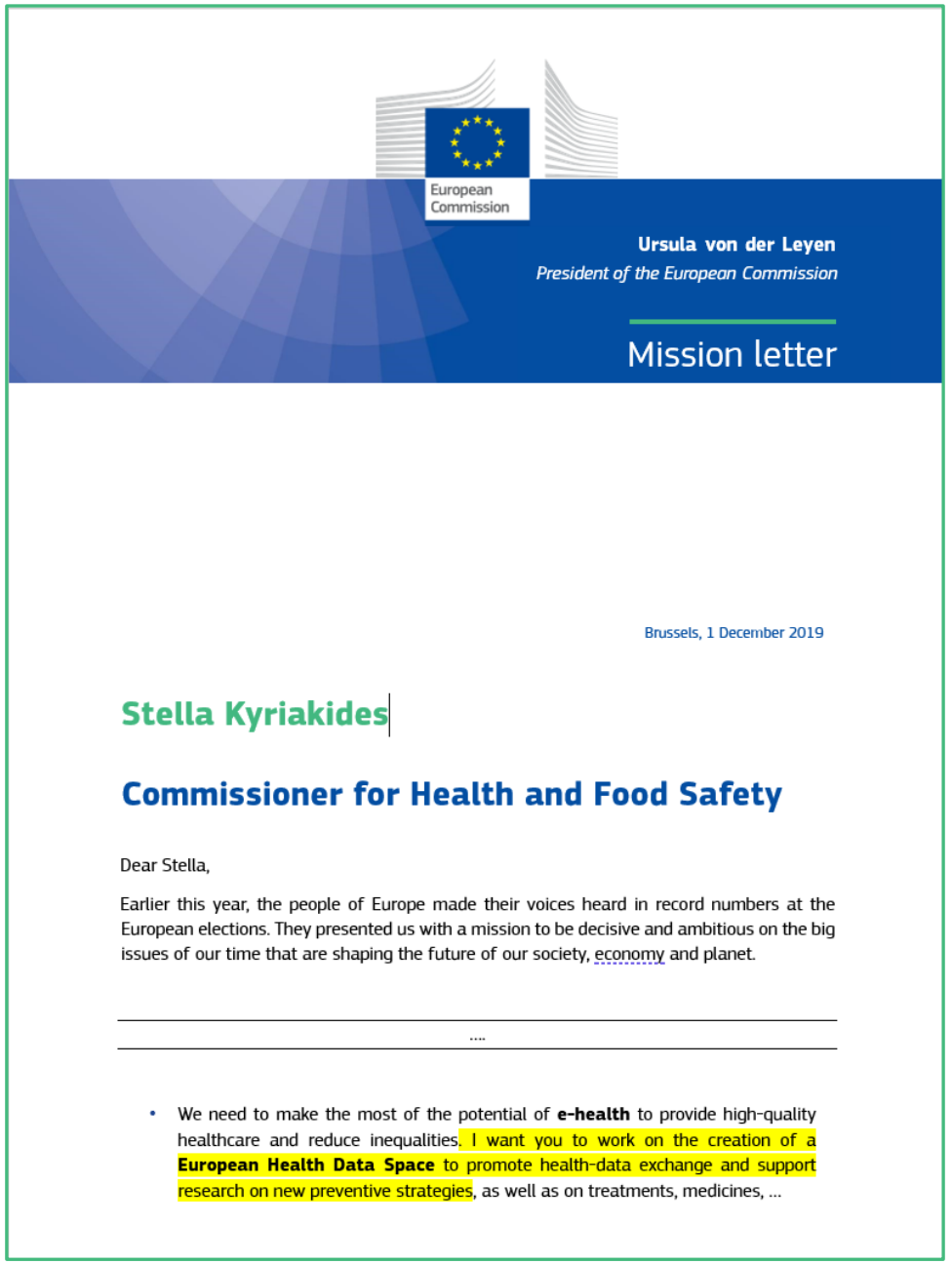
European Health Data Space

First of the many

European Commission



European Commission

Ursula von der Leyen

President of the European Commission

Mission letter

Brussels, 1 December 2019

Stella Kyriakides

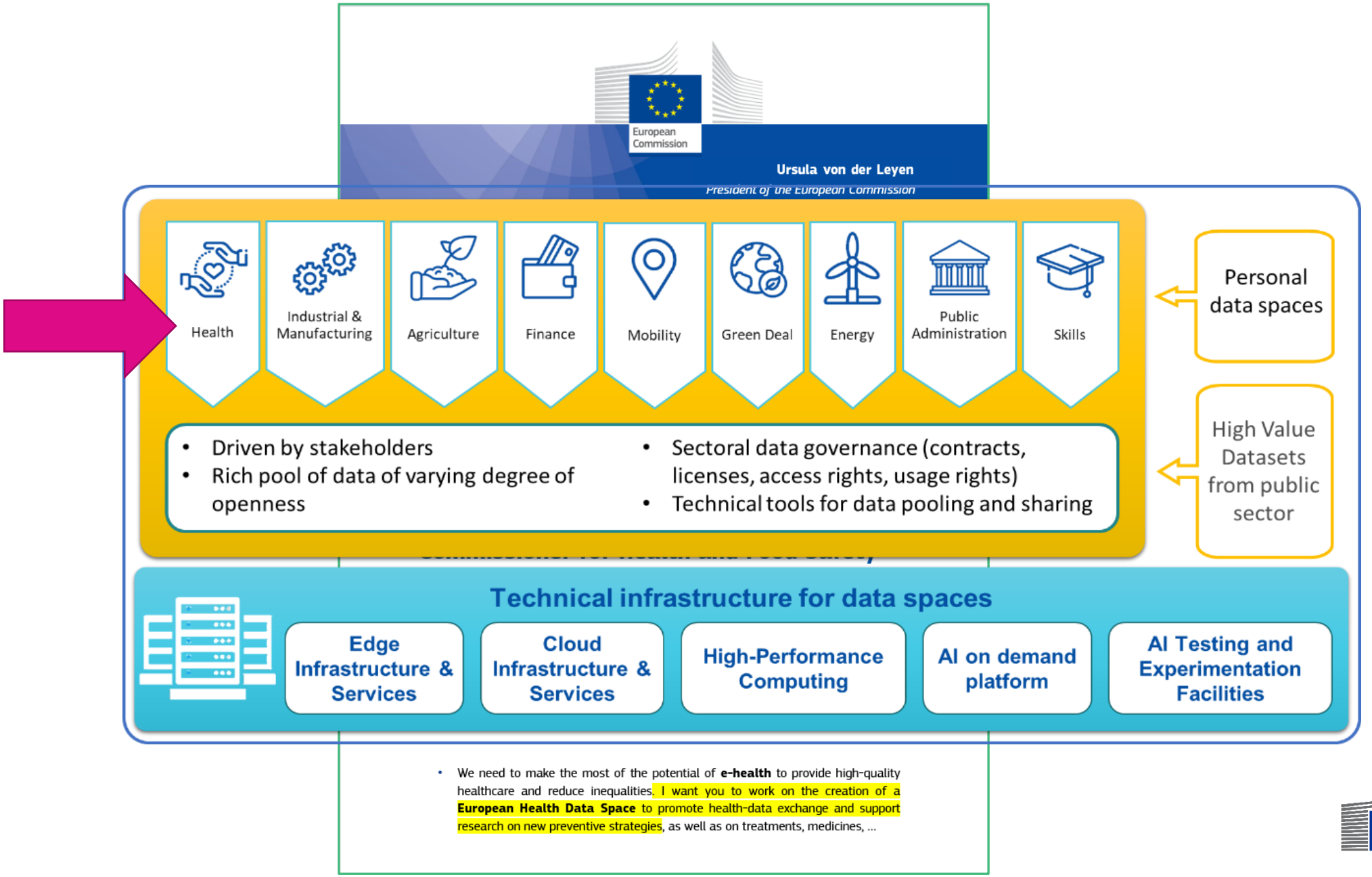
Commissioner for Health and Food Safety

Dear Stella,

Earlier this year, the people of Europe made their voices heard in record numbers at the European elections. They presented us with a mission to be decisive and ambitious on the big issues of our time that are shaping the future of our society, economy and planet.

