of and access to* health data

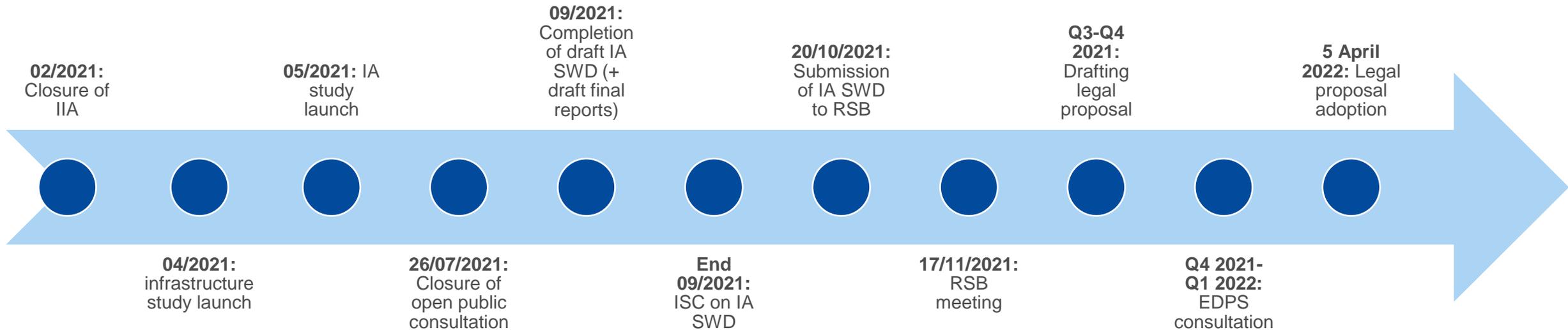
## SCOPE & EXPECTED IMPACT



## MEANS



# Detailed timeline



# Thank you

Contact:  
Ornella.Martinello@ec.europa.eu



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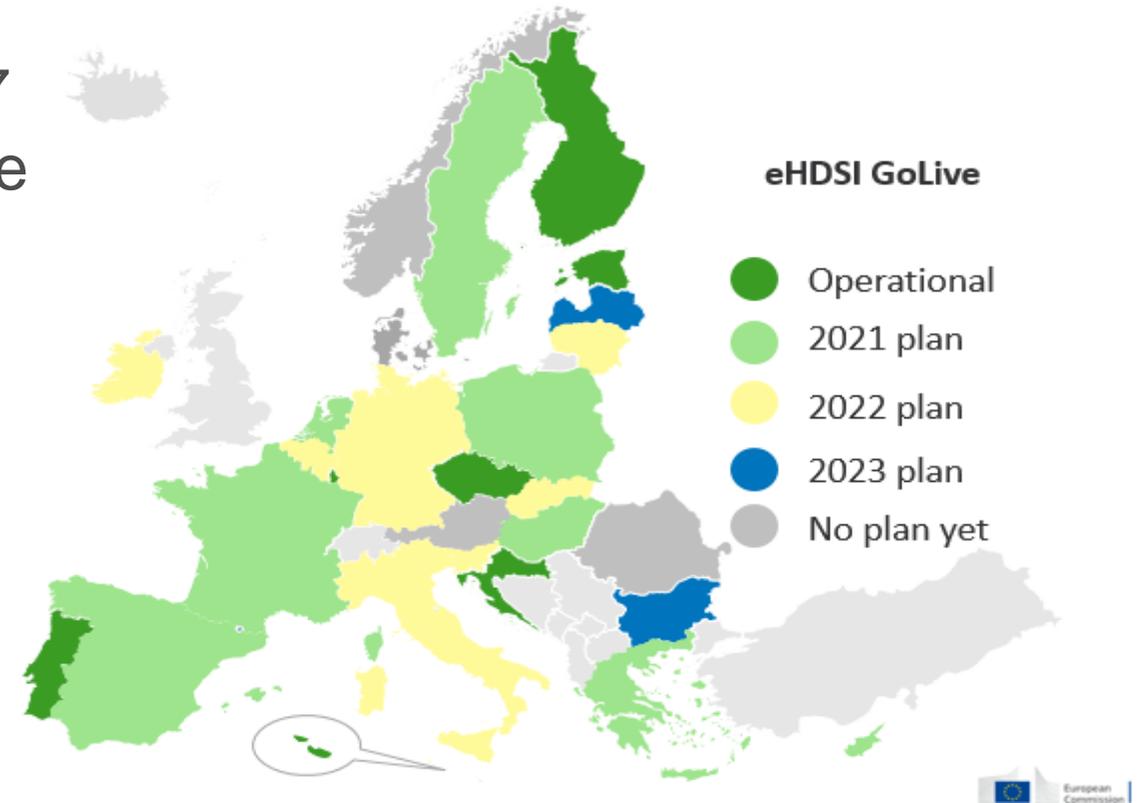
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# EHDS1: MyHealth@EU: cross-border exchange of patients' data

