- Please keep your microphone **muted**
- **Questions during the session?** Please use the chat box. We will address the questions in the second part of the webinar
- Note that this webinar will be **recorded** and made available on our IHE-Europe [YouTube channel](#)
- Slides will be **available on IHE-Europe** [webpage](#)

Register here: https://connectathon.ihe-europe.net/ihe-europe-experience-days-2025

European Health Data Space – EHDS Roadmap in Austria

IHE Europe Webinar Series
25 April 2025

European Health Data Space is set to play a leading role in facilitating the exchange of all EU citizens when crossing borders, as well as nationally

Quelle: Flux AI – erstellt durch Helene Prenner

The European Strategy for data at a glance

The **European Strategy for data** (2020) aims to make the EU a leader in a data-driven society.

The **Data Governance Act** (2020) facilitates data sharing across sectors and Member States.

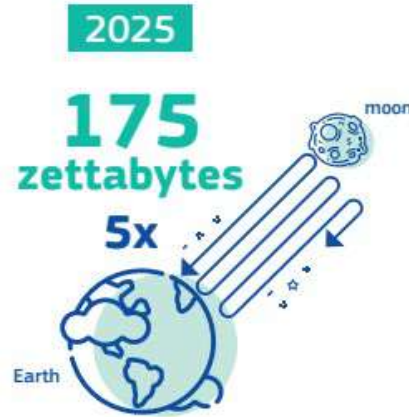The **Data Act** (2022) clarifies who can create value from data.

Ten **European common data spaces**, ranging from industry to mobility, from European Green Deal to energy and health.

Global data volume will grow:

2018
33 zettabytes
Earth
Stored on 512 GB tablets, it would form a tower that reaches the moon.
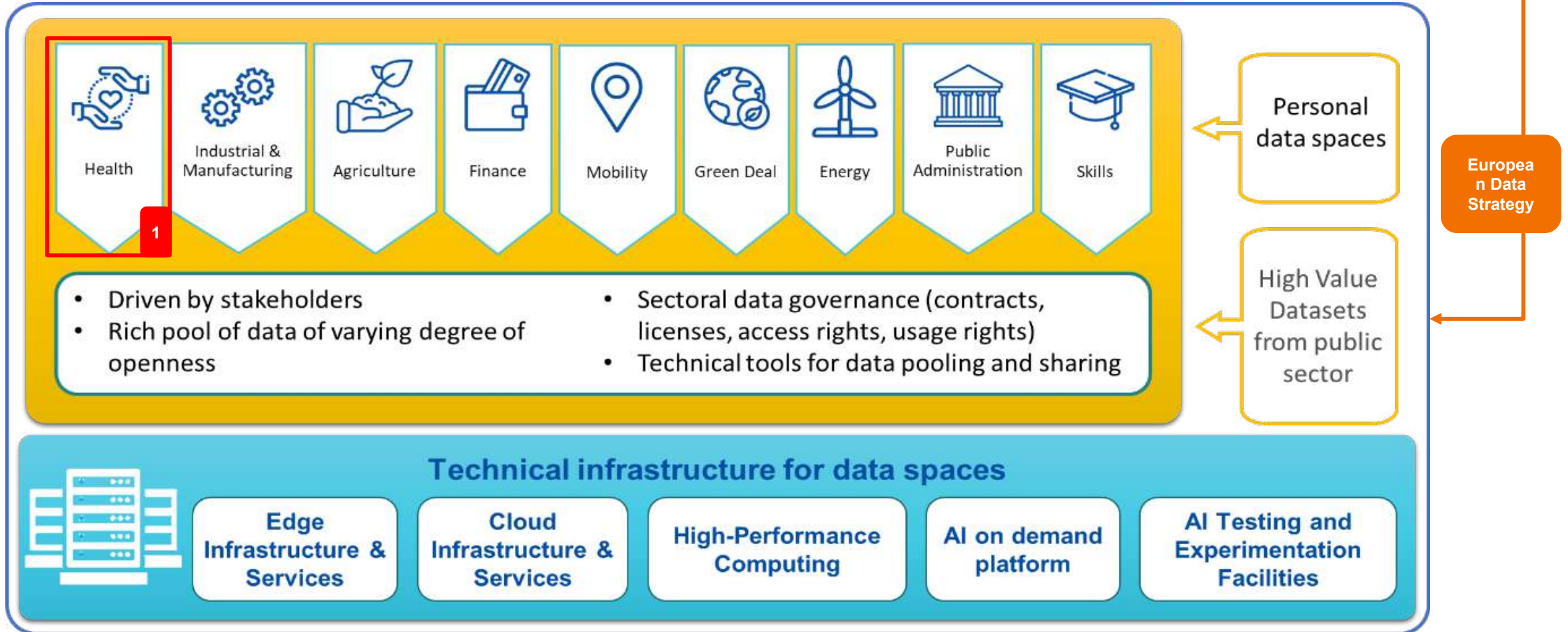
2025
175 zettabytes
5x
moon
Earth
Enough to make the journey to the moon and back five times.