....

- We need to make the most of the potential of **e-health** to provide high-quality healthcare and reduce inequalities. I want you to work on the creation of a **European Health Data Space** to promote health-data exchange and support research on new preventive strategies, as well as on treatments, medicines, ...


European Commission
Ursula von der Leyen
President of the European Commission
Health
Industrial & Manufacturing
Agriculture
Finance
Mobility
Green Deal
Energy
Public Administration
Skills
Personal data spaces
High Value Datasets from public sector
• 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
Technical infrastructure for data spaces
Edge Infrastructure & Services
Cloud Infrastructure & Services
High-Performance Computing
AI on demand platform
AI Testing and Experimentation Facilities
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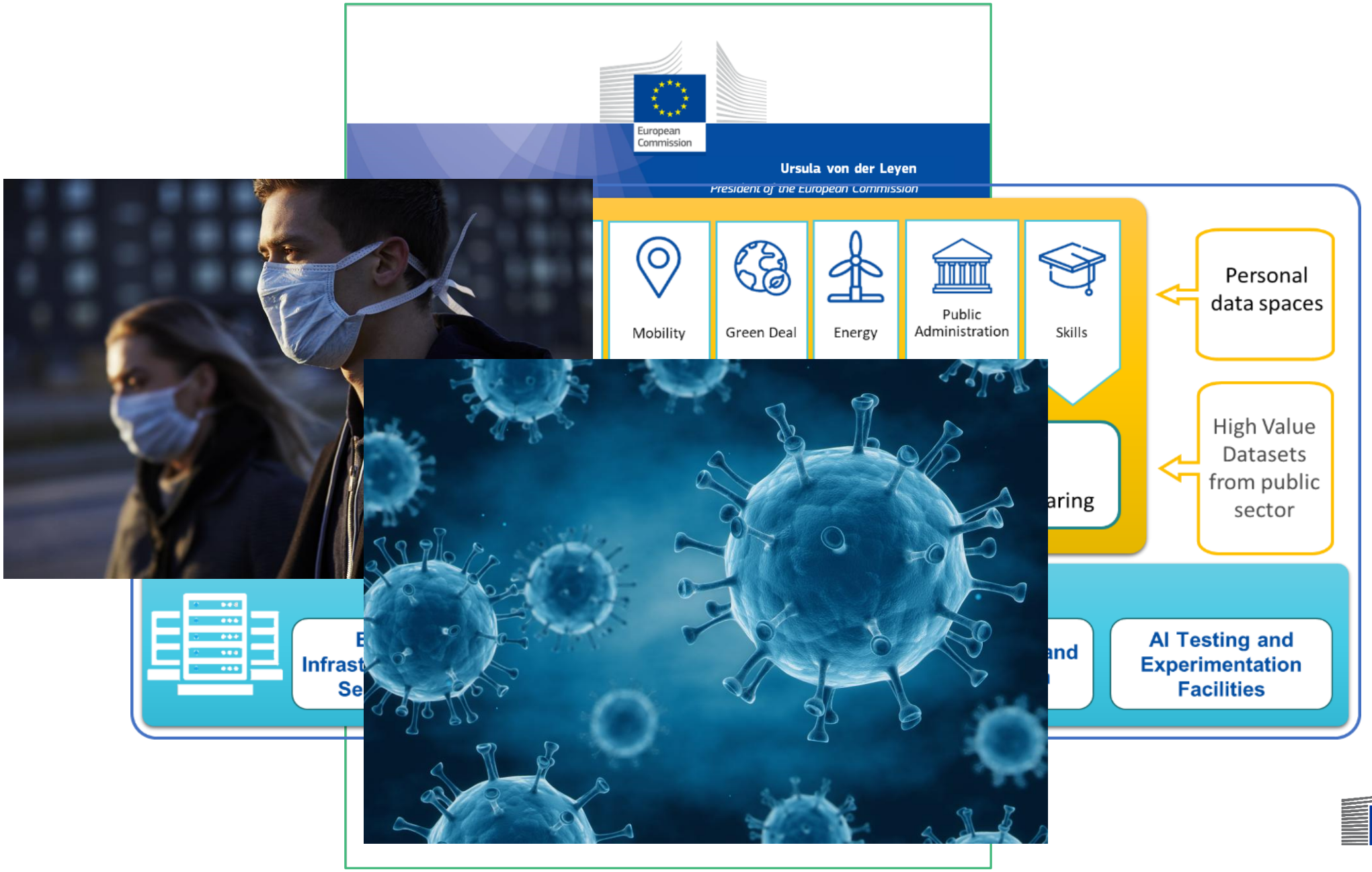
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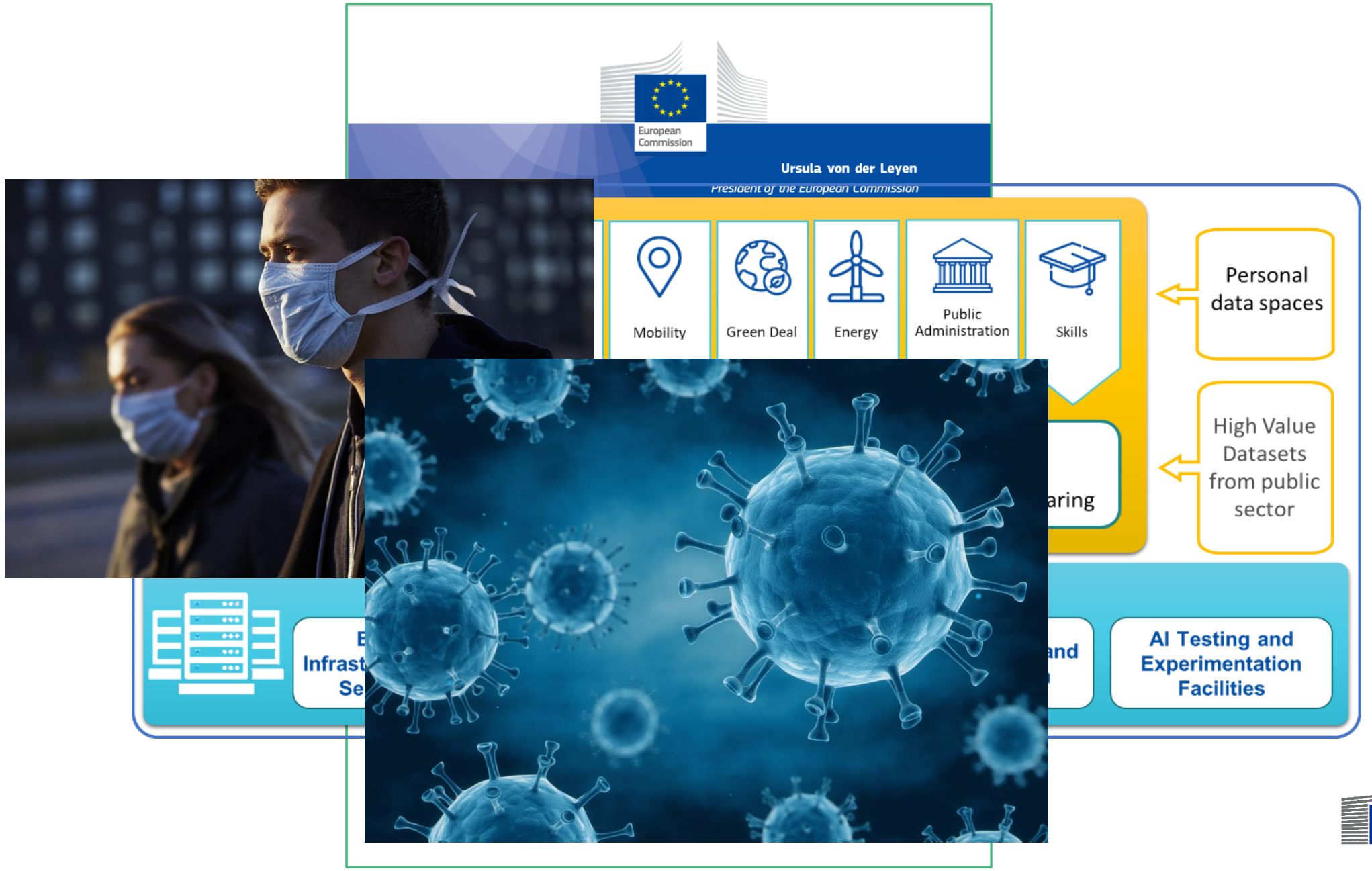
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EUROPEAN
COMMISSION

