European Health Data Space

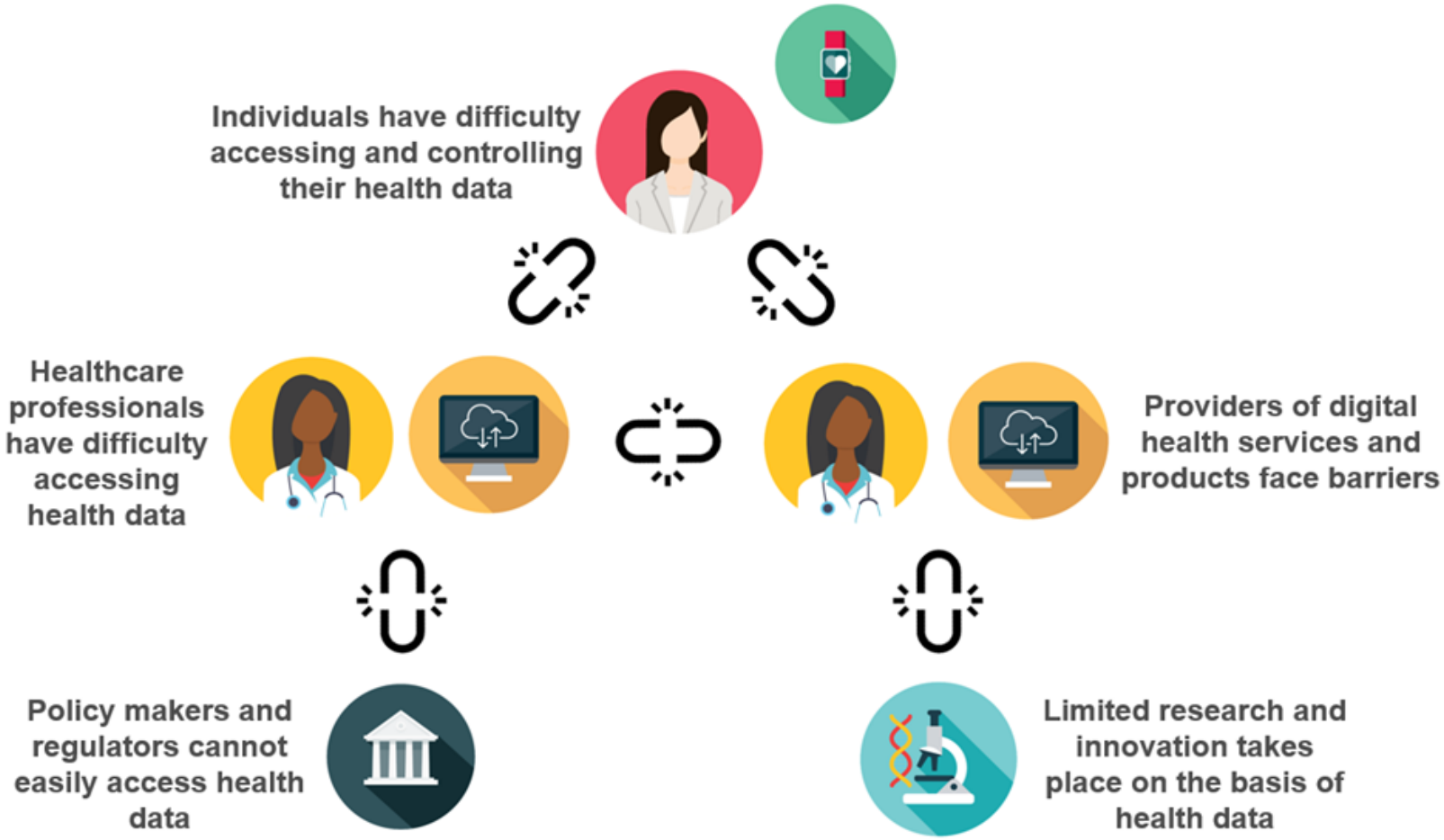
Harnessing the power of health data for people, patients and innovation

