



European Health Data Space

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

July 01, 2022



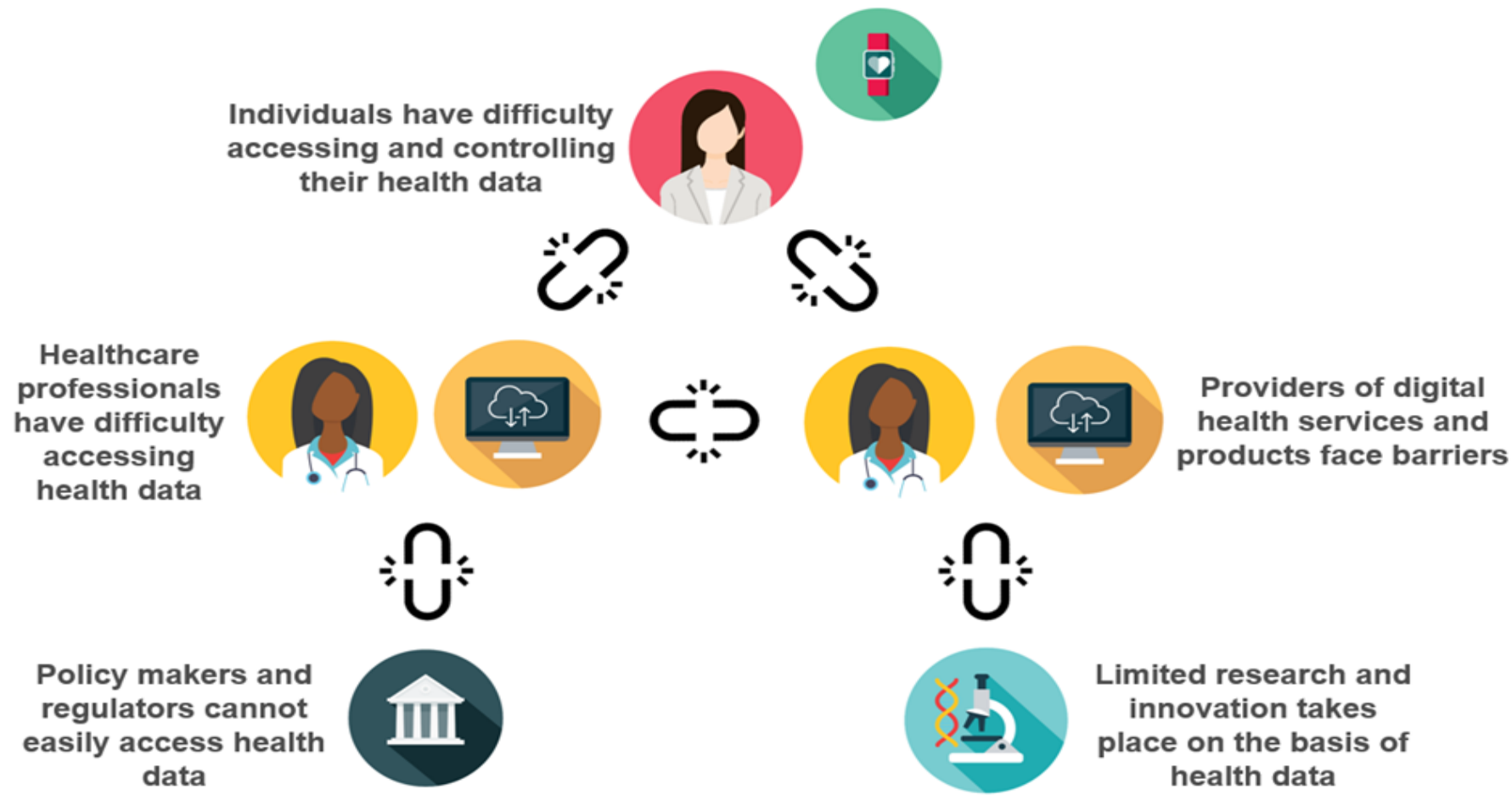
Policy context



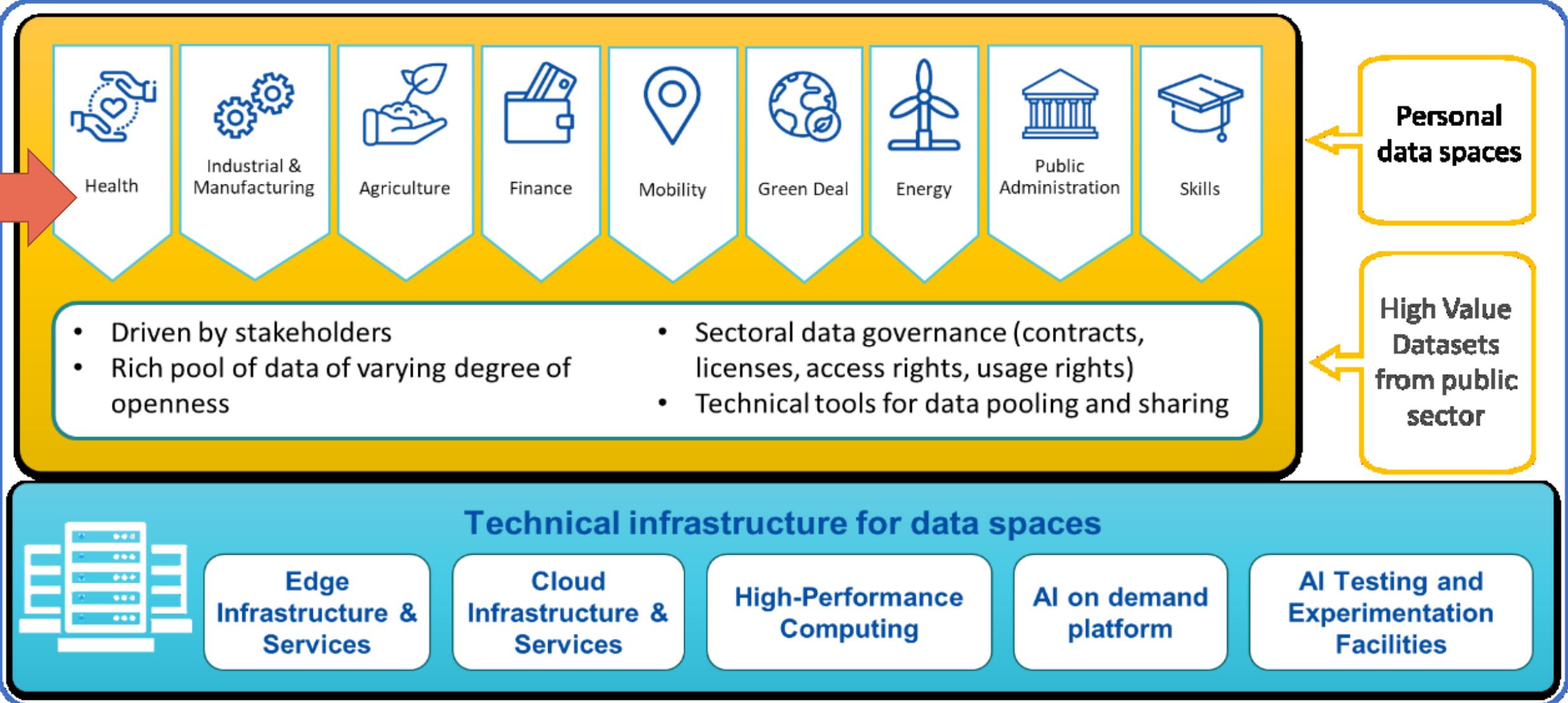
Why act now?

