



Setting up services by Health Data Access Bodies - Secondary use of health data (EHDS) DI-g-22-22.01

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**)

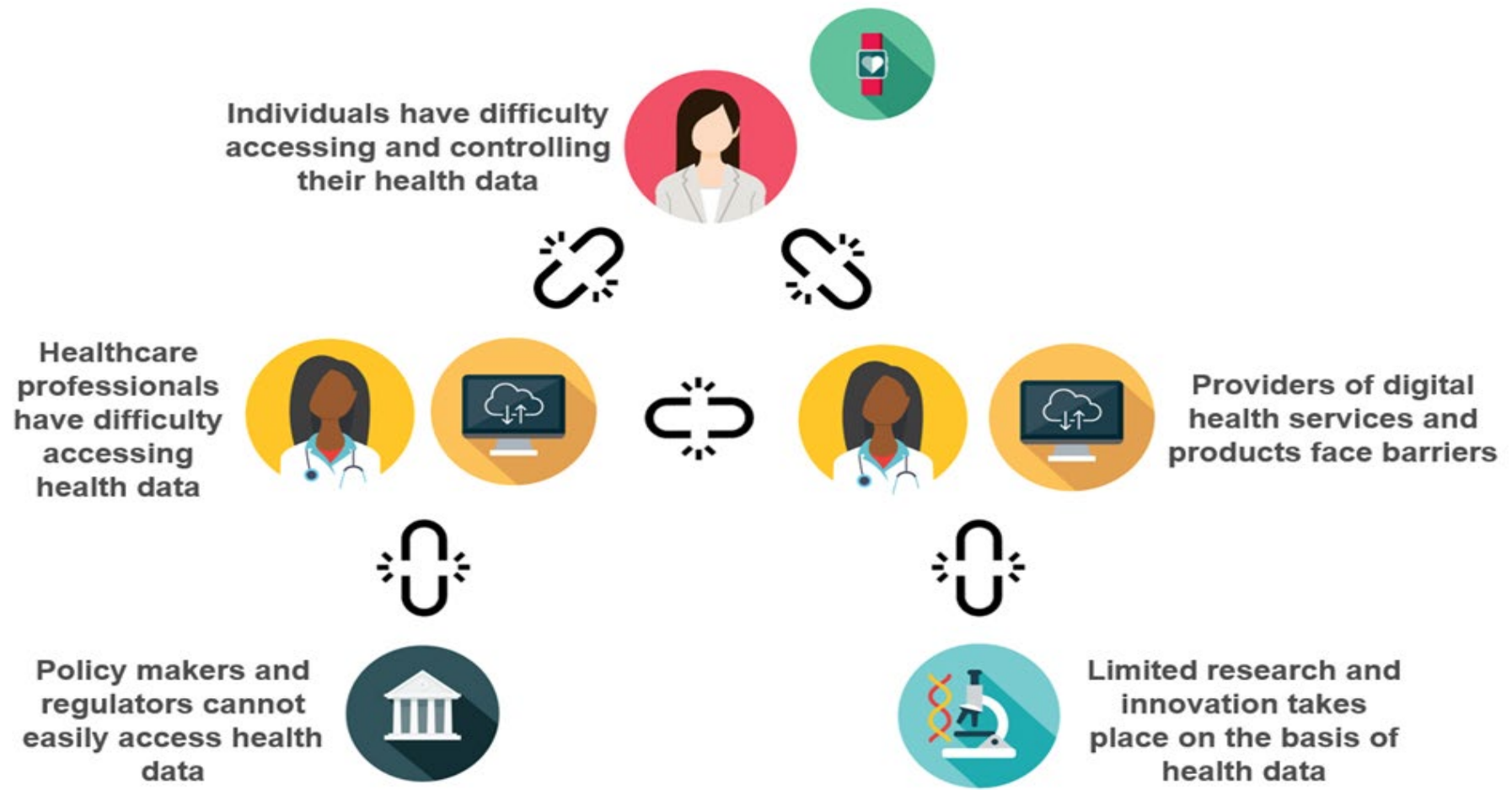
WP 2022 Digital heading approx. EUR 75 million

- 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**)

Why acting now?

- **The 2020 European Strategy for Data** announced the Commission's plans for European data spaces, including EHDS
- The COVID-19 pandemic has clearly demonstrated **the importance** of digital services in the health domain, and has triggered **an important acceleration in the uptake** of digital tools. The European Digital Covid Certificate – positioned the EU as a **global leader and standard setter in digital health**
- The challenge now is **to maintain this momentum** on the importance of health data