May 2022

Why act 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



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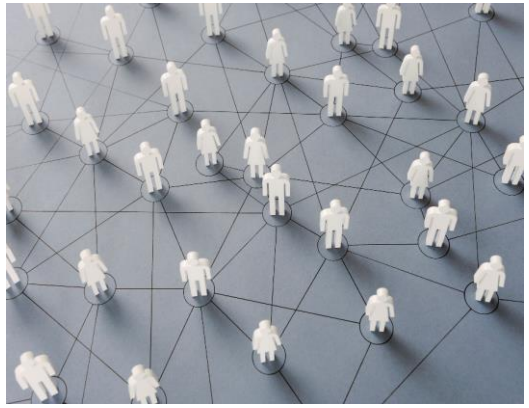
Regulation provides rules, common standards and practices, infrastructures and a governance framework for the of electronic health data for healthcare, research, innovation and policy making – creation of European Health Data Space (EHDS)

Empower individuals to access and control their personal health data



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

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

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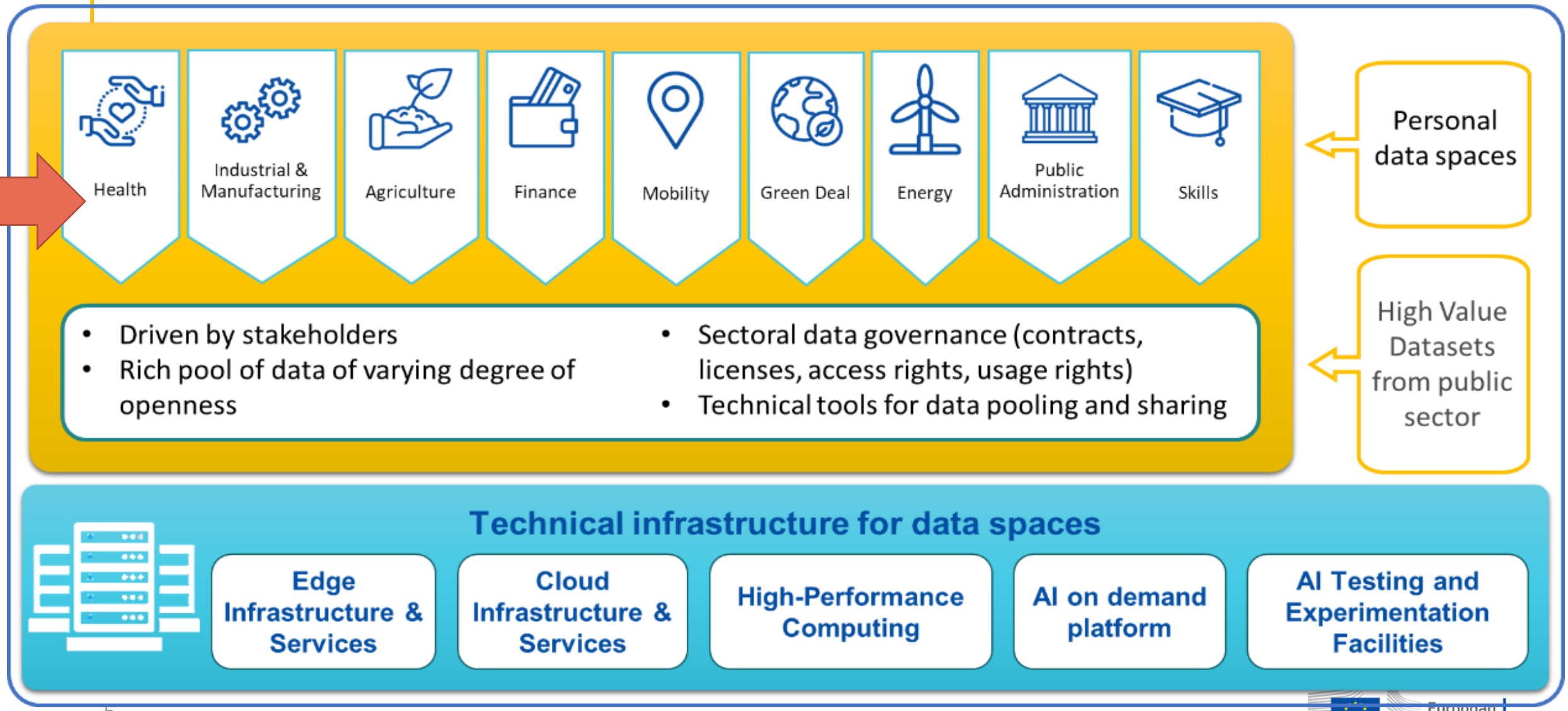
EHDS – **the first** sector specific European Data Space