Strasbourg, 3.5.2022
COM(2022) 197 final

2022/0140 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the European Health Data Space

(Text with EEA relevance)

{SEC(2022) 196 final} - {SWD(2022) 130 final} - {SWD(2022) 131 final} - {SWD(2022) 132 final}

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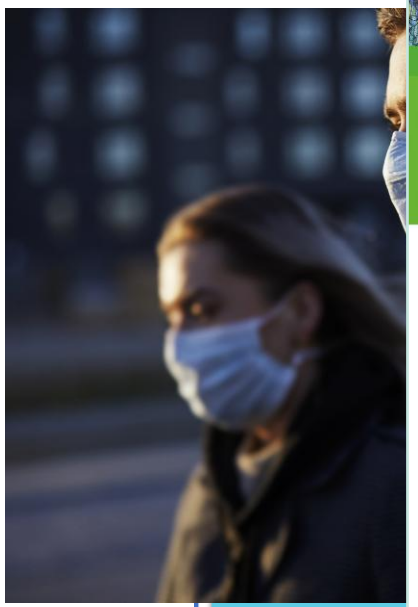

European Commission - Press release

Commission welcomes European Parliament's adoption of the European Health Data Space and regulation on substances of human origin

Brussels, 24 April 2024

The Commission welcomes the adoption by the European Parliament today of the **European Health Data Space (EHDS)** and new rules to **increase the safety and quality of substances of human origin (SoHO)**. These are two cornerstones of a **strong European Health Union** which protects the health of citizens and improves the resilience of healthcare systems.

The European Health Data Space (EHDS)

This groundbreaking initiative, put forward by the Commission in May 2022, has two main aims:

- to place citizens at the centre of their healthcare, granting them full control over their data, with the goal of achieving **better healthcare across the EU**;
- to allow the use of health data for **research and public health** purposes, under strict conditions.

Thanks to the new rules, **citizens will benefit from immediate and simple access to their digital health data when in the EU, regardless of their location.** For instance, when a patient seeks healthcare abroad, healthcare professionals will be able, when necessary, to access key information from the patient's home Member State. This will **improve evidence-based decision making**, **reduce repetition of tests and examinations** and **enhance patient care**.

