



Joint Action on preparatory actions for a European Health Data Space - **primary use of data (for healthcare)** DI-g-22-22.06

A photograph of the European Union flag, which is blue with twelve gold stars arranged in a circle. The flag is being held up by two hands, and it is waving in the wind. The background is a blurred green landscape with trees.

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EU4Health and the EHDS

WP 2021 Digital heading approx. EUR 33 million

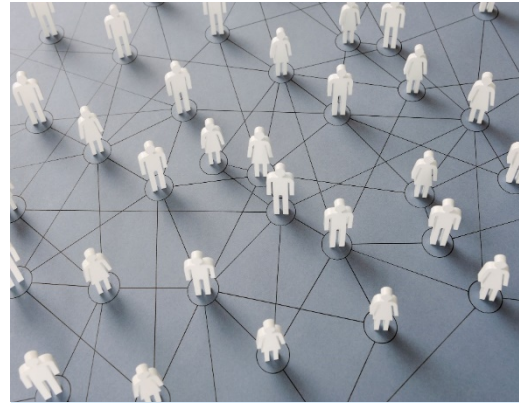
- Grants for an infrastructure pilot on secondary uses of health data (HealthData@EU) (**EUR 5 million**)
- Grants for a pilot on patients' access to health data (**EUR 2 million**)
- Grants to support for semantic interoperability (**EUR 7.2 million**)
- Grants for the expansion of services of MyHealth@EU (**EUR 11 million**)
- Core services MyHealth@EU and HealthData@EU pilot, capacity building (**EUR 8 million**)

WP 2022 Digital heading approx. EUR 75 million

- Grants for new services of MyHealth@EU (**EUR 30 million**)
- Grants for the development/establishment of Health Data Access Bodies (**EUR 30 million**)
- Joint Action on primary uses of health data in the EHDS (**EUR 4 million**)
- Core services MyHealth@EU/HealthData@EU (**EUR 10 million**)

Proposal for a European Health Data Space (EHDS) – Adopted!

Empower individuals to access and control their personal health data (Chapter II)