EHDS – links with other legal proposals and initiatives

GDPR

EHDS builds upon GDPR rights and further develops some of them

European Health Union

EHDS will boost the work of EU Cancer plan, HERA, Pharmaceutical Strategy for Europe

Data Governance Act, Data act

EHDS complements and provides more tailor-made rules for the health sector

EU cybersecurity framework (NIS directive)

EHDS complements and provides more tailor-made rules for the health sector

Artificial Intelligence Act

EHDS supports and complements training of AI, interoperability of AI and EHR systems and data quality

Medical Device Regulations

If manufacturers claim interoperability of devices with EHR systems –EHDS requirements apply

Legal basis and scope of health data

- **Legal basis - Article 16 TFEU** and **Article 114 TFEU**
- **Article 16-** EHDS is building upon GDPR, strengthening the rights to the protection of personal health data and building on possibilities of EU law for processive sensitive health and genetic data
- **Article 114** - EHDS aims to improve the functioning of the internal market and the free movement of goods and services to avoid legislative fragmentation in the internal market and different rules and practices across the EU
- **Full respect of Article 168 TFEU –** EHDS does not intervene in organisation and delivery of health services and medical care of Member States
- **Non-personal** and **personal health data** in scope

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 (MFF)**

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The scope of EHDS

Strengthens the rights of individuals in relation to greater control over their electronic health data:

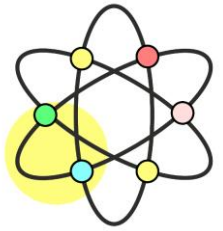
Access, share health data with health professionals nationally or cross-border, add information, rectify errors, restrict access, know what health professional accessed data, issue and accept health data in a common European format, strengthen interoperability.

Rules for electronic health record systems (EHR systems)

Rules and mechanisms supporting the secondary use of electronic health data

Mandatory cross-border infrastructures for primary and secondary use of health data

