



European Health Data Space

Harnessing the value of health data

27/02/2025

EHDS webinar series

1. Primary Use and Requirements for EHR systems
- 2. Secondary Use**
3. Implementation and Governance – who does what?

Agenda

1. EHDS in a nutshell
2. Secondary use
3. What infrastructures will provide support?
4. Transition and next steps
5. Q&A

Target audience: health data holders, health data users, health data access bodies

1 EHDS in a Nutshell

Why this Regulation (now)?
Three legs of the Regulation



Ursula von der Leyen
President of the European Commission

Mission letter

Brussels, 1 December 2019

Stella Kyriakides

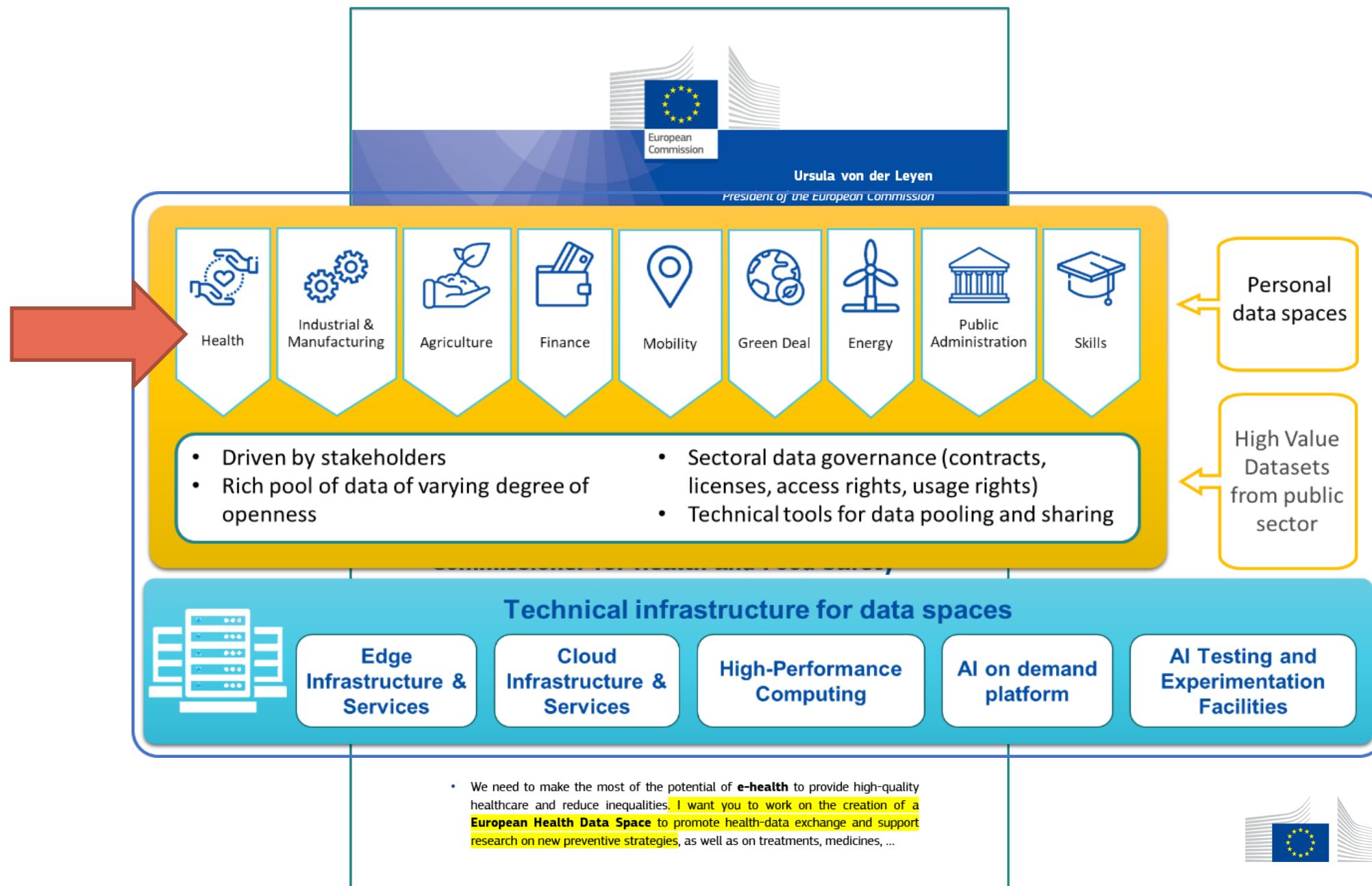
Commissioner for Health and Food Safety

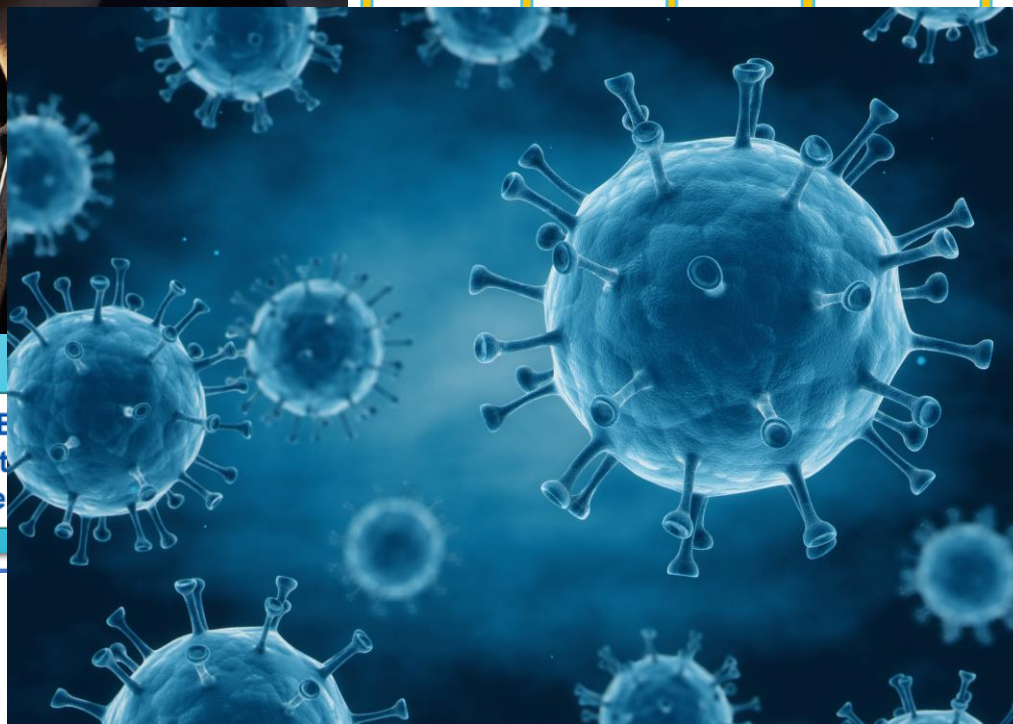
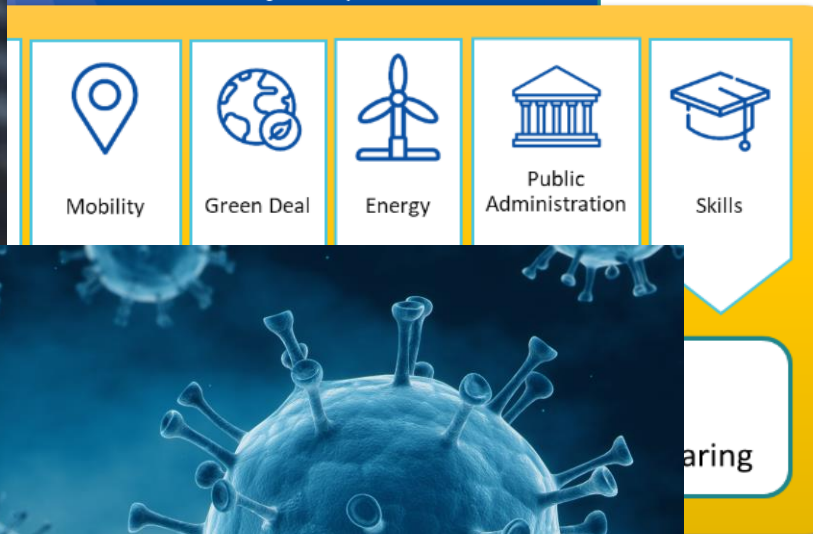
Dear Stella,

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, ...









Heating, ventilation and air-conditioning systems in the context of COVID-19: first update

10 November 2020

Key messages

- It is now well-established that COVID-19 transmission commonly occurs in closed spaces;
- If well-maintained and adapted for use in the COVID-19 pandemic, heating, ventilation and air-conditioning (HVAC) systems may have a complementary role in decreasing potential airborne transmission of SARS-CoV-2;
- Four bundles of non-pharmaceutical interventions (NPIs) should be considered to reduce potential airborne transmission of SARS-CoV-2 in closed spaces: the control of COVID-19 sources in closed spaces; engineering controls in mechanically ventilated (by HVAC systems) and naturally ventilated closed spaces; administrative controls; and personal protective behaviour.

Scope of this document

This document provides guidance on heating, ventilation and air-conditioning (HVAC) systems in closed spaces in the context of the COVID-19 pandemic.