Main challenges in harnessing the power of health data



Chapter IV Secondary use of health data I

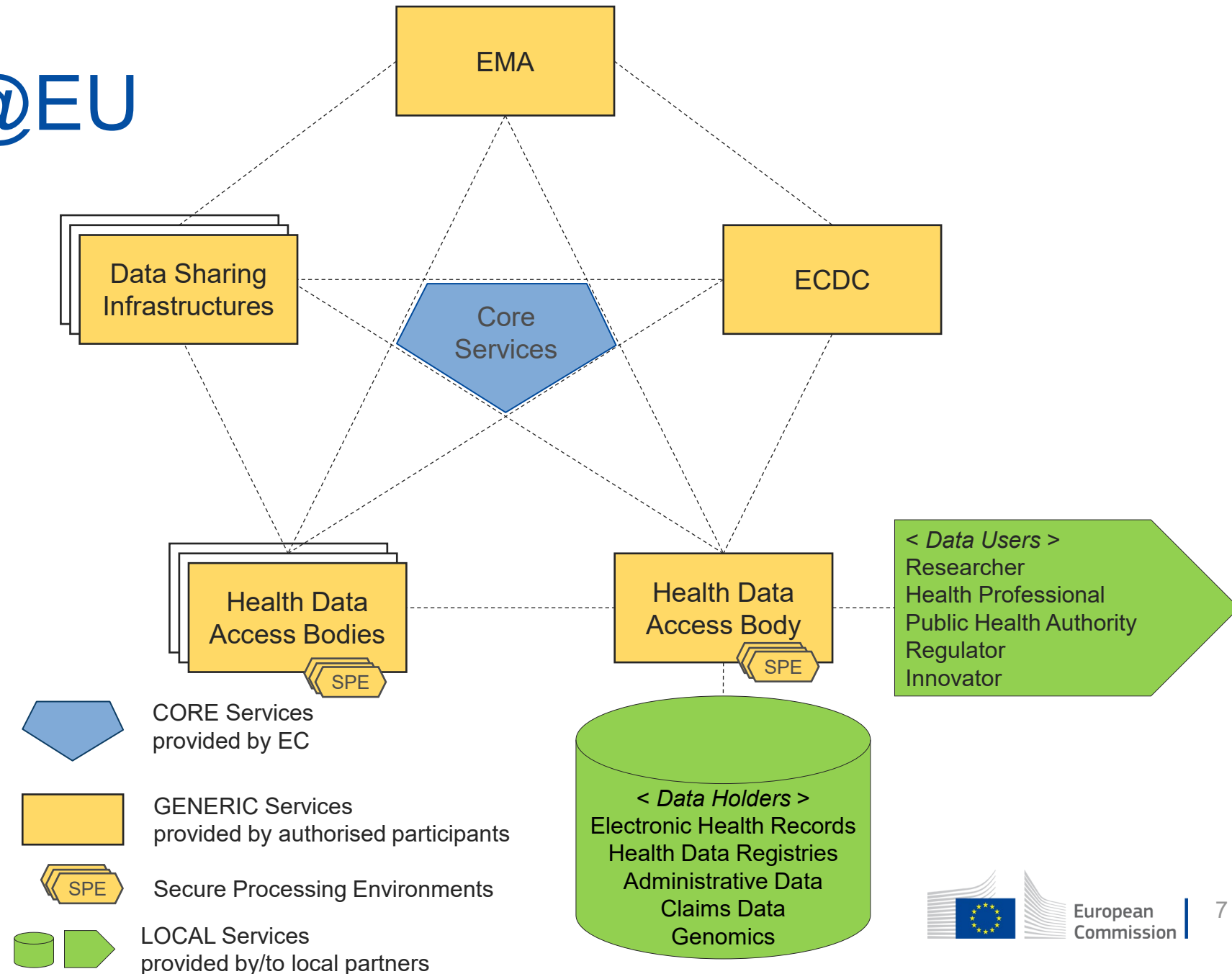
- **Set of minimum categories** of electronic data for **secondary use** that can be used for defined **purposes** (supporting policy making, regulatory activities, research, innovation and development of health products, training of AI algorithms e.g. for medical devices). Defines **prohibited purposes** (eg use of data against persons, commercial advertising, increasing insurance, develop dangerous products) (Art. 33, 34, 35)
- Set up a **health data access body/bodies** for secondary use of electronic health data (Art. 36) – *building upon the Data Governance Act*
- **The tasks and obligations** of the health data access body, the data holders and the data users (Art. 37, 38, 39)
- Implementation of **data altruism** in health (Art.40)
- Sets **the duties for data holders** (Art. 41)

Chapter IV Secondary use of health data II

- General provisions on transparency and structure of **fees calculation** (Art. 42), building upon Data Governance Act
- **Penalties** by health data access bodies (Art. 43)
- Conditions and requirements **for data permit for the secondary of** electronic health data (data minimization, data access, incl. access to data for public and EU institutions, access to data from a single data holder, data permit, data request, secure processing environment) (Art. 44 – Art.51)
- Development of the **new decentralised EU cross-border infrastructure** for secondary use (**HealthData@EU**) (Art. 52)
- Setting up and fostering **cross-border access** to electronic health data and mutual recognition (Art 53, 54)
- **Dataset description** and their **quality**, establishment of **EU Dataset Catalogue** (Art. 55, 56, 57)

HealthData@EU

- New infrastructure for secondary uses of health data
- Connecting health data access bodies and data sharing infrastructures
- Several health data access bodies are established, or in the process, across Member States



Direct grant to Member States: for setting up services by **Health Data Access Bodies** - Secondary use of health data (DI-g-22-22.01)

Budget: EUR 30 million

- Objectives
 - *Support Member States in establishing and strengthening health data access bodies with a view to preparing, ensuring readiness and using a common approach for the secondary use of health data in the EHDS.*
- Activities to be funded:
 - a) Design, establishment and deployment of national services and infrastructures for secondary uses
 - b) Design, establishment and deployment of cross-border services and infrastructures
 - c) Improvement of data quality

Thank you

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