- **MyHealth@EU**
- **HealthData@EU**

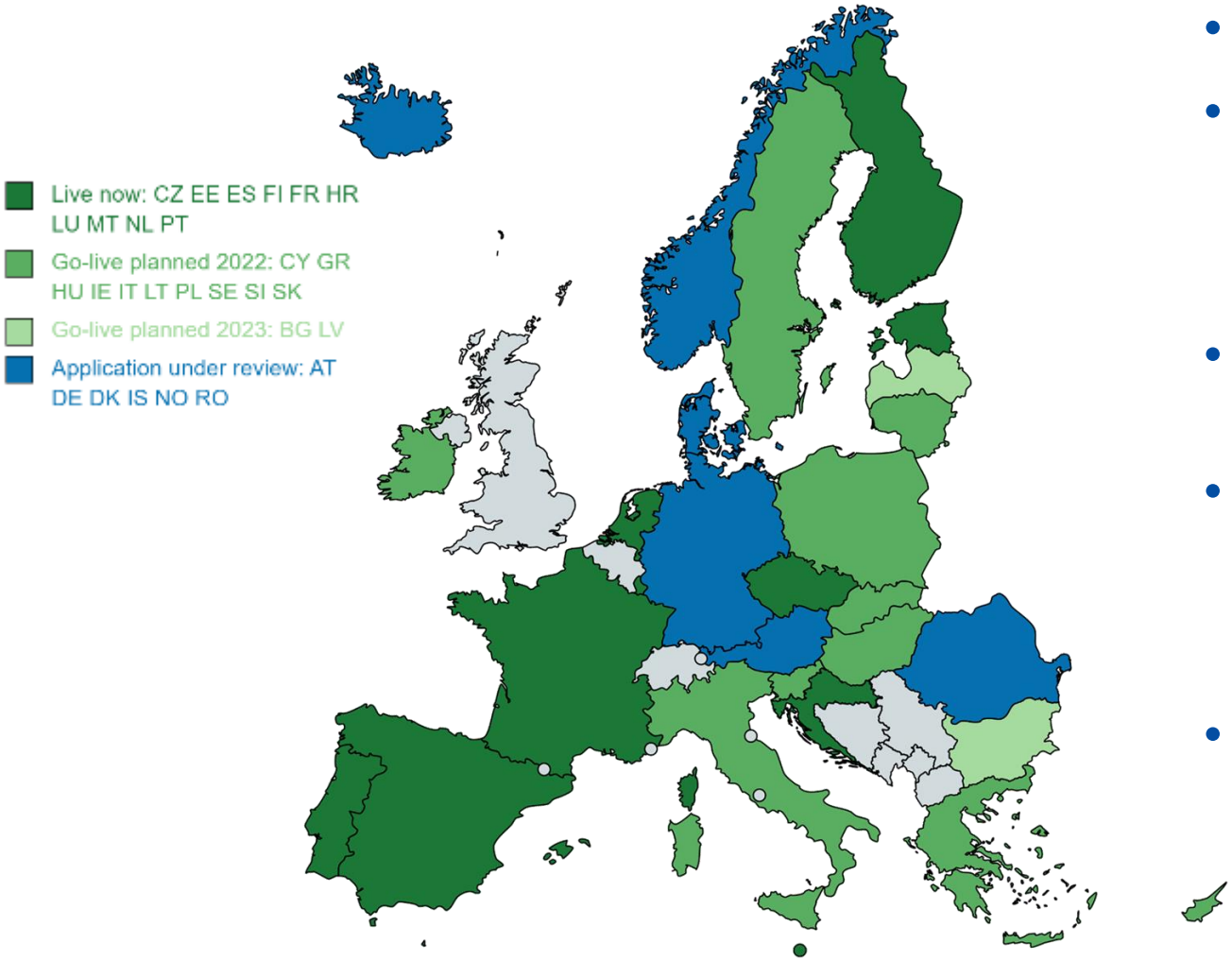


Chapter II Primary use of electronic health data

- Develops **additional rights** of individuals to complement the rights provided under the GDPR in relation to their electronic health data (Art. 3)
- Sets out the provision for the **access by health professionals** to personal electronic health data (Art. 4)
- **Identifies** some type of electronic health data **as a priority** to be integrated in the EHDS in a staged process (Art.5) with deferred application (art 72)
- 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)

Minun terveyteni @ EU

Sähköiset terveyspalvelut – digitaalinen palveluinfrastruktuuri
Euroopan unionin tarjoama palvelu



- Currently 10 Member States are live
- The number of connected Member States will grow rapidly in the years ahead - there are plans for all Member States to join **MyHealth@EU until 2025.**
- Currently there are 2 services: Patient Summary and ePrescription
- This is being expanded to include Medical images, Laboratory results, Discharge letters, Rare disease data and other health information categories
- A Pilot project will explore Patient Access to their health data in MyHealth@EU

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Chapter III EHR systems and wellness applications

- Implementing **a mandatory self-certification scheme** for EHR systems, relation with medical devices and high risk AI systems (Art. 14 – 16)
- **The obligations** of each economic operator of EHR systems (Art. 17 – 22)
- The **requirements** related **to 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)

Chapter IV Secondary use of health data I

- Defines **a 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 eg 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)