Changes to the current update

The first update of the ECDC ventilation guidance document contains:

- key new findings that emphasise four bundles of NPIs to reduce the risk of SARS-CoV-2 transmission in closed spaces;
- updated references on the evidence of transmission in closed spaces;
- recommendations based on the new evidence and on national and international guidance; and
- an overview of national guidance ventilation documents in the context of COVID-19 based on an inquiry sent to ECDC's National Focal Points (NFPs) for Preparedness and Response and NFPs for Influenza and other respiratory diseases.

Target audience

Public health authorities in the European Union and European Economic Area (EU/EEA) and the United Kingdom (UK).

Suggested citation: European Centre for Disease Prevention and Control. Heating, ventilation and air-conditioning systems in the context of COVID-19. 10 November 2020. Stockholm: ECDC; 2020.
© European Centre for Disease Prevention and Control, Stockholm, 2020.

rsula von der Leyen
e European Commission



Energy



Public
Administration



Skills

Personal
data spaces

High Value
Datasets
from public
sector

aring

and
**AI Testing and
Experimentation
Facilities**



European
Commission



Heating, ventilation and air conditioning systems in the context of COVID-19
update
10 November 2020

Key messages

- It is now well-established that COVID-19 transmission can occur in indoor spaces with mechanical ventilation (HVAC) systems.
- If well-maintained and adapted for use in the context of COVID-19, HVAC systems may have a role in reducing the transmission of SARS-CoV-2.
- Four bundles of non-pharmaceutical interventions to reduce the risk of airborne transmission of SARS-CoV-2 in domestic and public buildings: engineering controls in mechanically ventilated spaces; administrative controls; and personal protective measures.

Scope of this document
This document provides guidance on heating, ventilation and air conditioning systems in the context of the COVID-19 pandemic.

Changes to the current guidance
The first update of the ECDC ventilation guidance includes:
• key new findings that emphasise four bundles of measures to reduce the risk of transmission in closed spaces;
• updated references on the evidence of transmission;
• recommendations based on the new evidence;
• an overview of national guidance ventilation to ECDC's National Focal Points (NFPs) for Priority Respiratory Diseases.

Target audience
Public health authorities in the European Union and other countries.

Suggested citation: European Centre for Disease Prevention and Control. Heating, ventilation and air conditioning systems in the context of COVID-19. 10 November 2020. Stockholm: ECDC; 2020.
© European Centre for Disease Prevention and Control



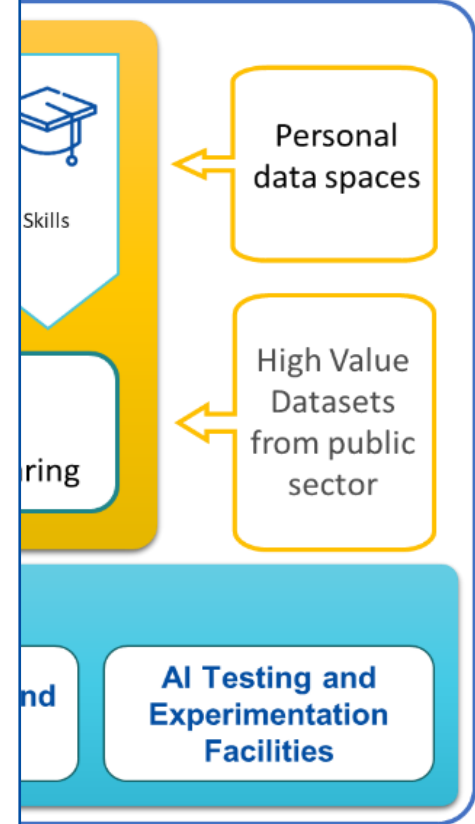
Strasbourg, 3.5.2022
COM(2022) 197 final
2022/0140 (COD)

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}

EN

EN





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

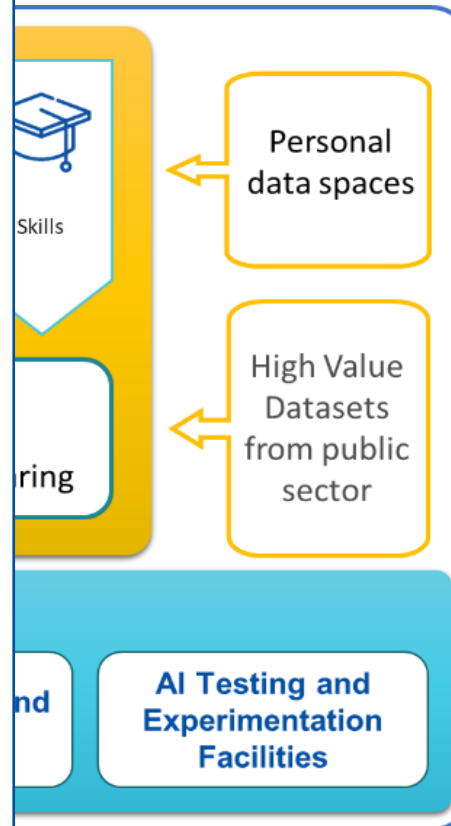
The new regulation, proposed by the Commission in July 2022, provides a holistic approach for the regulation of substances of human origin. The new rules notably **include better protection of recipients and donors of substances of human origin, as well as children born from medically assisted reproduction**.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