- **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



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

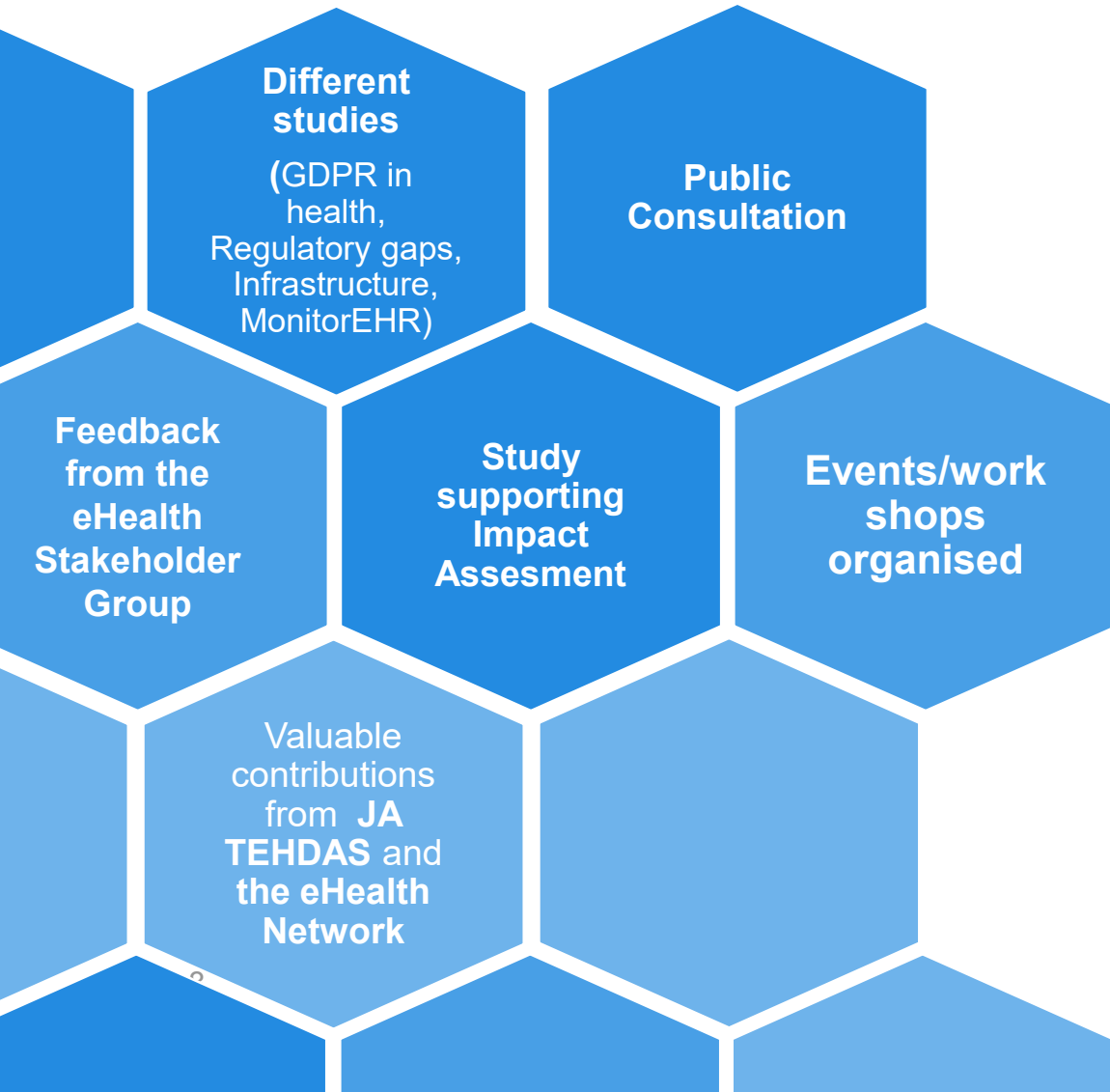
Medical Device Regulations

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

Impact assessment



Preparatory process and consultation results



Online consultation on the EHDS (3 May - 26 July 2021)

382 contributions

EU citizens (26%), NGOs (21%), academic/research institutions (14%), companies/business organisations (11%), business associations (8%), public authorities (5%), non-EU citizens (2%), trade unions (1%) and consumer organisations (1%).

Respondents came from **23 EU** Member States and 8 non-EU countries.

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

Contents of the Regulation



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)

Primary Use of health data

For healthcare purposes



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)

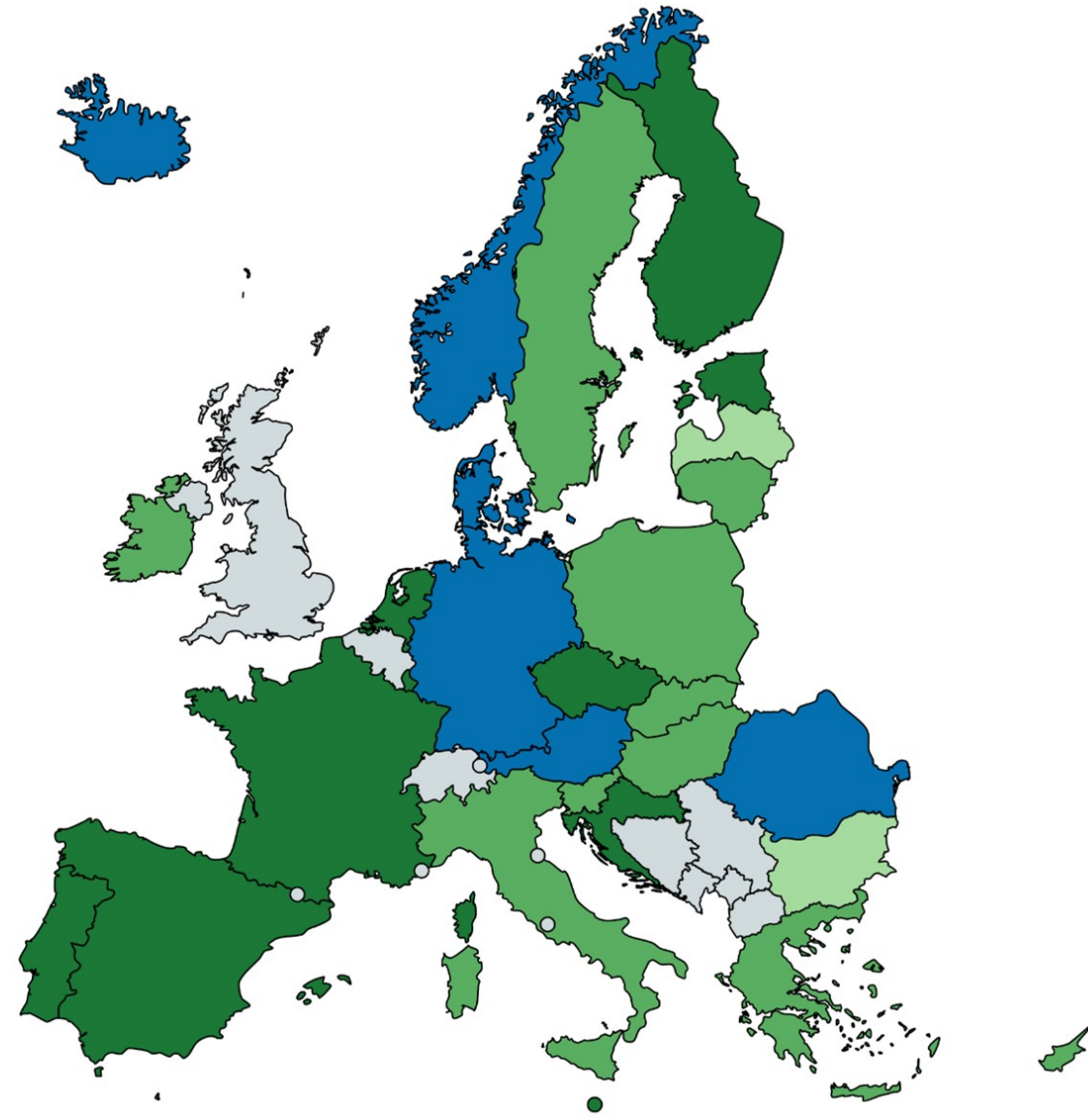
Chapter III EHR systems and wellness applications