120 Milliarden €

Einsparungen im EU-Gesundheitssektor pro Jahr

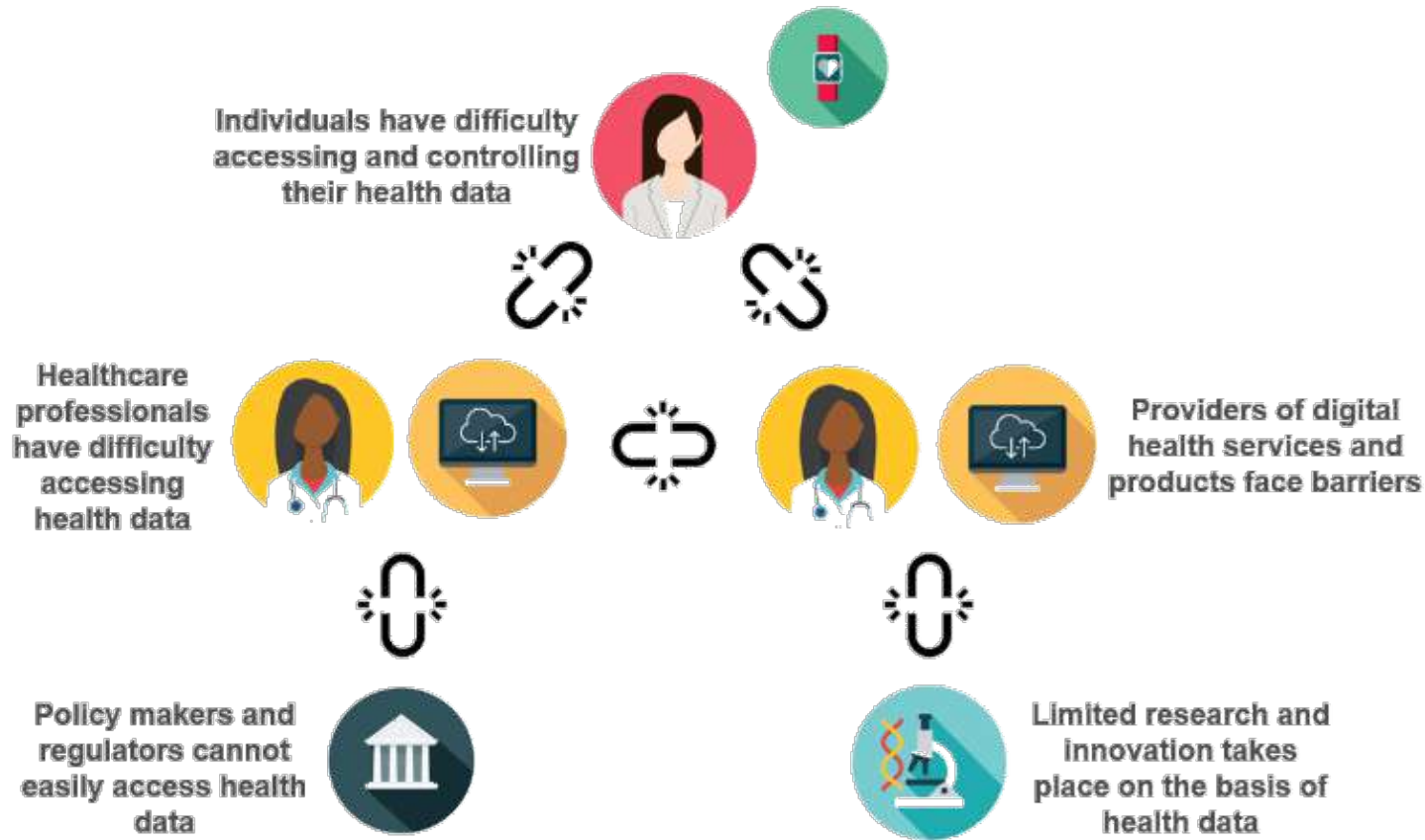Europe's Digital Decade – Digital Target 20230