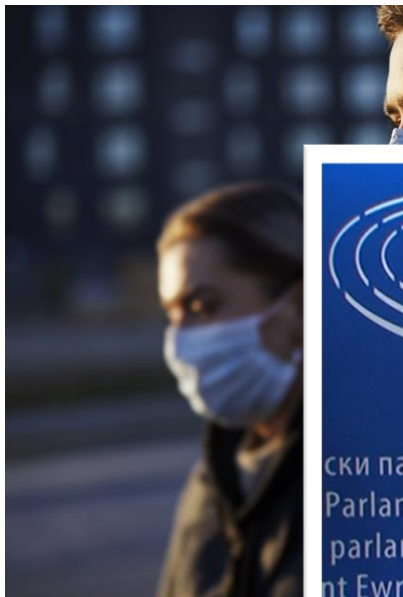
inal) -



EN



European
Commission



European Commission - Press release



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

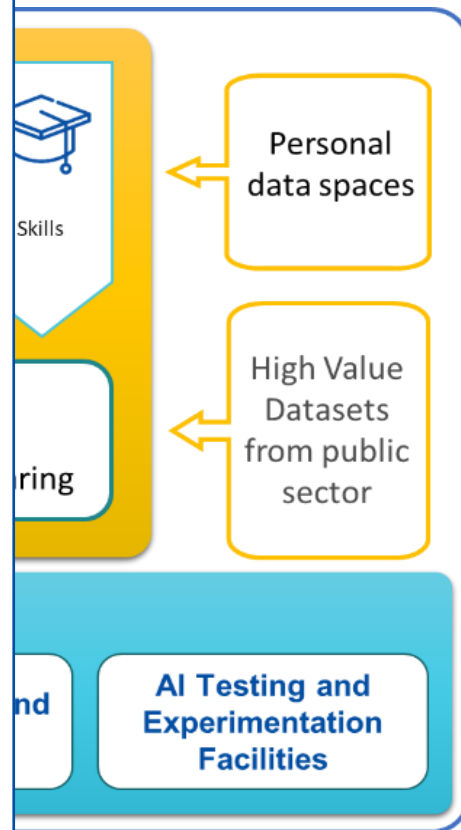
Brussels, 24 April 2024

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.



- 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



European Commission

EN

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

EHDS in a Nutshell – Primary Use

How?

- 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.

EHDS in a Nutshell – EHR systems

How?

- Product legislation for two components of EHR systems: interoperability and logging;
- Full harmonisation for those two components;
- Approach based on new legislative framework for product legislation, incorporating recent developments from other product legislation.

2 Secondary Use

What are the benefits for whom?

Who will have to make which data available?

How can users apply for access to data?

What are the safeguards?

What infrastructures will provide support?

EHDS in a Nutshell – Secondary Use

How?

- Common European rules on who has to make which data available for which purposes and under which conditions
- Health Data Access bodies as orchestrators
- Permits for data use, common safeguards
- Data catalogues of available datasets
- Common infrastructure

Benefits of secondary use

For regulators and policymakers

- Easier access to health data for purposes of public health, patient safety, general functioning of healthcare systems...
- Better evidence basis for regulatory activities and policy-making.

