Towards a common European Health Data Space (EHDS)

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

07/07/2021

Context

Common Data Spaces: Health · Industrial & Manufacturing · Agriculture · Finance · Mobility · Green Deal · Energy · Public Administration · Skills

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)

A European Health Data Space

▶ **OBJECTIVES**

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

▶ **SCOPE & EXPECTED IMPACT**

Use of health data (primary)	• **Access and control of patient over their data & exchange of health data** (incl. cross-border) **for healthcare provision** • **Digital health services and products** (including telehealth and m-health);	→	**High quality & safe healthcare provision**
Re-use of health data (secondary)	• **Research, innovation** • **Policy and regulatory decisions**	→ →	**Facilitated research & innovation** **Data-enabled policy-making**

▶ **MEANS**

Legal / Governance	**Quality of data**	**Infrastructure**	**Capacity building**

European Commission

Better regulation process

Inception Impact Assessment

Public consultation (3 May – 26 July 2021)

Impact Assessment (Q3 2021)

(studies, consultations, TEHDaS JA, etc.)

Consultation EDPS

Legal proposal (Early 2022)
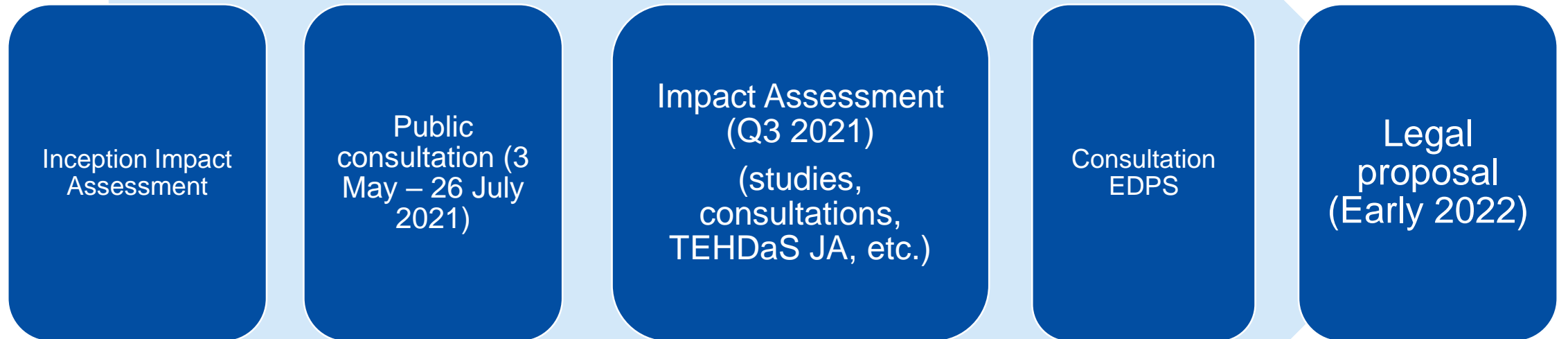
See Have Your Say entry

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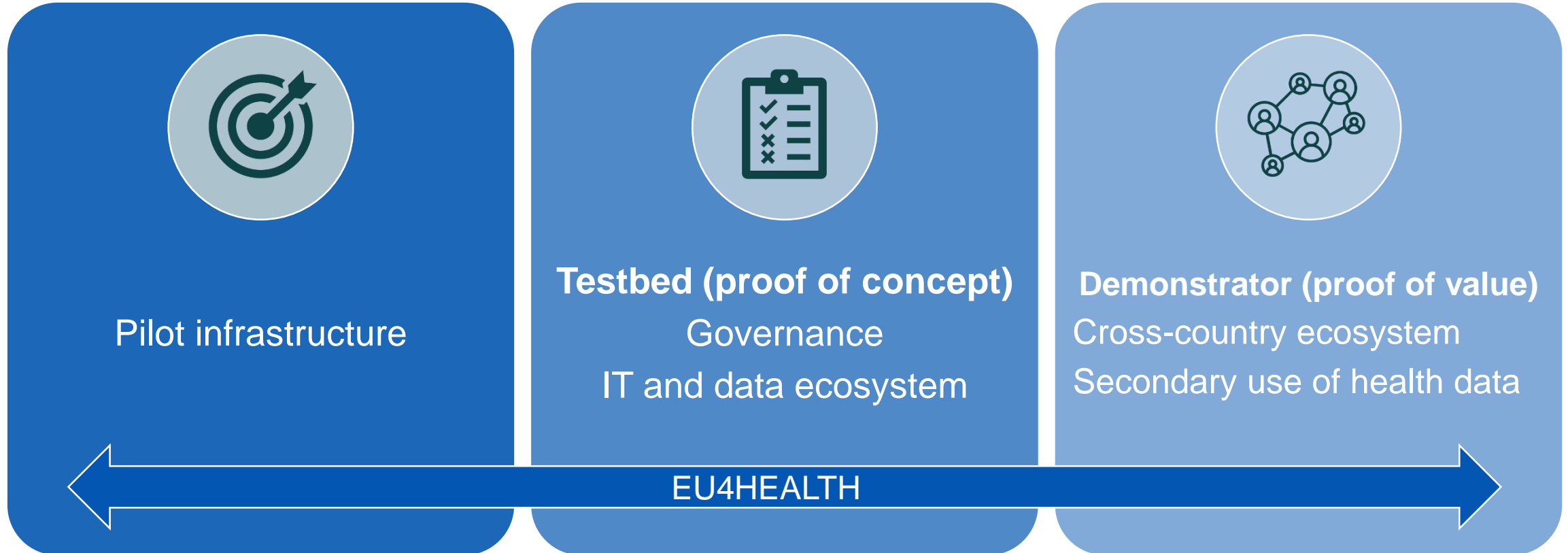
EHDS1: MyHealth@EU: cross-border exchange of patients' data