- 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)

MyHealth@EU

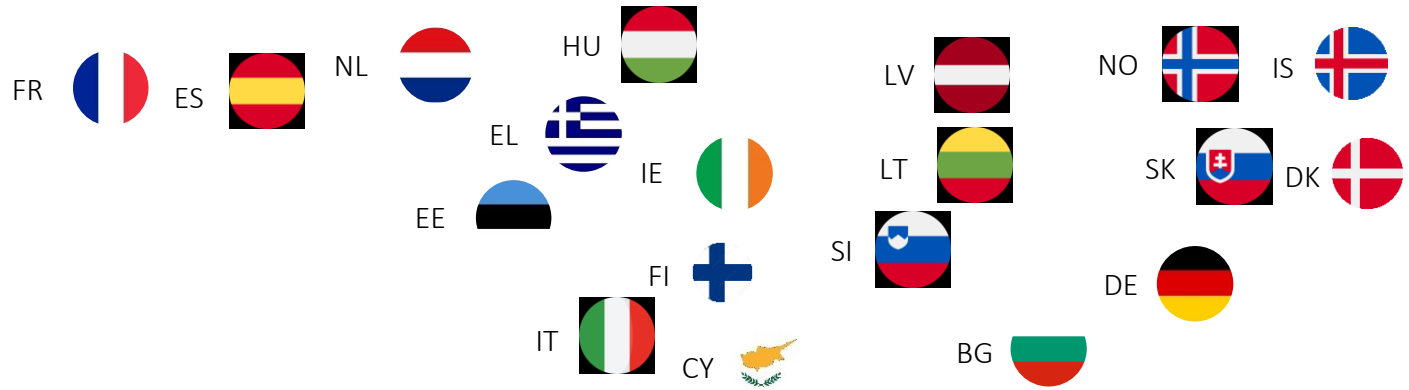
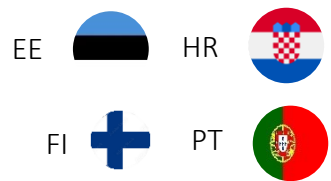
- MyHealth@EU is the existing infrastructure that connects health providers in 10 Member States.
- It allows them to exchange health data such as Patient Summaries and ePrescription. These services will be expanded to include other priority categories.

■ Live now: CZ EE ES FI FR HR
LU MT NL PT
■ Go-live planned 2022: CY GR
HU IE IT LT PL SE SI SK
■ Go-live planned 2023: BG LV
■ Application under review: AT
DE DK IS NO RO