Health	Industrial & Manufacturing	Agriculture	Finance	Mobility	Green Deal	Energy	Public Administration	Skills

1

- Driven by stakeholders
- Rich pool of data of varying degree of openness

- Sectoral data governance (contracts, licenses, access rights, usage rights)
- Technical tools for data pooling and sharing

Personal data spaces

High Value Datasets from public sector

European Data Strategy

Technical infrastructure for data spaces

Edge Infrastructure & Services	Cloud Infrastructure & Services	High-Performance Computing	AI on demand platform	AI Testing and Experimentation Facilities

23.04.2025

Figure 2 – Problems in controlling, using and sharing health data

Individuals have difficulty accessing and controlling their health data

Healthcare professionals have difficulty accessing health data

Providers of digital health services and products face barriers

Policy makers and regulators cannot easily access health data

Limited research and innovation takes place on the basis of health data

Source: https://health.ec.europa.eu/publications/communication-commission-european-health-data-space-harnessing-power-health-data-people-patients-and_en

EHDS is designed to solve the following problems:

- o Access and control over your own data
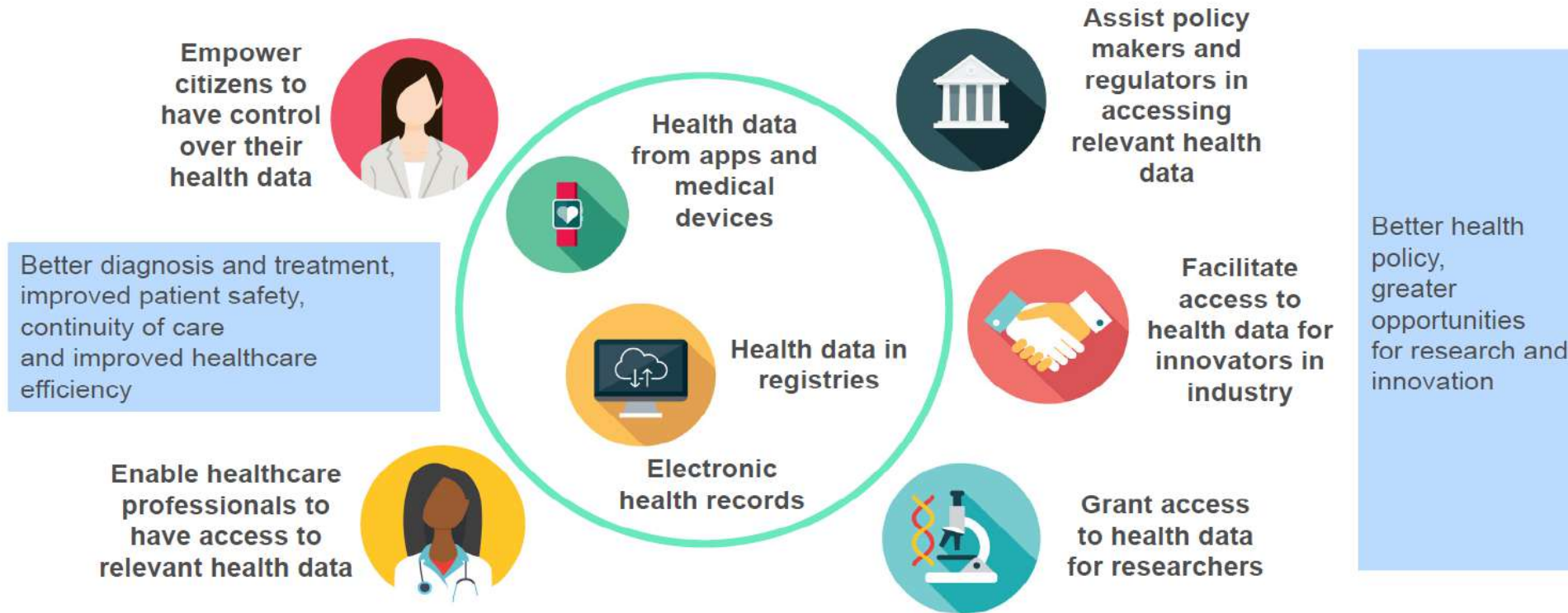- o Doctors and HP access to primary data