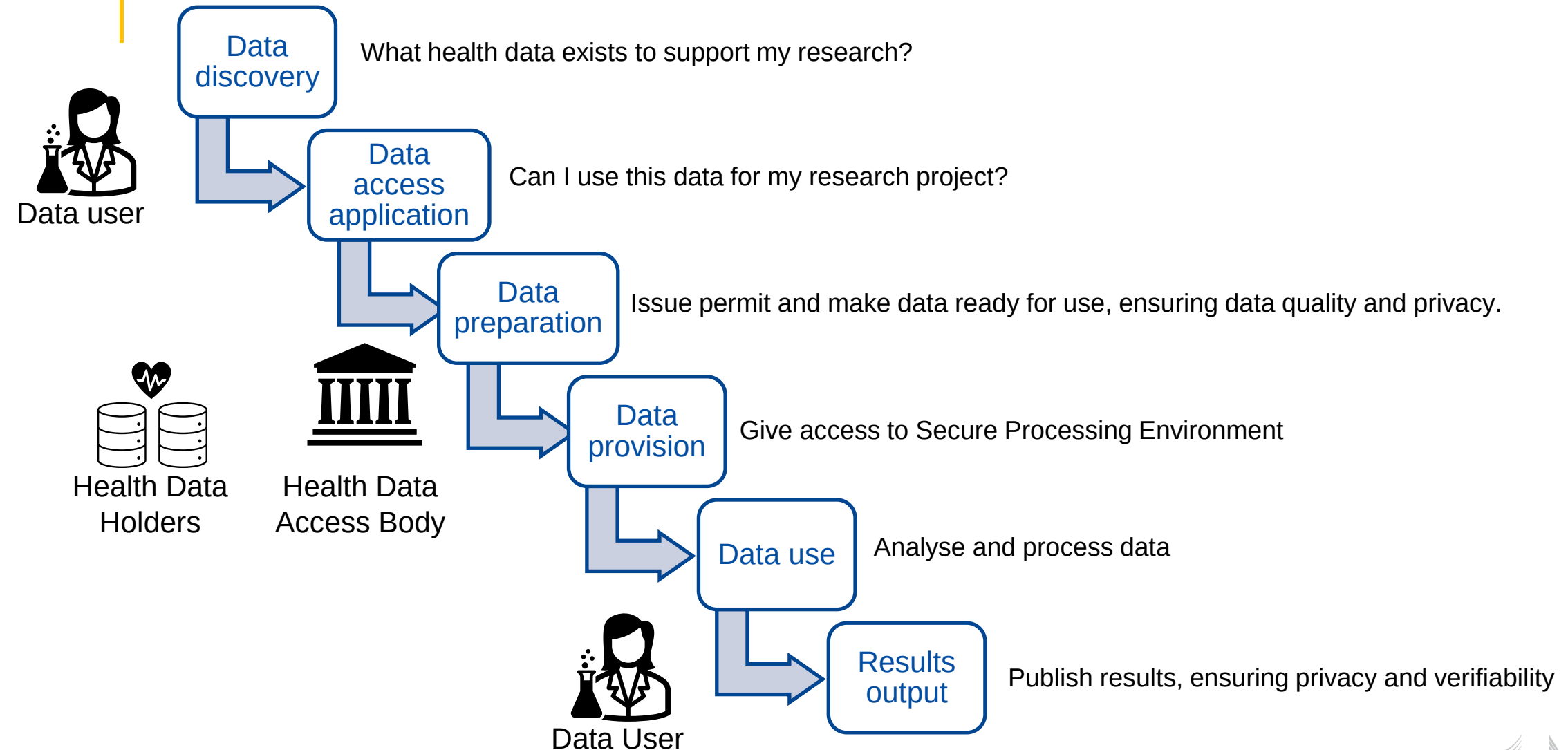
For patients

- In the long run: research leading to new and better treatments
- Transparency of data use

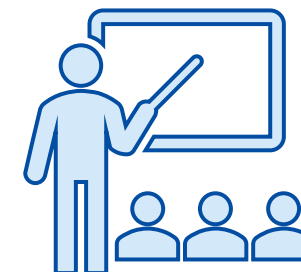
For researchers, including in industry

- Easier access to data for research and development;
- Knowing which health data of which quality are available where;
- Easier and more cost-efficient access to data;
- Easier merging of data, including cross-border .

User journey



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**.



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.

Scope exclusions and non-exclusivity

- Does not affect reporting obligations => e.g. pharmacovigilance and notifiable disease reporting stay the same;
- Does not affect other further processing laid down by Union or MS law;
- Does not affect other frameworks for secondary use => they can continue to exist;
- Cannot be used for law-enforcement purposes.

Data categories



electronic health data from **EHRs**;
healthcare-related **administrative data**, including
dispensation, claims and **reimbursement** data

automatically generated personal electronic health
data, through **medical devices**;
data from **wellness applications**;
other health data from medical devices.



population-based health data **registries** (public health
registries);
data from medical registries and **mortality registries**;
data from registries for medicinal products and medical
devices;
health data from **biobanks** and associated databases.



human **genetic, epigenomic and genomic** data;
other **human molecular** data such as proteomic
transcriptomic, metabolomic, lipidomic and other
-omic data;

Data on factors impacting health, including **socio-economic, environmental
and behavioural determinants** of health;

Aggregated data on **healthcare needs, resources** allocated to healthcare,
the provision of and access to healthcare, healthcare expenditure and
financing;

Pathogen data, impacting on human health

data from **clinical trials, clinical studies** and **clinical
investigations** subject to Regulation (EU) 536/2014, Regulation
[SOHO], Regulation (EU) 2017/745 and Regulation (EU)
2017/746, respectively;

data from **research cohorts, questionnaires** and surveys
related to health, after the first publication of results



Health Data Access Bodies (HDABs) and Union Health Data Access Service

Articles 55 to 59

- HDABs as orchestrators with public interest tasks:
 - Publish dataset catalogues
 - Assess and decide on applications;
 - Liaise with health data holders;
 - Ensure data gets made available;
 - Provide public transparency.
- Member States can designate one or more HDABs.
- Union Health Data Access Service to be set up as functional equivalent to HDABs for data held by EUIBs.