The EHDS also establishes a **strong legal framework for the re-use of health data** for research, innovation and public health purposes in full compliance with strict EU data security and access criteria, fundamental rights and cybersecurity rules. The data will help **develop life-saving treatments and personalised medicines** and improve European crisis **preparedness.**

Substances of human origin

The new regulation, proposed by the Commission in July 2022, provides a holistic approach for the regulation of substances of human origin. The new rules notably **include better protection of recipients and donors of substances of human origin, as well as children born from medically assisted reproduction.** The new framework foresees:

- Clear rules covering **all substances of human origin** except solid organs, such as faecal microbiota and human breast milk;
- **Registration of all entities** that carry out activities that could affect the safety and quality of SoHO;
- **Reinforced expertise**, building on existing technical bodies, notably the European Centre for Disease Prevention and Control (ECDC) and the European Directorate for the Quality of Medicines & HealthCare (Council of Europe), to keep technical guidelines up to date;
- **More innovation,** with a common procedure to assess and authorise SoHO preparations, proportionate to the risks these bring;
- Strengthened **national oversight**, and EU support for national authorities (such as training and IT);
- New measures supporting **supply continuity** that will help Member States to take action when the supply of critical SoHO is threatened;
- A **SoHO Coordination Board (SCB)** will be established, with and for Member States. It will support the implementation of the new regulation and provide legal clarity;
- Finally, the **digital EU SoHO Platform** will be created, to gather all required information, streamline reporting and increase visibility to citizens.

Next steps

COUNCIL

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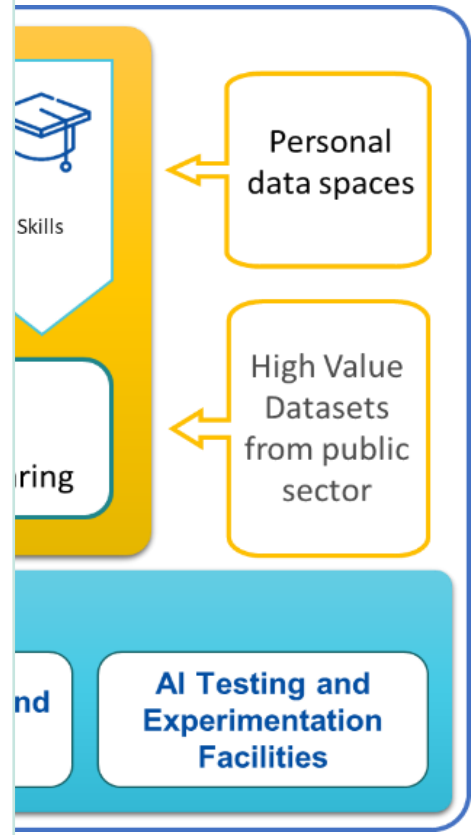


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Document 32025R0327

Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 (Text with EEA relevance)

PE/76/2024/REV/1

OJ L, 2025/327, 5.3.2025, ELI: http://data.europa.eu/eli/reg/2025/327/oj (BG, ES, CS, DA, DE, ET, EL, EN, FR, GA, HR, IT, LV, LT, HU, MT, NL, PL, PT, RO, SK, SL, FI, SV)

In force

ELI: http://data.europa.eu/eli/reg/2025/327/oj

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Official Journal of the European Union

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L series

2025/327

5.3.2025

REGULATION (EU) 2025/327 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 11 February 2025

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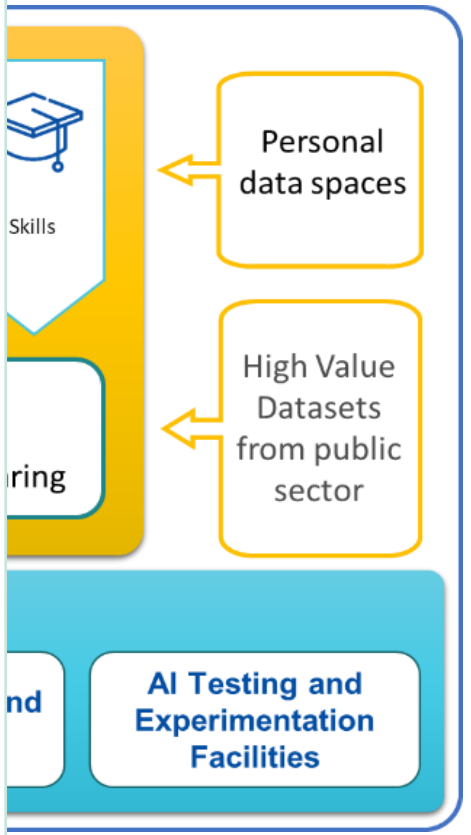

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EHDS in a Nutshell – what is it about?