- o Lowering market barriers for digital healthcare providers

- o Research Access to secondary data
- o Policy & supply planning Access to secondary data

European Data Strategy 2020

May 2022, EHDS Regulation - Proposal

Empower citizens to have control over their health data

Assist policy makers and regulators in accessing relevant health data

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

Health data from apps and medical devices

Facilitate access to health data for innovators in industry

Better health policy, greater opportunities for research and innovation

Health data in registries

Electronic health records

Enable healthcare professionals to have access to relevant health data

Grant access to health data for researchers

March 26th 2025: EHDS Regulation enters into force

source: https://health.ec.europa.eu/publications/communication-commission-european-health-data-space-harnessing-power-health-data-people-patients-and_en

23.04.2025

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)

New Governance Bodies:

EU: EHDS Board succeeds eHealth Network

National: Digital Health Authority, Market Surveillance Authority, Health Data Access Body

23.04.2025

Building on existing cooperation

MyHealth@EU under Cross-border Healthcare Directive

- Voluntary system for exchanging patient summaries, prescriptions and dispensations (= first group of priority categories)
- **15 countries** live with at least one service, up to **10 more** expected to go live with first service(s) this year

Evolution of MyHealth@EU for the EHDS

- Voluntary => mandatory
- New services
- New data categories

European Commission
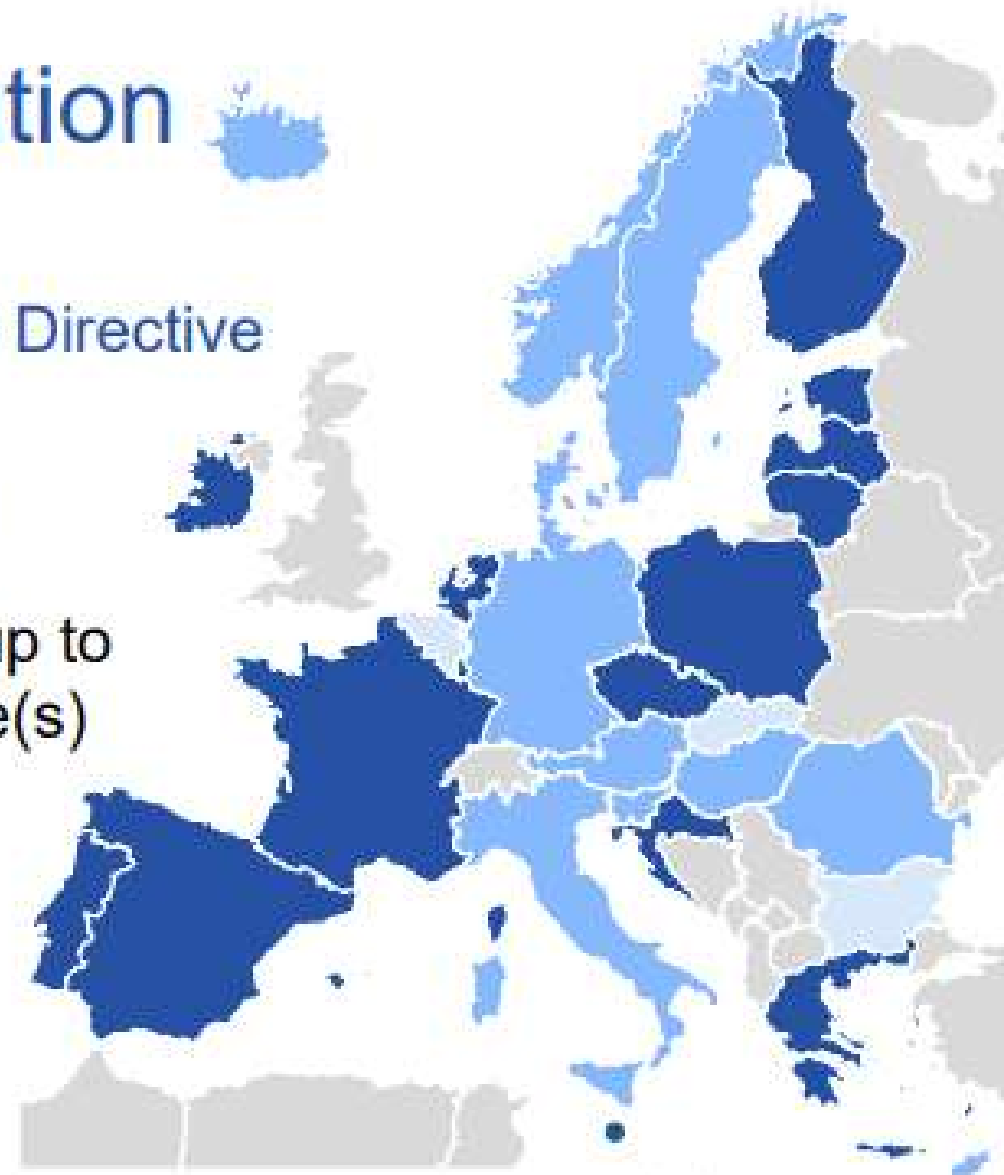
o **eHDSI to date**

  o (voluntary) cross-border infrastructure and projects (eHDSI)

  o Individual networking of existing/new systems

  o Use-Case based exchange

o **European Health Data Space - EHDS**

  o Requirements for **ELGA and e-Health** in Austria and EU

  o Requirements for **software manufacturers** in Austria and EU

  o **Rights for patients** in Austria and EU