Additional services to be added

ePrescription

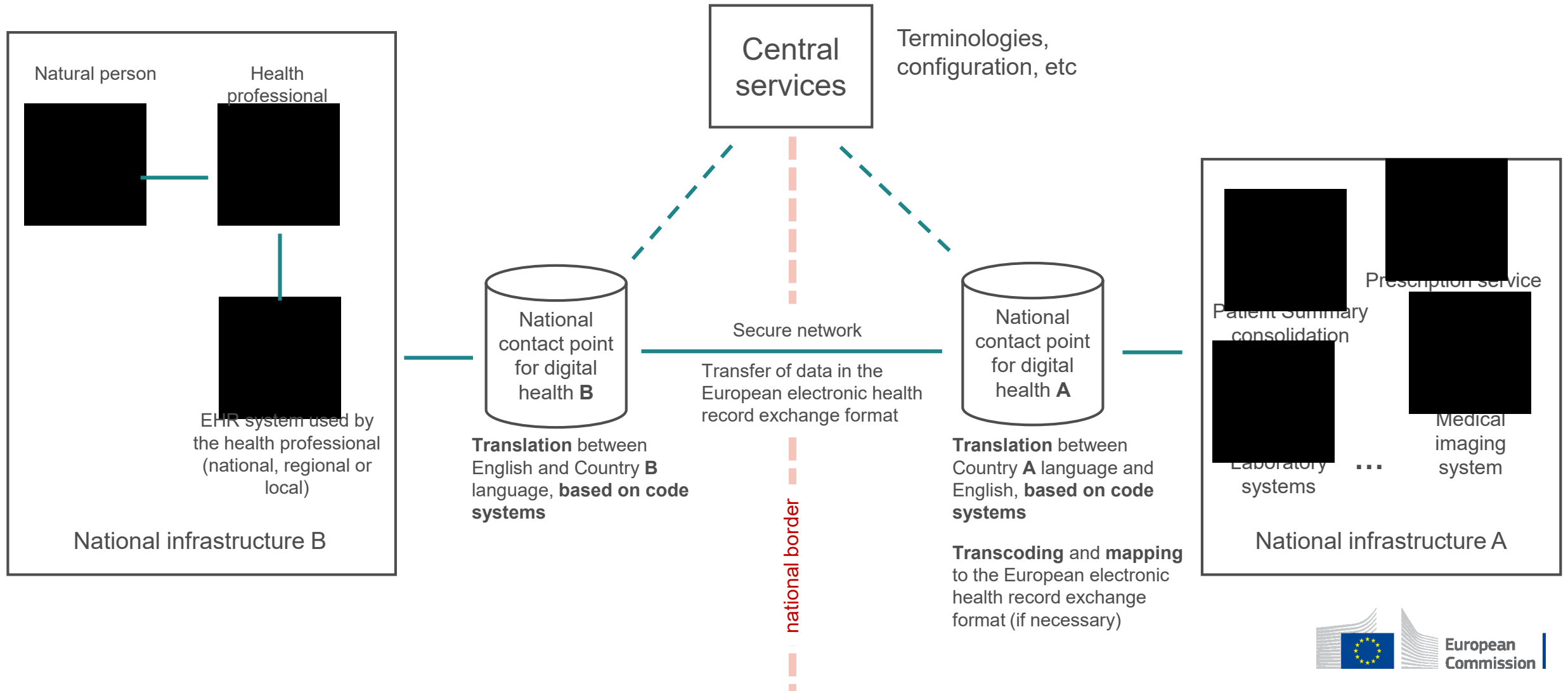


Patient Summary

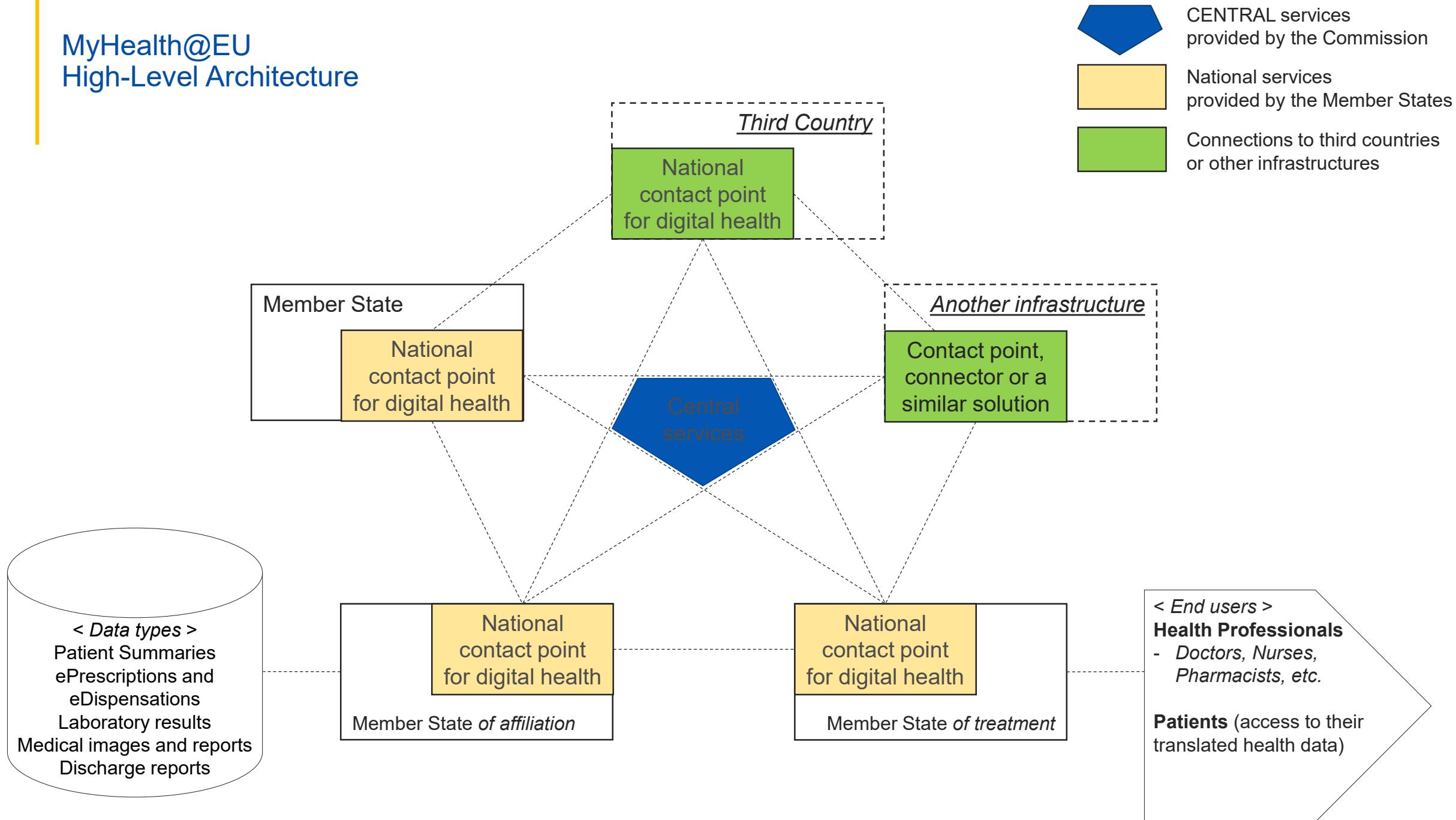


Timelines are approximate and subject to change

Basic data flow in a face-to-face healthcare service



MyHealth@EU High-Level Architecture





Key Performance Indicators

- Number of eP transactions since 2019: 38.253
- Number of PS transactions since 2019: 510
- Number of Hospitals connected (PS-B): 3.229
- Number of Pharmacies connected (eP-B): 24.044
- Citizens able to benefit from MyHealth@EU: 5.775.812