Dataset catalogues and quality labels

Dataset descriptions and dataset catalogues

- Data holders will have to provide basic descriptions of their datasets to HDABs => detailed elements to be set out in implementing act;
- HDABs publish catalogues;
- HealthData@EU federates national catalogues.

Data quality and utility label

- More detailed description of datasets, including 'levels' of label => detailed elements to be set out in implementing act;
- Mandatory if data collection received public funding => NB: funding *for collection* specifically, not for activities that result in incidental collection.
- Otherwise voluntary

Application procedures

Data Access Application

For processing personal electronic health data.

Includes **detailed application requirements** such as applicant details, data description, intended use, ethical assessments (where required by MS law), and security measures.

Data can be accessed in **pseudonymised format** unless **anonymised data** suffice for the purpose.

If accepted, the applicant receives a **data permit**.

= direct access to data under stricter conditions.

Data permits are generally granted for up to 10 years with possible extensions.

A streamlined procedure across EU

Single application form

Single permit template

Fees based on the complexity and duration of data access.

Data Request

For obtaining answers in **anonymised statistical format** only.

Less stringent application focused on identity, intended use, and safeguards without direct access to personal data.

= only statistical outputs from anonymised data, suitable for broader or public interest inquiries without personal data access.

Allowed and prohibited purposes



- **Public interest in the area of public and occupational health**, such as activities for protection against serious cross-border threats to health and public health surveillance or activities ensuring high levels of quality and safety of healthcare, including patient safety, and of medicinal products or medical devices;
- **Policy making and regulatory activities** to support public sector bodies or Union institutions, agencies and bodies, including regulatory authorities, in the health or care sector to carry out their tasks defined in their mandates;
- **Statistics**, such as national, multi-national and Union level official statistics defined in Regulation (EU) No 223/2009 related to health or care sectors;

Reserved for public sector bodies and Union institutions, offices, and agencies carrying out tasks under Union or national law, including third-party data processing on their behalf.

- vocational or higher **education or teaching activities** in health or care sectors;
- **scientific research** related to health or care sectors, **contributing to public health** or health technology assessment, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices, **with the aim of benefitting the end-users** including : development and innovation activities for products or services; training, testing and evaluating of algorithms, including in medical devices, in-vitro diagnostic medical devices, AI systems and digital health applications ;
- **improving delivery of care, treatment optimization and providing healthcare**, based on the electronic health data of other natural persons.



- Taking decisions **detrimental to individuals or groups** based on electronic health data, qualifying as decisions if they have legal, social, or economic impacts.
- Making **employment-related decisions** or offering less favorable terms in goods or services based on health data, including discriminatory decisions affecting insurance, credit, or loans.
- Conducting **advertising or marketing** activities.
- Developing products or services that could **harm individuals**, public health, or society, including illegal drugs, alcohol, tobacco, weaponry, or addictive products.
- Engaging in activities that **conflict with ethical** standards set by national law.

Safeguards

Secure Processing Environment (SPE)



SPE setup to restrict data access to **authorised users**.

State-of-the-art measures to prevent unauthorised data modification, access, or removal.

Logging and monitoring of activities within the SPE for compliance and audit purposes.

Download of personal data strictly prohibited.

Additional Safeguards



Legal and organisational measures to **protect intellectual property and trade secrets**.

Public transparency on data processing activities and outcomes.

Natural persons shall have the right to opt-out from the secondary use of their health data

at **any time** + **without stating reasons**

this right is reversible

through an easily accessible and understandable mechanism

*with the possibility for MS to have rules to ensure that for **selected purposes of public interest**, on **a case-by-case basis** and under **strict conditions**, also data of opted-out people may be made available*

Data Minimisation and Purpose Limitation

Access limited to data adequate, relevant, and necessary for specific, approved purposes.

Pseudonymised data provided unless anonymised data suffices, with strict controls on de-identification.

Opt-out

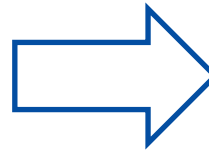
Natural persons have the right to opt-out from the secondary use of their health data through EHDS

at **any time** + **without stating reasons**

this right is reversible

through an easily accessible and understandable mechanism

*with the possibility for MS to have rules to ensure that for **selected purposes of public interest**, on a **case-by-case basis** and under **strict conditions**, also data of opted-out people may be made available*



What did the legislator leave open?