- 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

eHDSI GoLive

- Operational
- 2021 plan
- 2022 plan
- 2023 plan
- No plan yet

A pilot for the EHDS2

Pilot infrastructure

Testbed (proof of concept)
Governance
IT and data ecosystem

Demonstrator (proof of value)
Cross-country ecosystem
Secondary use of health data

EU4HEALTH

European Commission
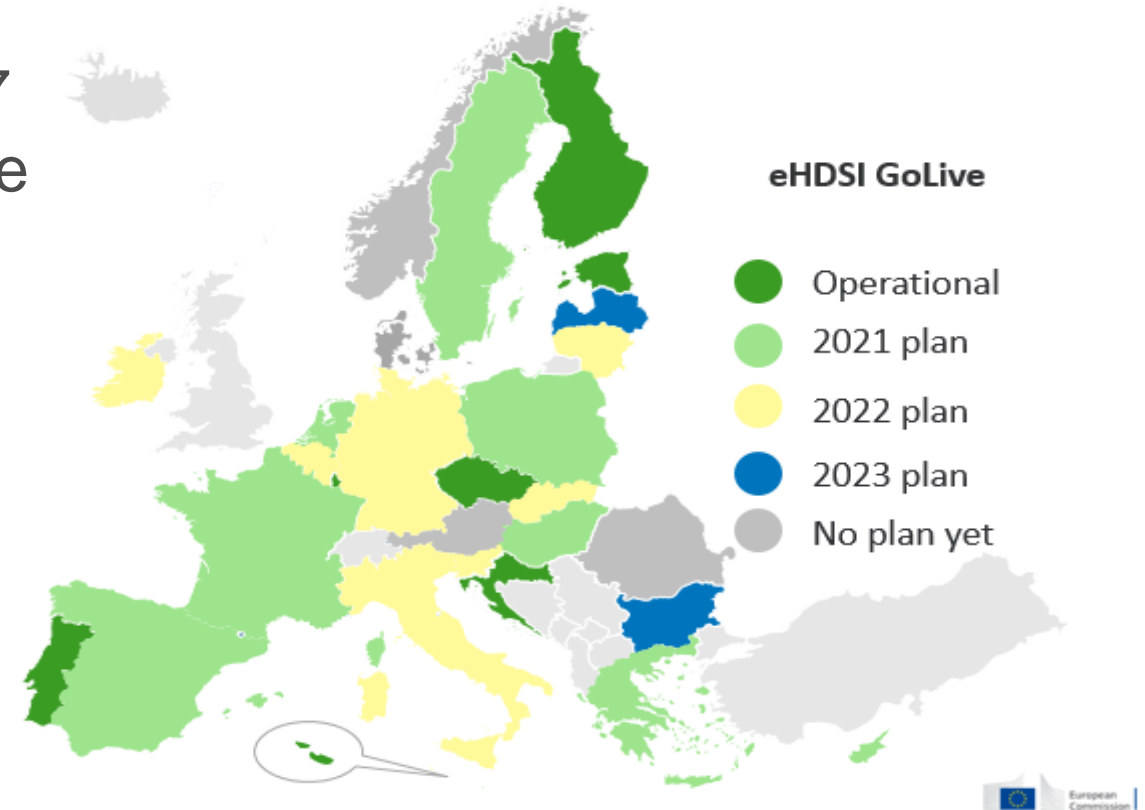
TEHDaS Joint Action

- 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

European
Commission

EU4Health and the EHDS

- *Strengthen health systems so that they can face epidemics as well as long-term challenges by stimulating*

  - *disease prevention and [health promotion](#) in an ageing population*

  - ***[digital transformation](#) of health systems***

  - *[access to health care](#) for vulnerable groups*

What the (short-term) future holds

- **Preparation of the impact assessment**
  - Consultations and studies ongoing
  - **Open public consultation open for input (May-July 2021)**

- **Legislative proposal** on the European Health Data Space in early 2022

- Cooperation with Member States and stakeholders in the **Towards a European Health Data Space (TEHDaS)** Joint Action

European Commission