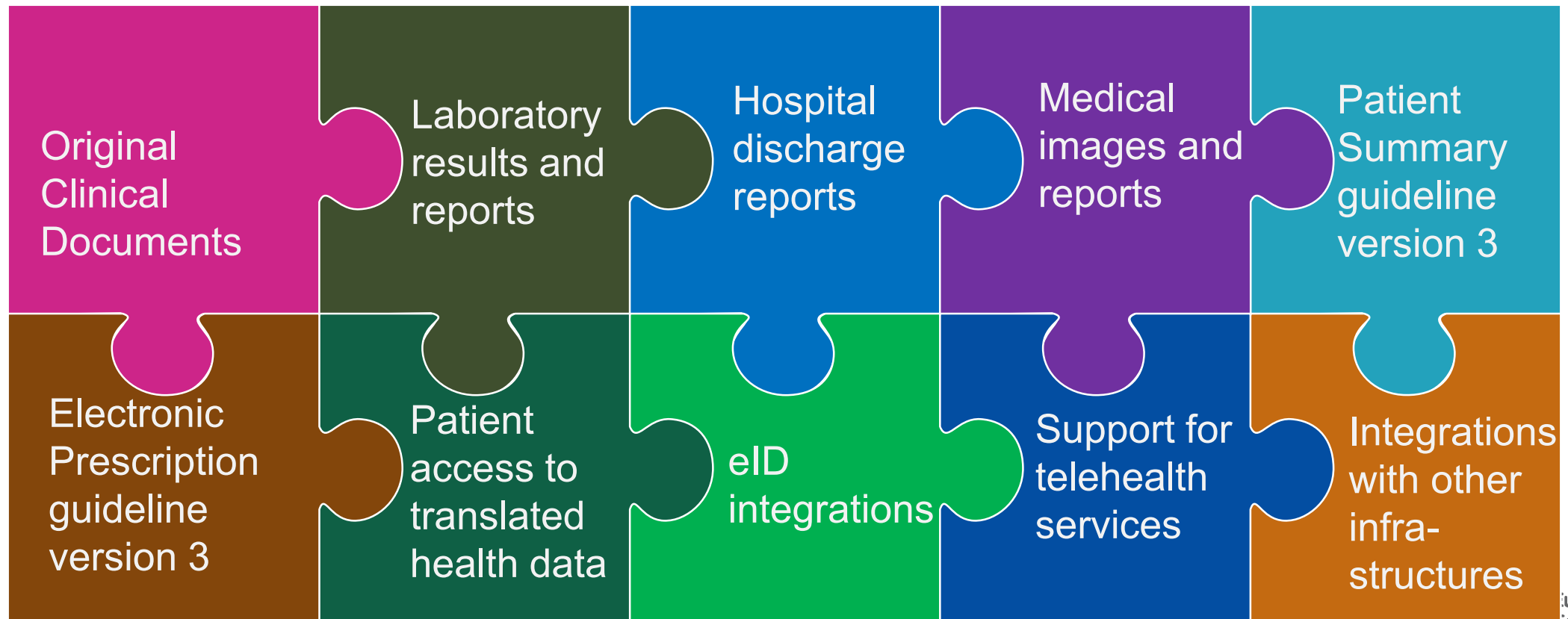
* Data are from the KPI's Q1 2022



Coverage of HCPs in the Member States

MS	Hospitals	Pharmacies	Other POC
CZ	15%		
EE		100%	
ES	10%		13%
FI		100%	
FR	100%	100%	100%
HR	100%	100%	100%
LU	100%		
MT	94%		
NL	1,7%		
PT	7,5%	0.03%	

Next possible steps for MyHealth@EU



Secondary Use of health data

for policy making, regulatory activities, research, innovation and personalised care



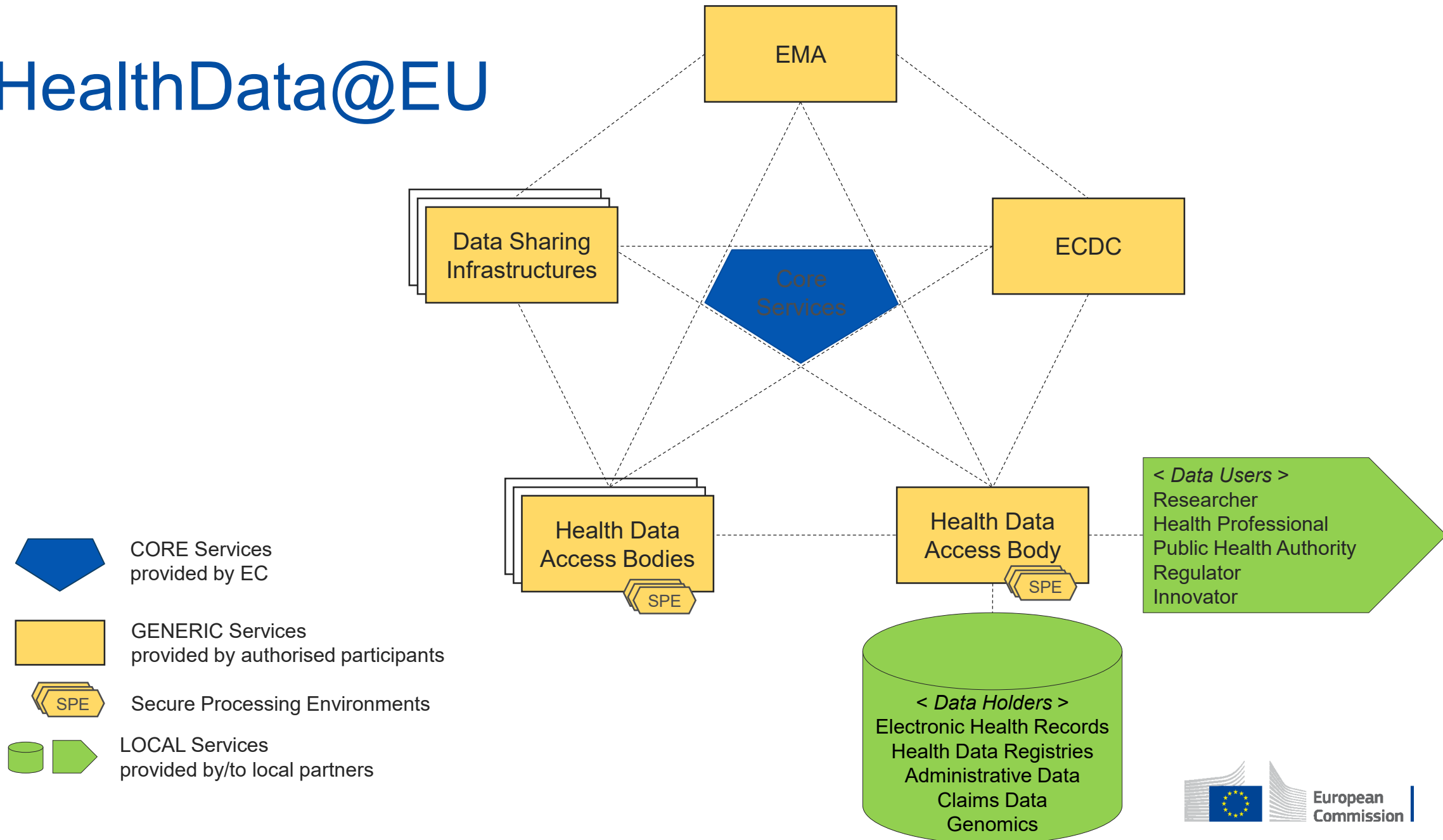
Chapter IV Secondary use of health data I