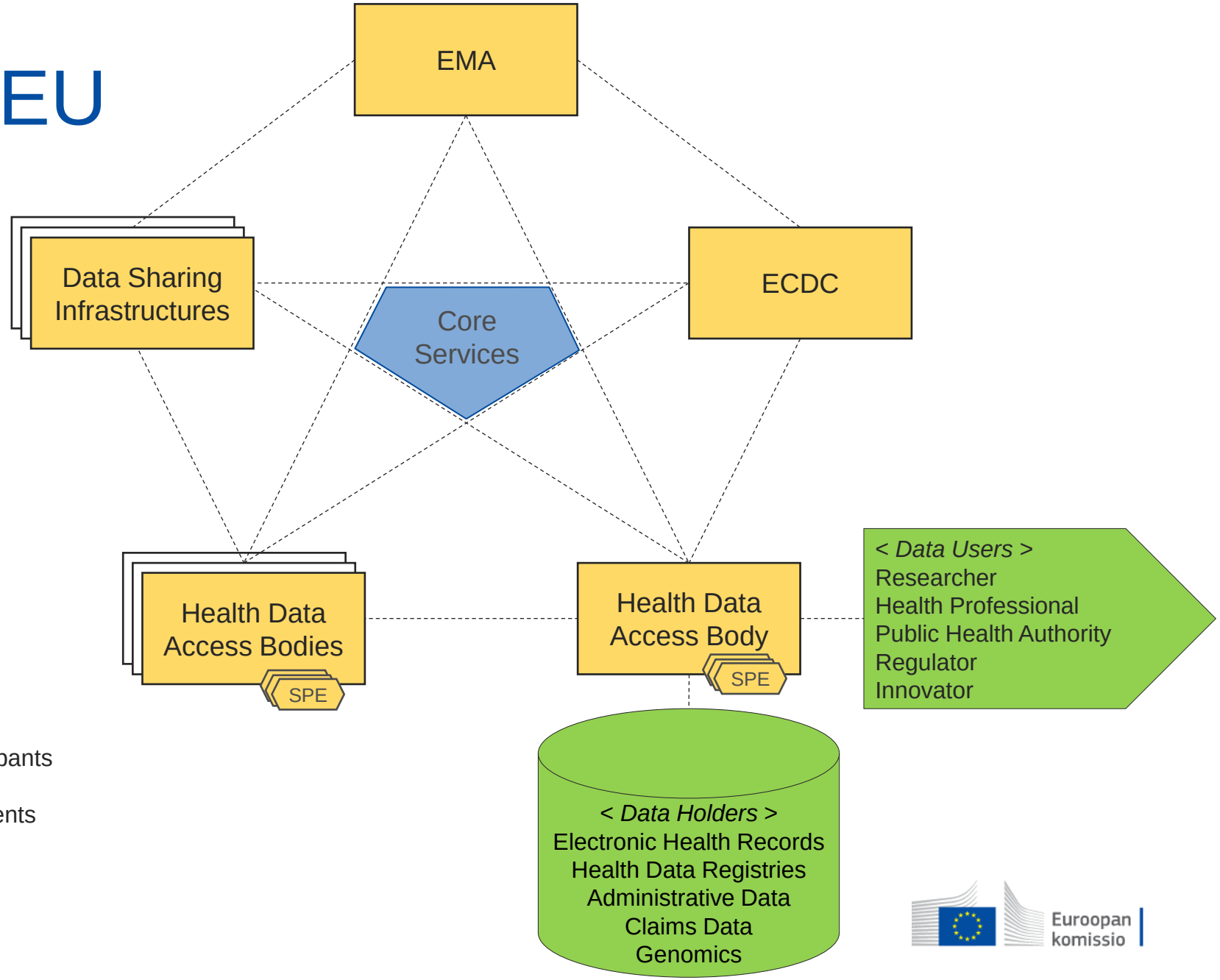
- Implementation of **data altruism** in health (Art.40)

- 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)
- The 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)
- **Provisions** on setting up and fostering **cross-border access** to electronic health data and mutual recognition (Art 53, 54)
- **Provisions** related **to dataset description** and their **quality,** establishment of **EU Dataset Catalogue** (Art. 55, 56, 57)

HealthData@EU



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Chapter V Additional actions