1. Primary use = use of data for the delivery of healthcare
   - Improving patients' access to their health data;
   - Ensuring seamless exchanges for continuity of healthcare.

2. Secondary use = use of data for research and public interest purposes
   - Making data available for research, policy-making etc. in a safe and secure way.

3. Requirements for electronic health record (EHR) systems
   - Creating a single market for electronic health records systems, supporting both primary and secondary use.

Primary Use

What’s in it for patients and health professionals?

EHDS in a Nutshell – Primary Use

- Strengthening patients' rights on defined categories of their own data;
- Patient- and health professional-facing services to access data;
- Building on existing voluntary MyHealth@EU infrastructure, not touching upon national rules on provision of care / management of healthcare systems.

Benefits for patients and health professionals

For patients

- Immediate and free of charge access to their own electronic health data in the priority categories.
- Easy sharing of data with health professionals, including cross-border.
- Possibility to add data, restrict access, see who accessed data, ask for rectification of errors.
- Have access in the European electronic health record exchange format, improving interoperability.
- Easy to use mechanisms for delegated access and appointing proxies
- (dependent on Member State choice): possibility for a full opt-out from exchanges using EHDS infrastructures for primary use.

For health professionals

- Easier and quicker access to their patients' data, including cross-border.
- European electronic health record exchange format will facilitate data sharing across systems by increasing interoperability.