Where and **how** to exercise it not defined in detail => flexibility for MS

Basic requirement is “**on/off switch**”

Mechanism to make data available

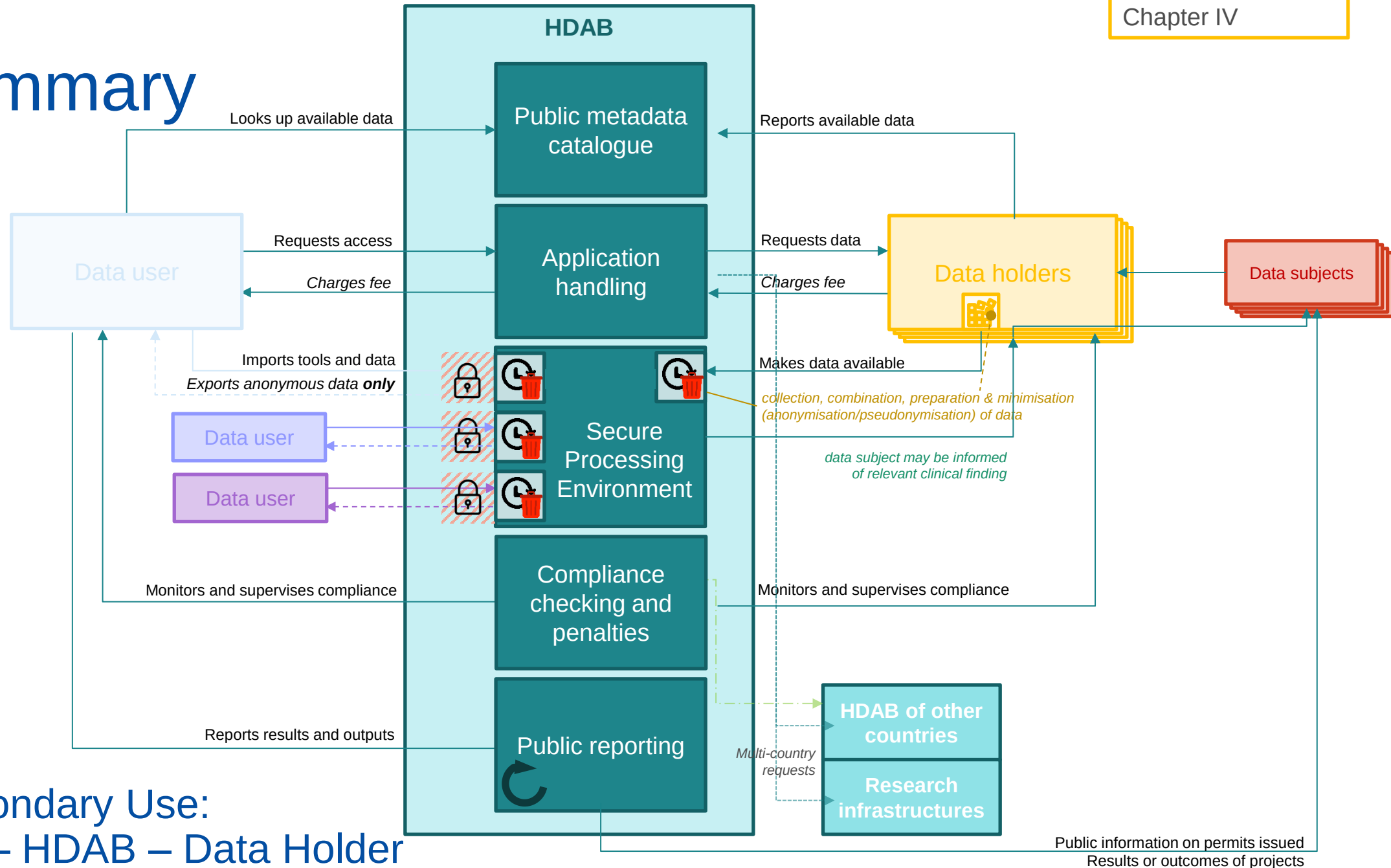
In practice only available for **public sector data users**

Temporal effect is only going forward, existing permits, extractions for SPEs etc. unaffected

Fees: who pays for what and when?

- General principles
 - Up to cost recovery : fee structure to be spelled out in IAs;
 - Discounts for certain health data user categories;
 - Non-discriminatory .
- Part for HDABs, part for health data holders
 - Entire amount paid to HDAB;
 - Part for holders or SPE providers passed through.
- When: not explicitly defined, however possibility for user to drop out after estimate of holder part implies two steps:
 - **Payment upon application**: costs for HDAB assessment
 - Upon estimate: part for holder + further costs for HDAB : **payment with permit**