  o Possibility of **secondary data** use in Austria and EU
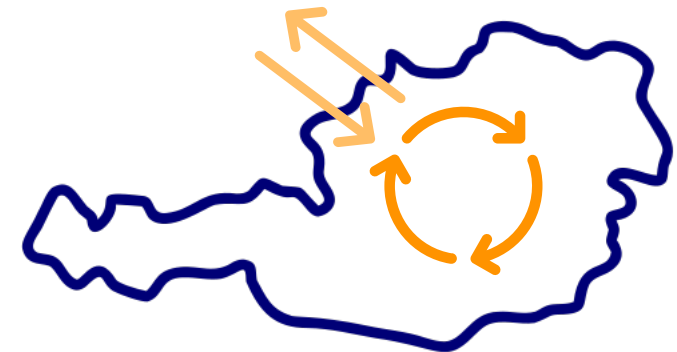
EHDS & MyHealth@EU

EHDS - Verordnung

Implementing Acts: European eHealth Exchange Format **(zB: EEHRxF) bis März 2027**

Austria

EU-MS

Cross Border

National Systems & Services

ELGA, KIS, AIS, Apps…

GDA rights & obligations

Access & connection:
Connection of all GDAs to MyHealth@EU services
EU-ID:
Access for all GDAs to MyHealth@EU only via personal 2FA authentication

Patients' rights

- EU-ID: Patients should also be able to use eIDs for identification in the portal as part of MyHealth@EU
- Access: Right to online access and request for rectification for patients and their data
- Substitute patients must be able to nominate user-friendly substitutes
- Contribute data yourself: Patients can contribute data themselves (flagged)

MyHealth@EU SERVICES

- Patient Summary
- e-prescriptions (eP/eD)
- medical images and findings;
- Results of medical examinations incl. laboratory results
- Discharge reports

+ MANDATORY FORMAT FOR EHR SYSTEMS

o **Patient Summary** – 4 years

    o **new**

o **ePrescription & eDispensation** – 4 years

    o existing– Integration & Update Format

o **Images and image reports** – 6 years

    o existing– Lower Austria, Vienna, Styria

o **Medical test results** – 6 years

    o existing– roll-out running & update format

o **Discharge reports** – 6 years

    o Existing – & Update format

An EHR system in accordance with EHDS will fulfill two core elements in the future:

The interoperability component: New EHR systems must be able to interact with software applications and devices from the same or different vendors to transmit and receive personal electronic health data. (= EEHRxF implementation)

The logging component: New EHR systems must be able to record logging information about access to personal electronic health information by users of the system (including identification of the specific individuals who accessed personal electronic health information; categories of data accessed; time and date of access; and source(s) of the data).