Priority categories

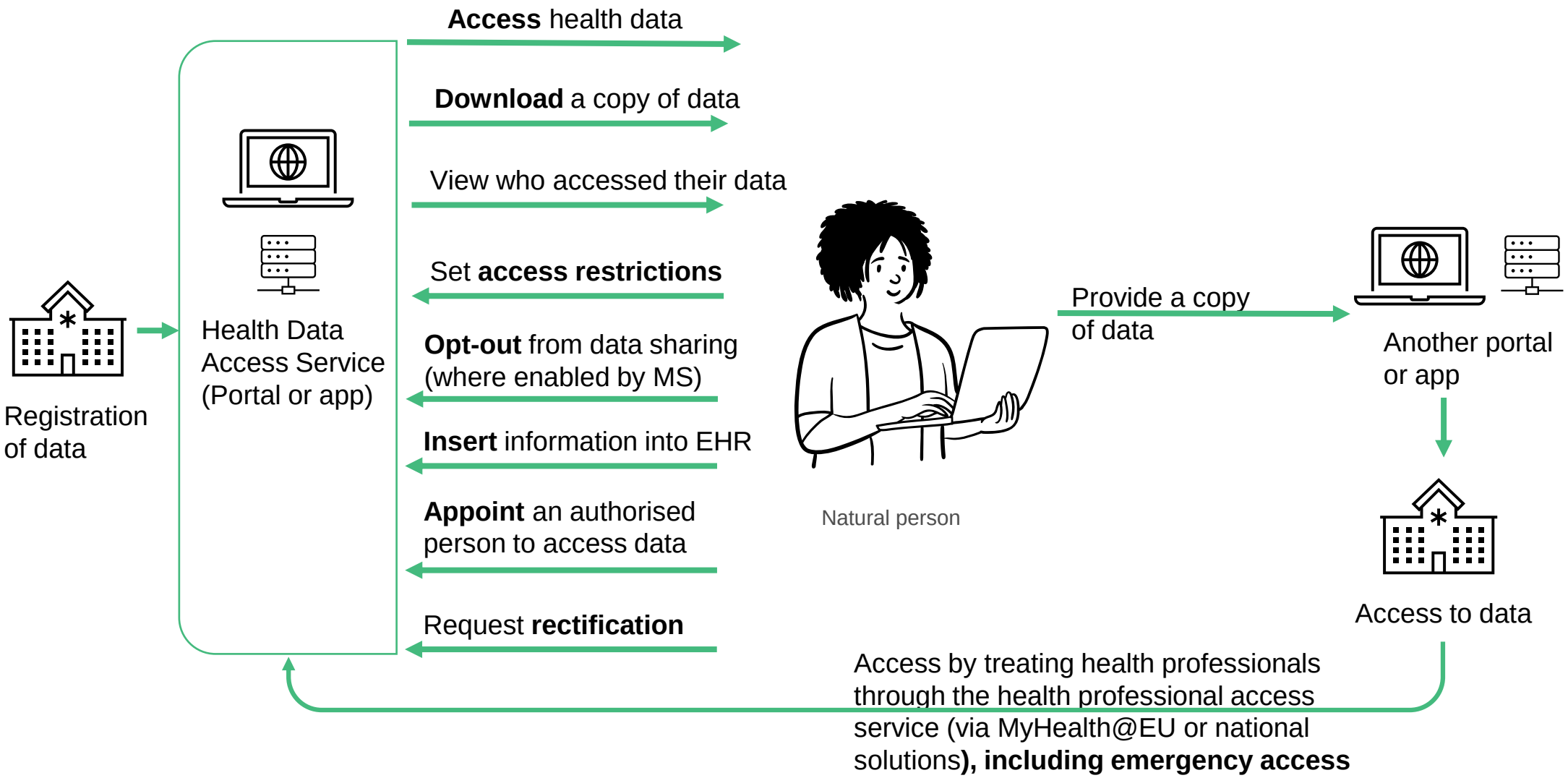
Group 1

- Patient summaries
- Electronic prescriptions
- Electronic dispensations

Group 2

- Medical imaging studies and related imaging reports
- Medical test results, including laboratory test and related reports
- Discharge reports

Rights of natural persons in primary use



Interoperability – how?

European Electronic Health Record exchange Format

European Commission

Defining European Electronic Health Record exchange Format

- **What**: European Commission to lay down specifications for European Electronic Health Record Exchange Format (EEHRxF)
- **When**: Deadline for European Commission 26/03/2027
- **Background**: see Commission Recommendation (EU) 2019/243 of 6 February 2019 on a European Electronic Health Record exchange format
- **Groundwork** by: Xt-EHR Joint Action (https://www.xt-ehr.eu/)

Zooming in: 3 pillars of the Format

Harmonised datasets

- *Containing electronic health data and defining structures, such as data fields and data groups for the representation of clinical content and other parts of the electronic health data*

Coding systems and values

- *To be used in datasets containing electronic health data*

Technical interoperability specifications

- *For the exchange of electronic health data, including its content representation, standards and profiles*

EEHRxF

Shorter version:

The EEHRxF is a set of technical specifications, targeted at ensuring the interoperability of electronic health record systems.

Fundamental principles for the Format

- It is essential that the standards used in the EHDS implementation are **freely accessible**.
- Key implementation resources like validators and guides **must remain open-source** and **accessible to the community to support widespread adoption and compliance** and ensure **transparency and openness**.
- We invite Standard Development Organisations, Member States, and stakeholders to engage with the Commission on ensuring open access to standards and key resources.

Importance of the EEHRxF

art 7
- fulfilling the rights of national persons
- especially in regard to their right to data portability

art 23
- cross-border sharing of health data in priority data categories in the EEHRxF

art 30
- manufacturers shall ensure that the EHRs are in conformity with essential requirements and common specifications
- including the interoperability component (Annex II)

Fill in copyright information.

Thank you