



# 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, ...



European Commission

Ursula von der Leyen

President of the European Commission



- 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

### 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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European Commission



European Commission

Ursula von der Leyen

President of the European Commission



Mobility



Green Deal



Energy



Public Administration



Skills

Personal data spaces

High Value Datasets from public sector

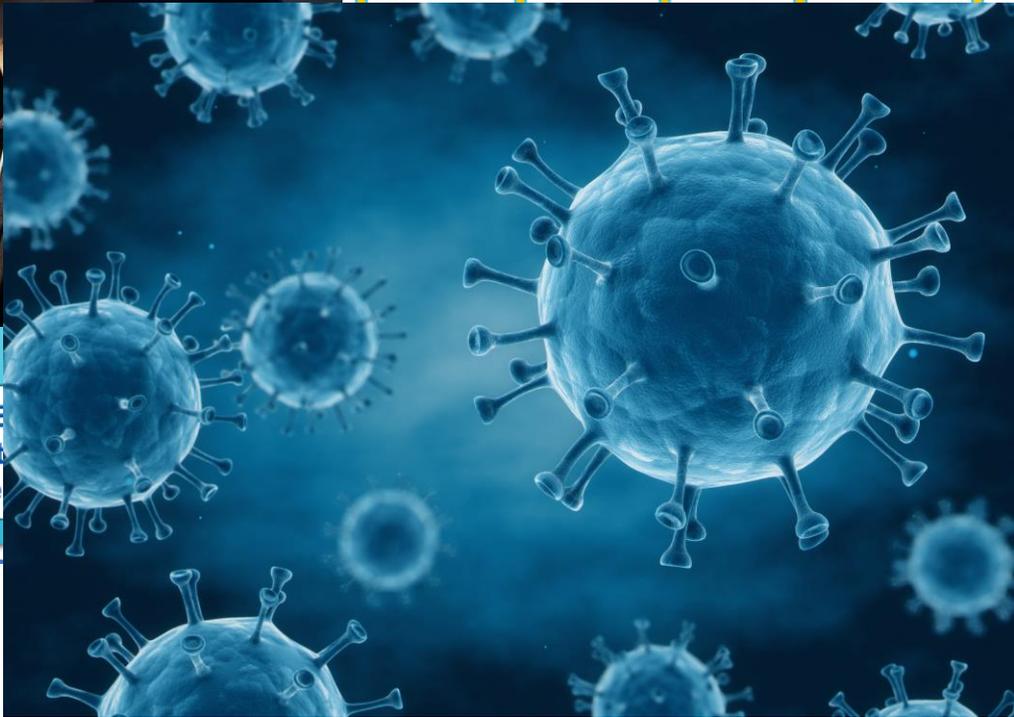
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AI Testing and Experimentation Facilities



European Commission



  
EUROPEAN CENTRE FOR  
DISEASE PREVENTION  
AND CONTROL

## 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:

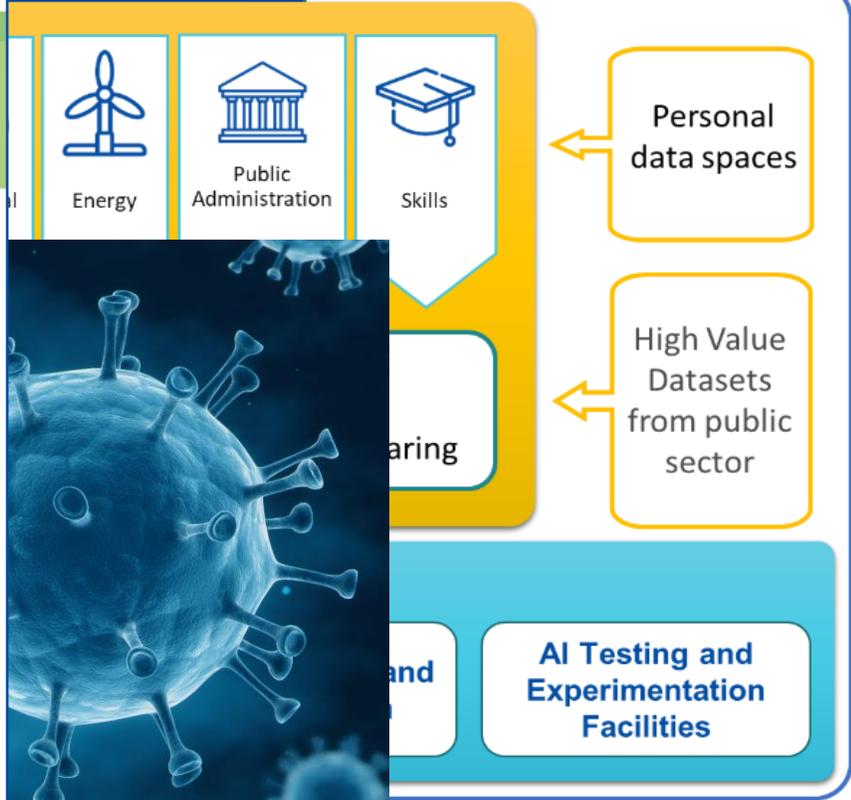
- key new findings that emphasise four bundles of NPIs to reduce the risk of SARS-CoV-2 transmission in closed spaces;
- updated references on the evidence of transmission in closed spaces;
- recommendations based on the new evidence and on national and international guidance; and
- an overview of national 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.