Conformity process

Technical conformity
1. National test environment
2. Technical documentation
3. (Self) registration

Inspections by the market surveillance authority
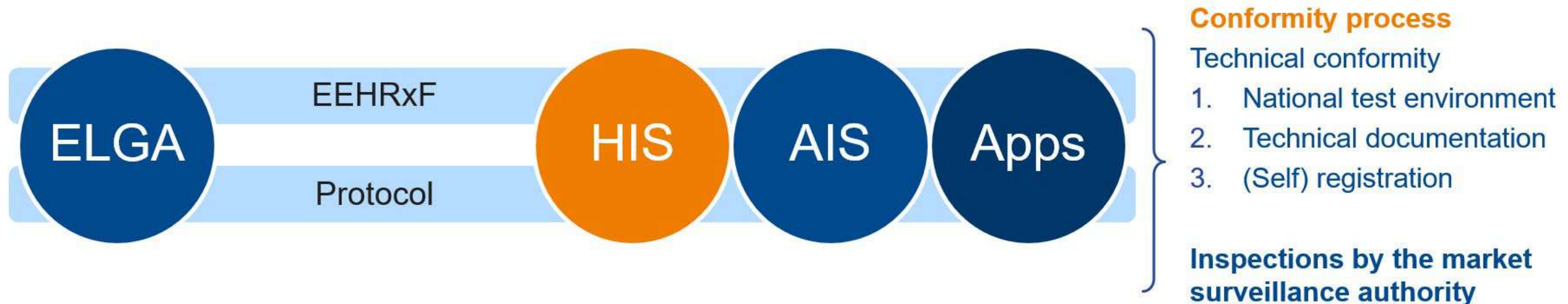
Health data holders: who is in scope ?

- Any natural or legal person, public authority, agency or other body in the **health or care sectors**; including reimbursement services when necessary;

- Any natural or legal person **developing products or services** intended for the health, healthcare or care sectors; developing or manufacturing wellness applications;

- Any natural or legal person **conducting research** related to the healthcare or care sectors;

- Any natural or legal person acting as a **mortality registry**;

- As well as any institution, body, office or agency of the **Union**;

+

Having the right or obligation to process personal data as controller or the ability to make non-personal data available.