- 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



Expected benefits



Entering into force

- The Regulation will start applying **1 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**

User perspectives

Empower citizens to have control over their health data



Better diagnosis and treatment, improved patient safety, continuity of care and improved healthcare efficiency

Health data from apps and medical devices



Health data in registries



Electronic health records



Enable healthcare professionals to have access to relevant health data

Assist policy makers and regulators in accessing relevant health data



Facilitate access to health data for innovators in industry



Grant access to health data for researchers



Better health policy, greater opportunities for research and innovation

Individuals: strengthened security

Primary use

Builds upon EU-cybersecurity legislation

Security/interoperability criteria for EHR systems + CE marking

Security audits for the MyHealth@EU (primary use) infrastructure

Strong authentication for patient and health professionals

Only persons entitled to access the data can get access to individual's data

Secondary use

Data processed in secure processing environments, compliant with high standards of privacy and (cyber)-security.

No personal data can be downloaded

Users cannot identify individuals

Audits of participants in HealthData@EU

Financial aspects

Funding

Overall funding for EHDS and its infrastructures

- Around € 800 mil

Earmarked funding: € 330 mil

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

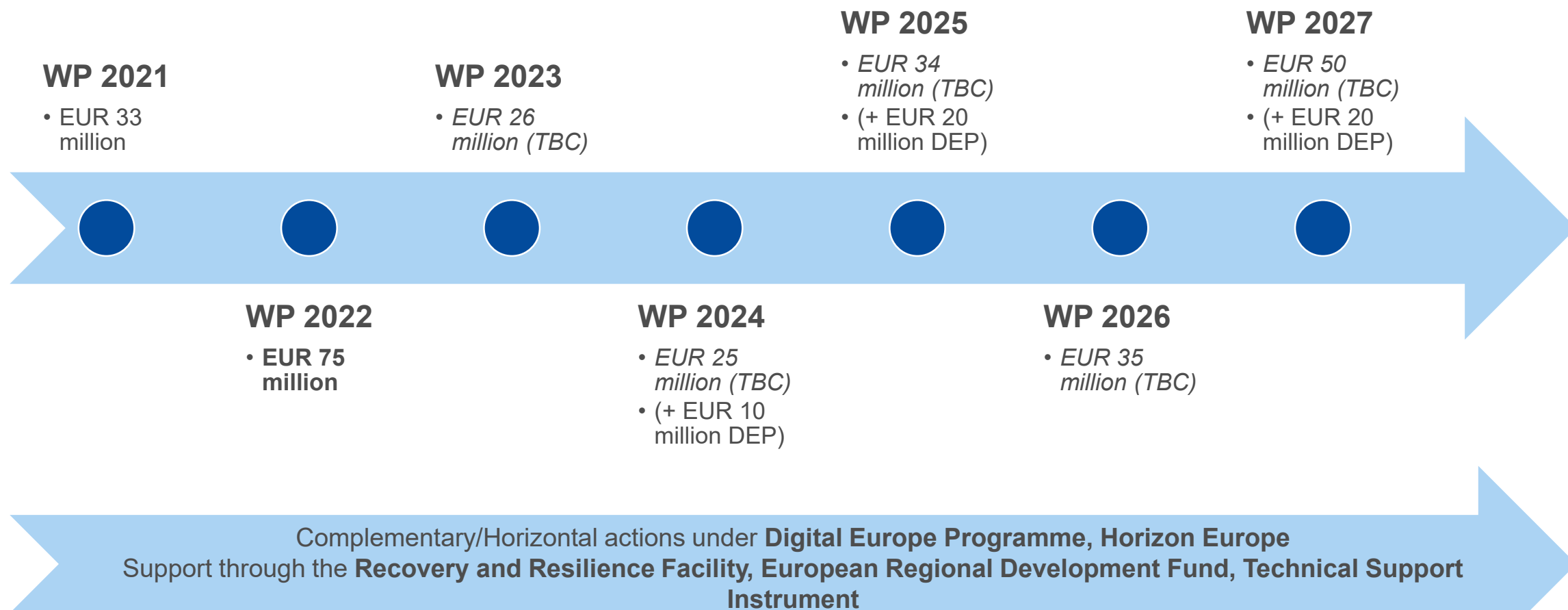
Complementary funding: ≥ € 480 mil

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

Funding for national investments

- RRF: € 12 bn
- ERDF
- InvestEU

EU4Health and the EHDS



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**)

Next steps

EHDS Regulation



Next steps for EHDS Regulation

- Negotiation with the Council of the EU and European Parliament.
- EDPS&EDPB opinion

Thank you



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