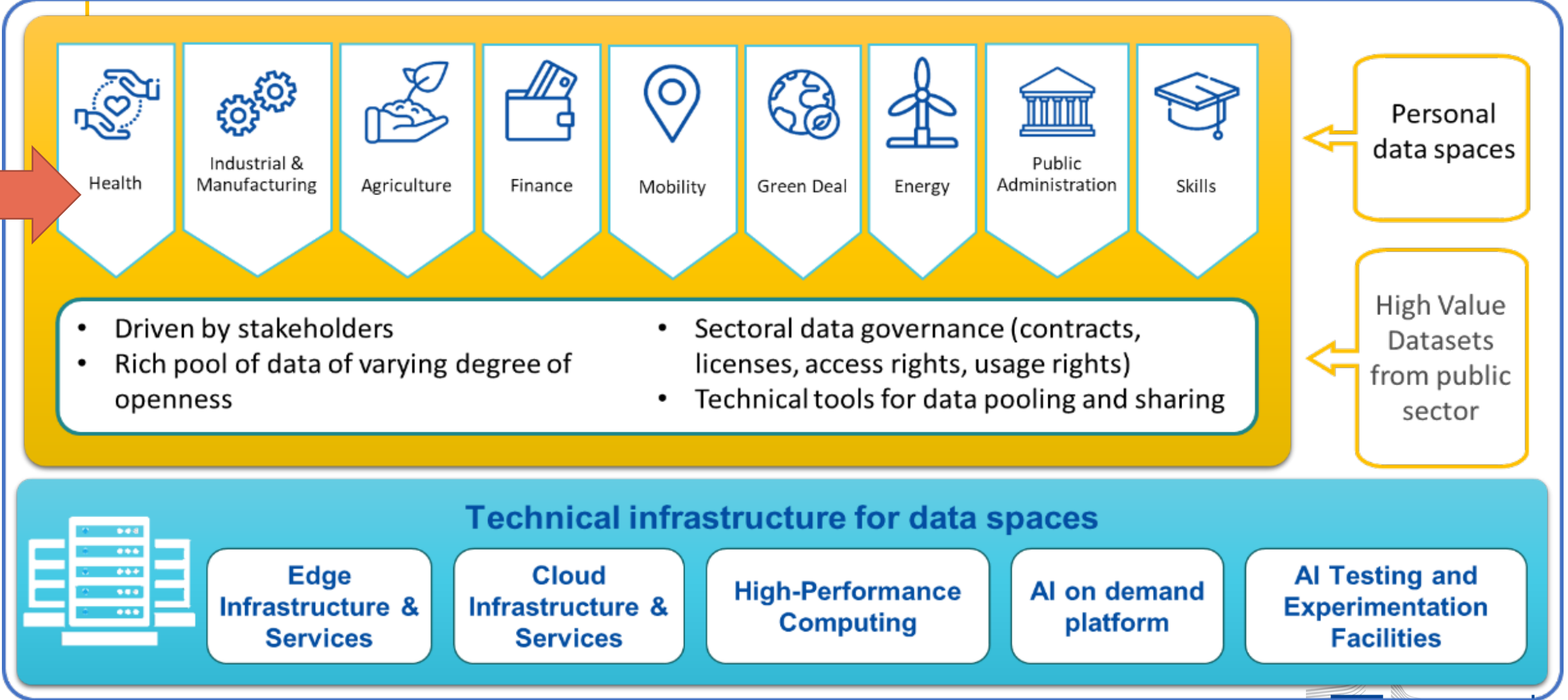


Ensure a consistent framework for the use of individuals' health data for research, innovation, policy-making and regulatory activities (Chapter IV)

Unleash the data economy by fostering a genuine single market for digital health services and products (EHR systems) (Chapter III)



EHDS – the first sector specific European Data Space



European Health Data Space (EHDS)

OBJECTIVES

Effective use of health data

SCOPE & EXPECTED IMPACT

Use of health data
(primary,
MyHealth@EU)

- Empower individuals to control their data
- Standardization and mandatory certification of EHR systems
- Voluntary labelling of wellness apps
- European Electronic Health Record Exchange Format

Single market for health data, data protection, free movement of people, digital goods and services

Re-use of health data
(secondary,
HealthData@EU)

- Health data access bodies
- Purposes for use and forbidden use
- Data permits, secure environments, no identification

Facilitated Research & Innovation

Better Policy Making

MEANS

Legal / Governance

Quality of data

Infrastructure

Capacity building/digitalisation

Chapter II Primary use of electronic health data

- **Additional rights** of individuals to complement the rights provided under the GDPR in relation to their electronic health data (Art. 3)
- **Access by health professionals** to personal electronic health data (Art. 4)
- Types of electronic health data **as a priority** to be integrated in the EHDS in a staged process (Art.5) with deferred application (art 71)
- Introduces **European electronic health record exchange format** (Art. 6)
- Requirements **for the registration** of personal electronic health data and **identification management** (Art. 7 and Art. 9), non-discrimination for provision of **telemedicine** (Art. 8)
- Set up a **digital health authority** and its tasks (Art.10) and right to lodge a complaint with the authority (Art 11)
- **Mandatory** participation in common infrastructure **MyHealth@EU** (Art. 12)
- **Supplementary services** to MyHealth@EU, including **interoperability with third countries and international organisations** (Art 13)

Chapter III EHR systems and wellness applications

- **Mandatory self-certification scheme** for EHR systems (Art. 14 – 16)
- **Obligations** of each economic operator of EHR systems (Art. 17 – 22)
- **Requirements on the conformity** of such EHR systems (Art 23 - 27)
- **Market surveillance authorities** for EHR systems (Art.28 – 30)
- Provisions on the **voluntary labelling** of wellness applications (Art. 31)
- **EU database** for certified EHR systems and labelled wellness applications (Art. 32)

Direct grants to Member States' authorities: preparatory actions for a European Health Data Space - **primary use of data (for healthcare) (DI-g-22-22.06)**

Joint Action

Budget: EUR 4 million

Applicants: Member State authorities

- Objectives
 - *To enhance cooperation among Member States regarding **primary** uses of health data*
- Activities to be funded:
 - a) Preparing guidelines and technical specifications on interoperability of medical images, laboratory results and discharge letters towards the **European electronic health record exchange format (EEHRxF)**;
 - b) Preparing guidelines and technical specifications on interoperability of **telehealth, mobile health and other health software**;
 - c) Preparing guidelines and technical specifications on the use of electronic identification in health, for health professionals and patients taking into account the developments of the **European Digital Identity Framework**;

Direct grants to Member States' authorities: preparatory actions for a European Health Data Space - **primary use of data (for healthcare) (DI-g-22-22.06)**

Joint Action

Budget: EUR 4 million

Applicants: Member State authorities

- Objectives
 - *To enhance cooperation among Member States regarding **primary** uses of health data*
- Activities to be funded:
 - d) preparing guidelines and technical specifications on **cross-border telehealth, including telemonitoring;**
 - e) preparing an assessment framework and technical specifications for the evaluation of the quality of **mobile wellness applications;**
 - f) preparing an assessment framework and technical specifications for the evaluation of the interoperability of **electronic health records, personal health data spaces and other software in health;**
 - g) preparing guidelines and technical specifications on **the quality of mobile wellness applications.**

Thank you

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