established in the EU

Exemptions

Individual researchers and natural persons

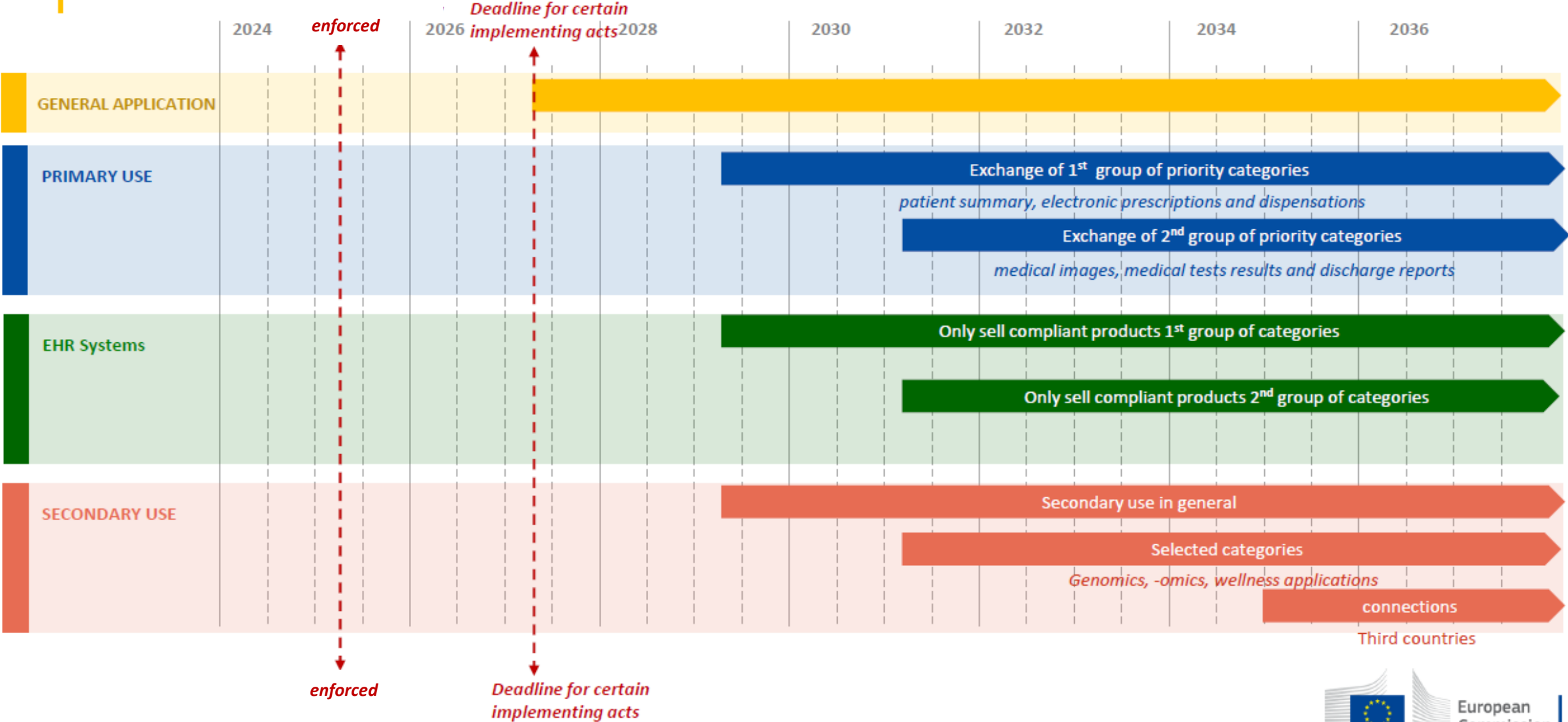Micro-enterprises as per Recommendation 2003/361/EC