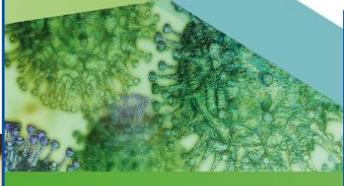
### Target audience

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.  
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rsula von der Leyen  
European Commission



## Heating, ventilation 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 (MV) systems.
- If well-maintained and adapted for use in the context of COVID-19, MV systems may have a role in reducing the transmission of SARS-CoV-2.
- Four bundles of non-pharmaceutical interventions (NPIs) to reduce the risk of airborne transmission of SARS-CoV-2 in mechanically ventilated spaces: engineering controls in mechanically ventilated spaces; administrative controls; and personal protective equipment (PPE).

### Scope of this document

This document provides guidance on heating, ventilation and air conditioning (HVAC) 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 NPIs in closed spaces;
- updated references on the evidence of transmission in indoor spaces;
- recommendations based on the new evidence on the role of MV systems;
- an overview of national guidance ventilation to ECDC's National Focal Points (NFPs) for PPE in 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 systems in the context of COVID-19. 10 November 2020. Stockholm: ECDC; 2020.

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

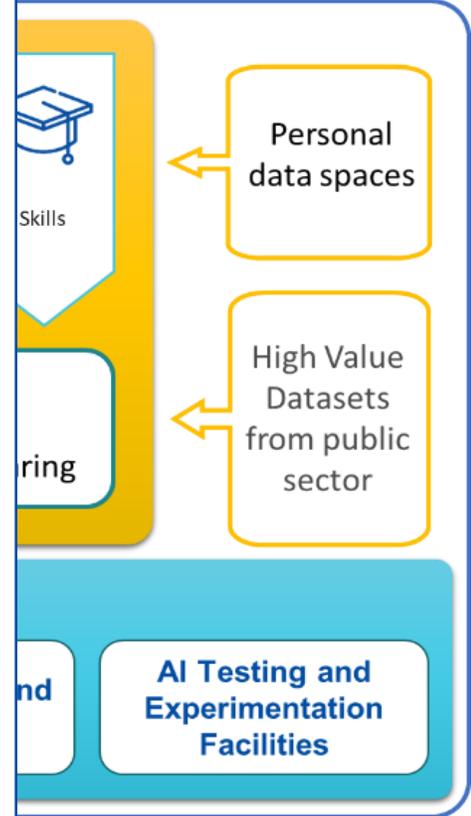
Proposal for a  
**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**  
on the European Health Data Space

(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**

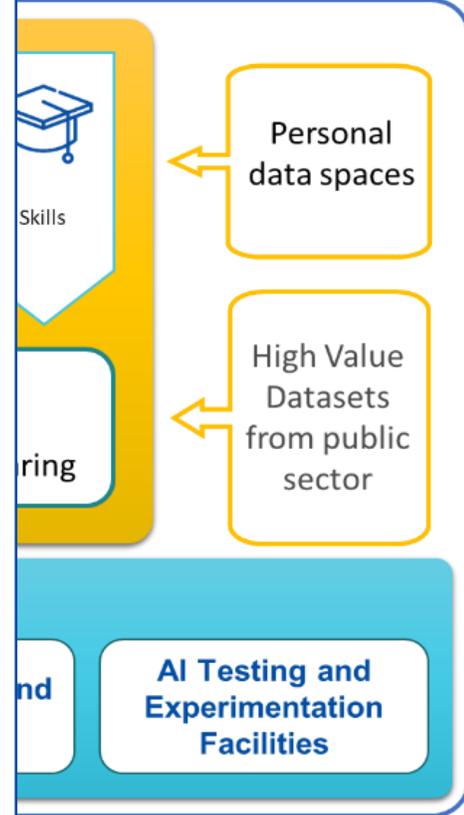
The new regulation, proposed by the Commission in July 2022, provides a holistic approach for the regulation of substances of human origin. The new rules notably **include better protection of recipients and donors of substances of human origin, as well as children born from medically assisted reproduction**.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

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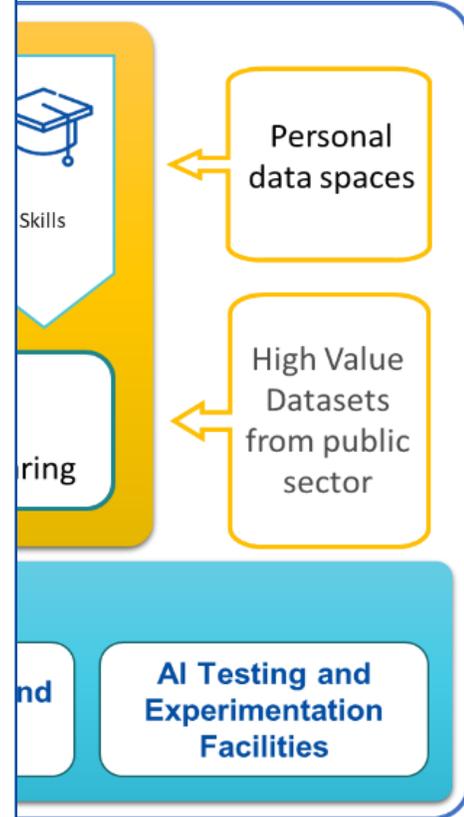
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#### Next steps