Summary



EHDS Secondary Use:
Data User – HDAB – Data Holder

3 What infrastructures will provide support?

HealthData@EU

Infrastructures – HealthData@EU

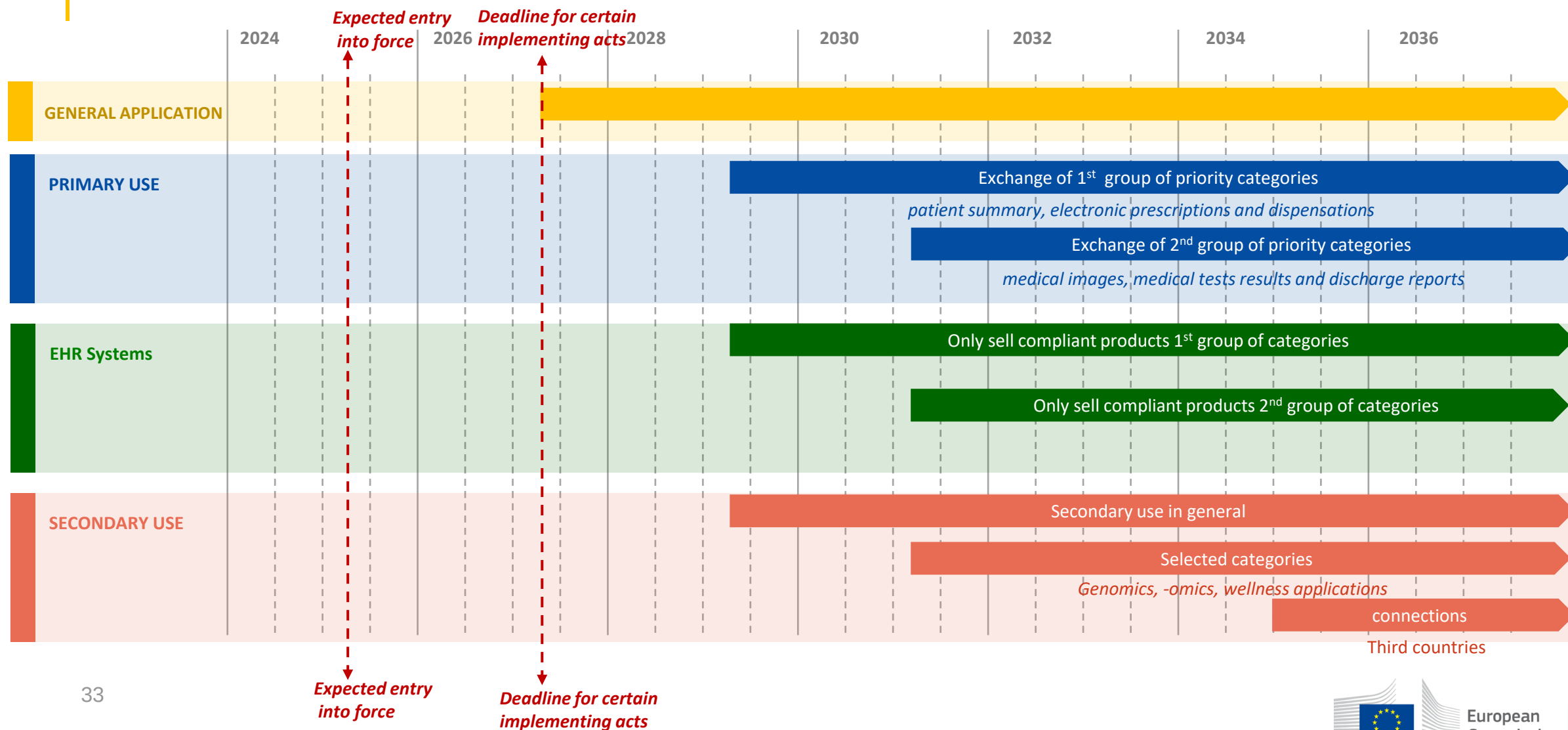
What does HD@EU actually do?

- Connecting **contact points** to the **central platform**
 - Federating data catalogues
 - Receiving and dispatching applications
 - (COM can provide SPE in certain conditions)
- *Quite different data handling from MyHealth@EU*

4 Transition & next steps

By when will all of this happen?
How do we get there?

EHDS – Overall timeline for application



What will happen when?

- For health data holders:
 - Early 2029: provide dataset descriptions for most categories and be ready to make those data available;
 - Early 2031: provide dataset descriptions for remaining categories and be ready to make those data available
- For health data users:
 - Early 2029: can submit applications for most data categories
 - Early 2031: can submit applications for remaining data categories

What will happen when?

- For Member States:
 - Early 2029: have HDABs set up and ready to receive applications for most of Art. 51 data categories;
 - Early 2031: extension to remaining categories.
- For Commission/EU institutions:
 - Same timeline as for the other actors.

Preparatory work and next steps

Joint actions, projects etc. to generate input for technical specifications, sharing best practices, etc.:

- [Xt-EHR](#) (primary use)
- [TEHDAS2](#) (secondary use)
- [HealthData@EU Pilot](#) (secondary use)
- [QUANTUM](#) (data quality labelling)
- Direct grants for MS and capacity building support
- eHealth Network, Community of practice...

Thank you!

Questions? Answers!



© European Union 2024

Unless otherwise noted the reuse of this presentation is authorised under the [CC BY 4.0](#) license. For any use or reproduction of elements that are not owned by the EU, permission may need to be sought directly from the respective right holders.