- Patient summaries and ePrescriptions: 7 Member States currently live; more in the process of onboarding in 2021/2022
- Beyond 2021: new services for images, laboratory results, discharge reports
- Access of patients to their health data



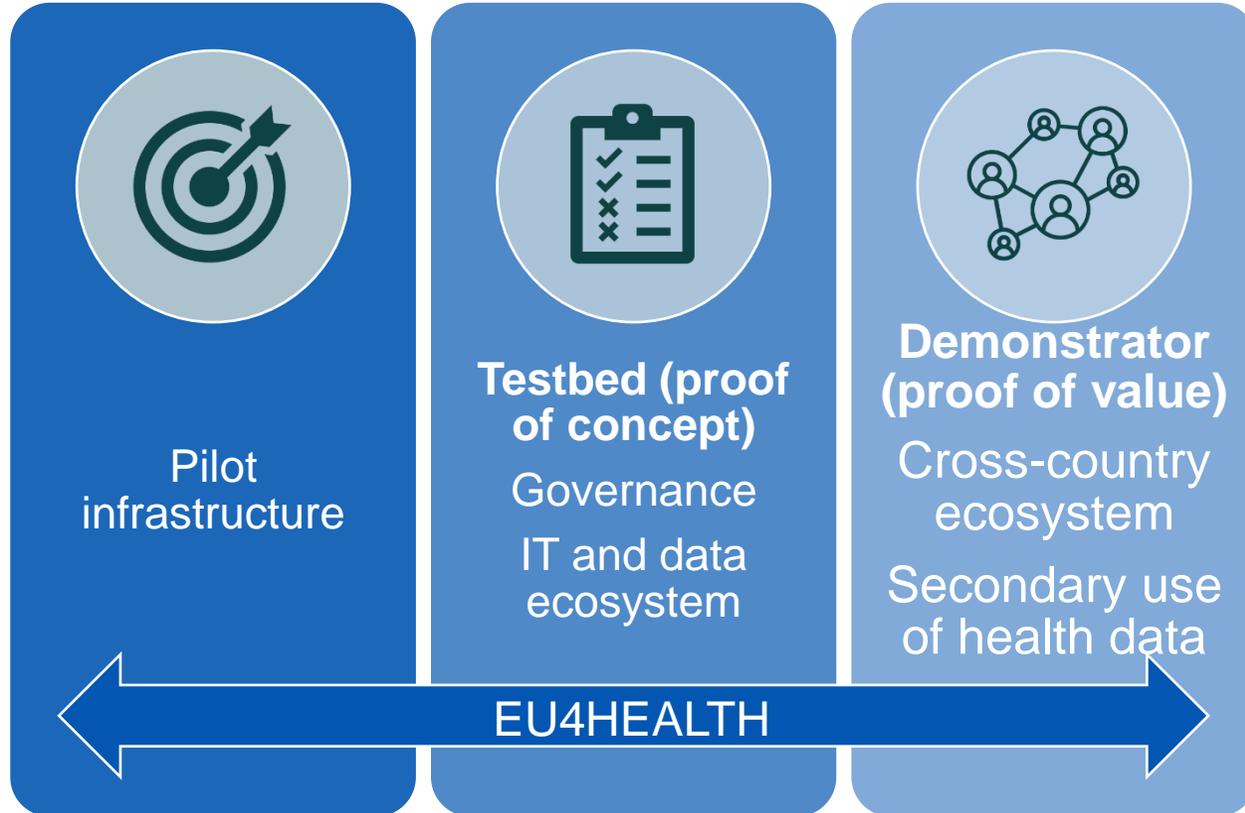
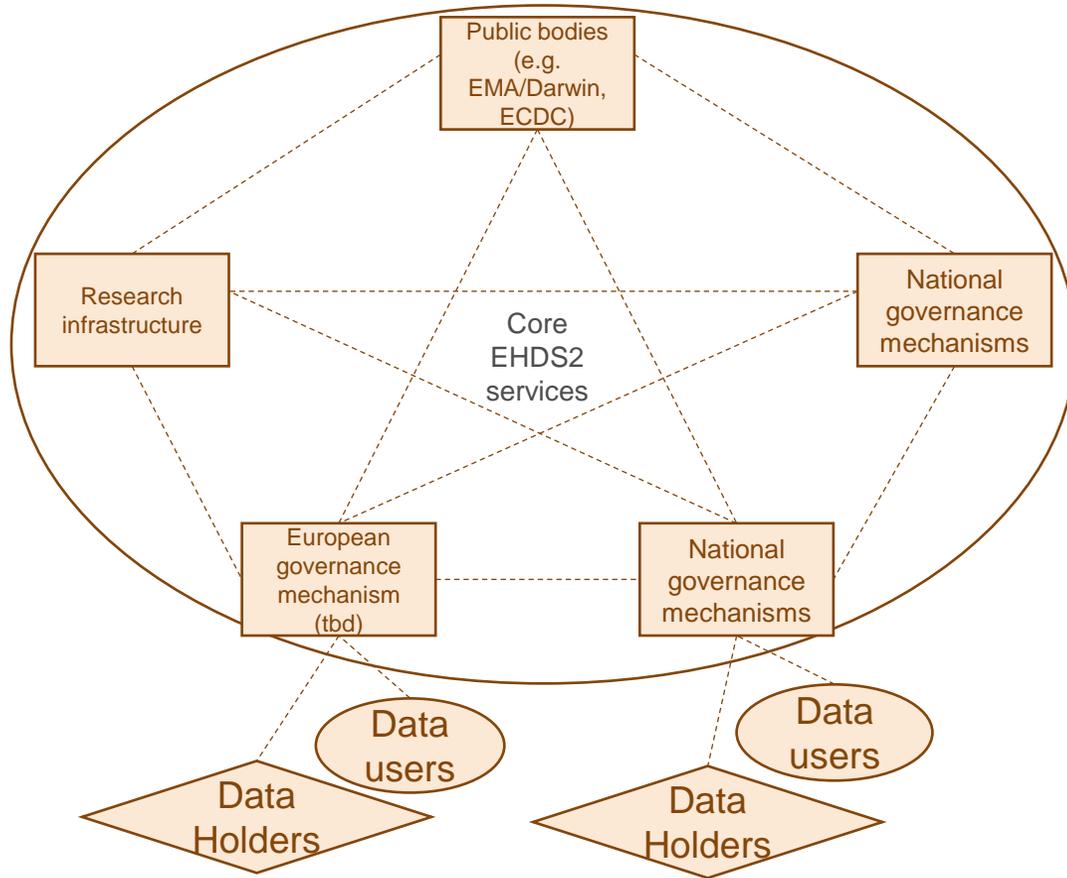
# EHDS2: TEHDaS Joint Action

- The project develops joint European principles for the secondary use of health data.
- It involves 25 countries.
- Several strands of work:
  - Dialogue about the EHDS
  - Sustainability of secondary uses of health data
  - Governance model for cross-border co-operation in the secondary use of health data
  - Reliability and compatibility of and access to health data for secondary use;
  - Role of individuals in the secondary use of health data



Towards  
European  
Health  
Data  
Space

# EHDS2: Infrastructure pilot in 2021 (EU4Health)



# EHDS: articulation within EU Regulatory Framework