National provisions

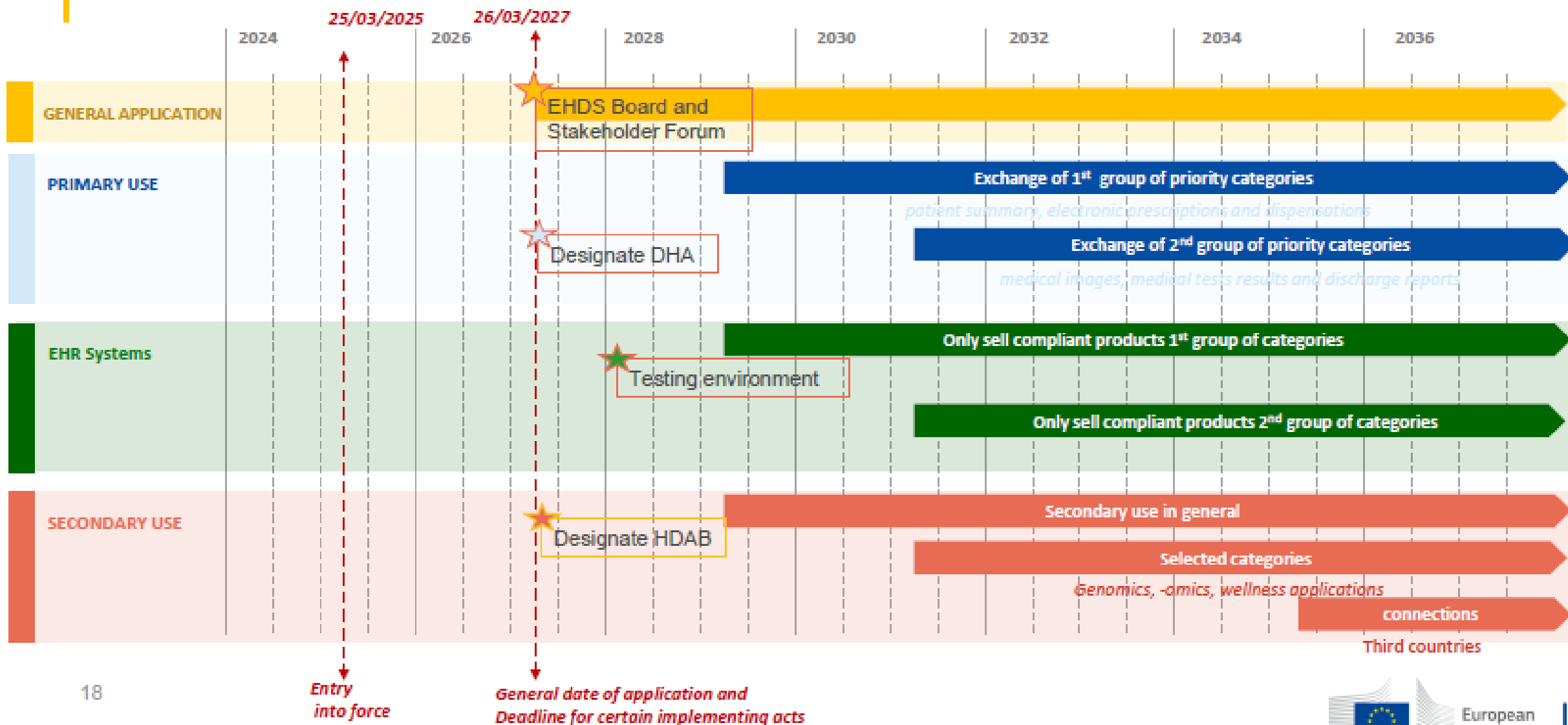Possibility for MS to extend obligations to exempted entities.

Possibility for MS to designate health data intermediation entities to fulfill these duties.

Notification to the Commission of any relevant national legislation.

European Commission

EHDS – Overall timeline for application

1. **Primary data use (national & cross-border):**

   1. **Fit4EHDS**
      - Requirements analysis and roadmap development: primary data usage
      - National project of ELGA GmbH, together with BMSGPK, Länder & SV
   2. **Xt-EHR (Extended EHR - Joint Action)**
      - Coordination of EEHRxF (European Exchange Formats) & EHR Requirements
   3. **At-eHDSI**
      - Connecting Austria to the European eHealth Digital Service Infrastructure
      - EU prescription (A/B)
   4. **AMHEN Austria MyHealth@EU New Services**
      - In addition to the EU prescription, other MyHealth@EU services will soon go live
      - Lab Results, Hospital Discharge Letters, Patient Summaries

2. **secondary data use**
   - National EU co-financed project of Gesundheit Österreich GmbH

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EHDS & MyHealth@EU: Current status & outlook

- **Timeline facts EHDS**
  - 16.12.2024: European Parliament has adopted EHDS
  - 21.01.2025: European Council has formally adopted the EHDS
  - 05.03.2025: Publication of the EHDS regulation
  - Entry into force on 26.03.2025

LINK: EHDS Regulation

LINK: EHDS Frequently Asked Questions

- **Outlook:**
  - Obligation to ePrescription/eDispensation & Pateint Summary according to EEHRxF: **March 26, 2029**
  - Requirement for imaging data, discharge reports and results of medical examinations, including laboratory and other diagnostic results and related reports under EEHRxF: **March 26, 2031**

- **Timeline facts for cross-border services that are already included in projects:**
  - 2026 : eP/eD (EU prescription) is finally implemented technically. Once the law has been passed, the services can be activated with the first countries that also already accept an EU prescription. These include: ES, PT, GR, EE, FI, CZ, HR, LT, LV, PL
  - 2026: PS *(Usecase B)*
  - 2026: Lab Results (Usecase A&B)
  - 2027: Hospital Discharge Letter *(Usecase B)*

Thank you and have a safe journey into a digital health future

Contact us and follow us

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