- Other measures to promote **capacity building** by the Member States (Art.59)
- Sets the **additional requirements for public procurement** and **Union funding** to comply with **EHDS** rules (Art. 60)
- **Third country transfer** of non-personal electronic health data (Art.61)
- **The provisions of the international access and transfer** for non-personal and personal data in the EHDS (Art.62, 63)

Governance (Chapter VI and VII)

- Current situation – eHealth Network is **voluntary**, soft cooperation – **not binding** decisions, not addressing the needs of secondary use of health data.
- EHDS is proposing:
  - **Article 14** of Directive 2011/24/EU **is deleted** (Art. 71)
  - **a new European Health Data Space Board (***high level representatives of digital health authorities (primary) and new health data access bodies (secondary) from all the Member States, the Commission, observers etc*). The Commission will chair these meetings. Among other tasks, it will assist Member States in coordinating practices, issue written contributions and to exchange best practices, facilitate cooperation of Member States etc

Governance (Chapter VI and VII)

- **comitology committee** (*both for primary and secondary*) – to provide an opinion on draft implementing acts (*now – more than 20 empowerments for implementing acts in the text*). They include one representative from every EU country and are chaired by a Commission. The rules and procedures applicable to committees are set out in **Regulation 182/2011**. The committee will adopt its rules of procedure on the basis of standard rules of procedure which have been published in Official Journal.

- **expert groups** (*both for primary and secondary*) - the Commission will prepare and adopt **binding** delegated acts (*now - more than 10 in the text)* after consulting these experts groups, composed of representatives from each EU country. It is a commitment under the Interinstitutional Agreement on Better Law-Making from 2016 that the Commission consults experts designated by the Member States on draft delegated acts.

- **joint controllership groups -** for two cross-border digital infrastructures (one for primary and another one for secondary uses of health data). The composition, organisation, functioning and cooperation of the sub-groups shall be set out in the rules of procedure adopted by those groups. The Commission is secretariat.

Chapter VIII Miscellaneous

- Provisions **on penalties (**Art. 69**)**
- **After 5 years** from the entry into force of this Regulation, the Commission shall carry out a targeted evaluation of this Regulation especially with regards to Chapter III (*EHR systems and wellness apps*). The evaluation shall include an assessment **of the self-certification of EHR systems** (Art. 70)
- **After 7 years** from the entry into force of this Regulation, the Commission shall carry out **an overall evaluation of this Regulation**, and submit a report on its main findings (Art. 70)

Funding

Overall funding for EHDS and its infrastructures

- Around € 800 mil

Earmarked funding: € 330 mil

- EU4Health: € 280 mil
- DEP: € 50 mil

Complementary funding: ≥ € 480 mil

- DEP: €140 mil
- CEF: €130 mil
- HE: € 210 mil

Funding for national investments

- RRF: € 12 bn
- ERDF
- InvestEU

Growth potential of health data economy

EUR 5.5 billion over ten years for EU from better access and exchange of health data in healthcare

EUR 5.4 billion over ten years for EU from better use of health data for research, innovation and policy making

Supporting studies and input

The EHDS proposal was drafted on the basis of input from:

- The Public Consultation
- Different studies (Nivel study, Regulatory gaps study, Impact Assessment, Infrastructure study, MonitorEHR study)
- Feedback from the eHealth Stakeholder Group
- Valuable contributions from TEHDAS and the eHN

Next steps

- The Regulation will be negotiated with the Council of the EU (*Member States*) and European Parliament. Usually it takes around 18 months.
- The Regulation will start applying **one year** after its adoption following the negotiations between co-legislators.
- However, the proposal foresees **several transitional periods** for the application of different elements of the proposal, especially related to the primary use of health data (*1 year from the entry into application of the Regulation for patient summaries and ePrescriptions and 3 years for images and image reports, laboratory results and discharge reports*)
- At the same time, all the Member States, as well as Norway and Iceland have applied under CEF and EU4Health **to connect to MyHealth@EU** and most of them intend to connect **by end of 2025**

Kiitos

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