# 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.

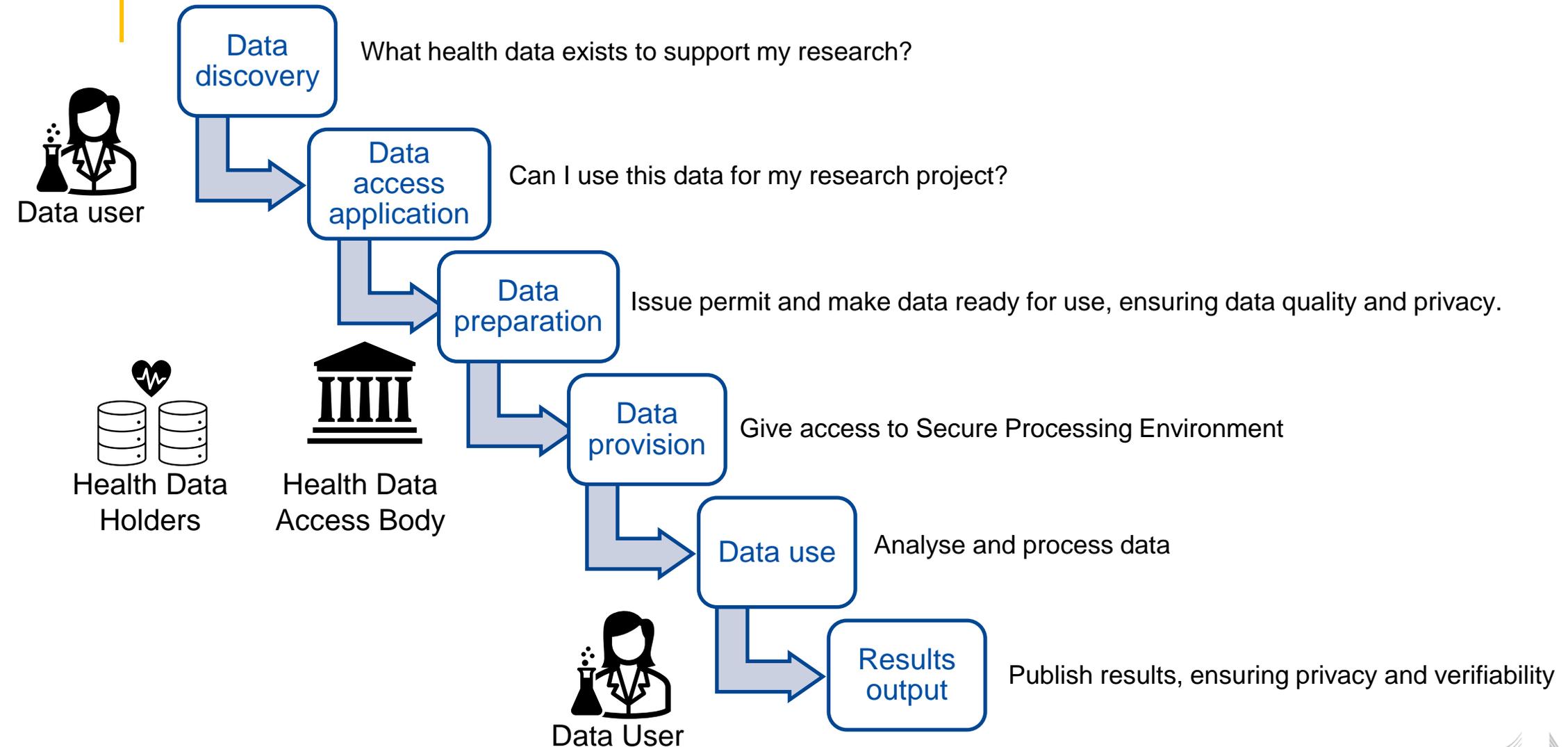
## For patients

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

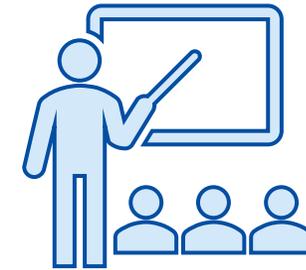
## For researchers, including in industry

- 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**.

*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.*

# 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:
  - 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

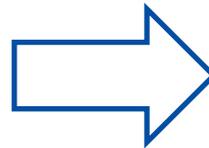
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### What did the legislators leave open?

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

Basic requirement is “*on/off switch*”

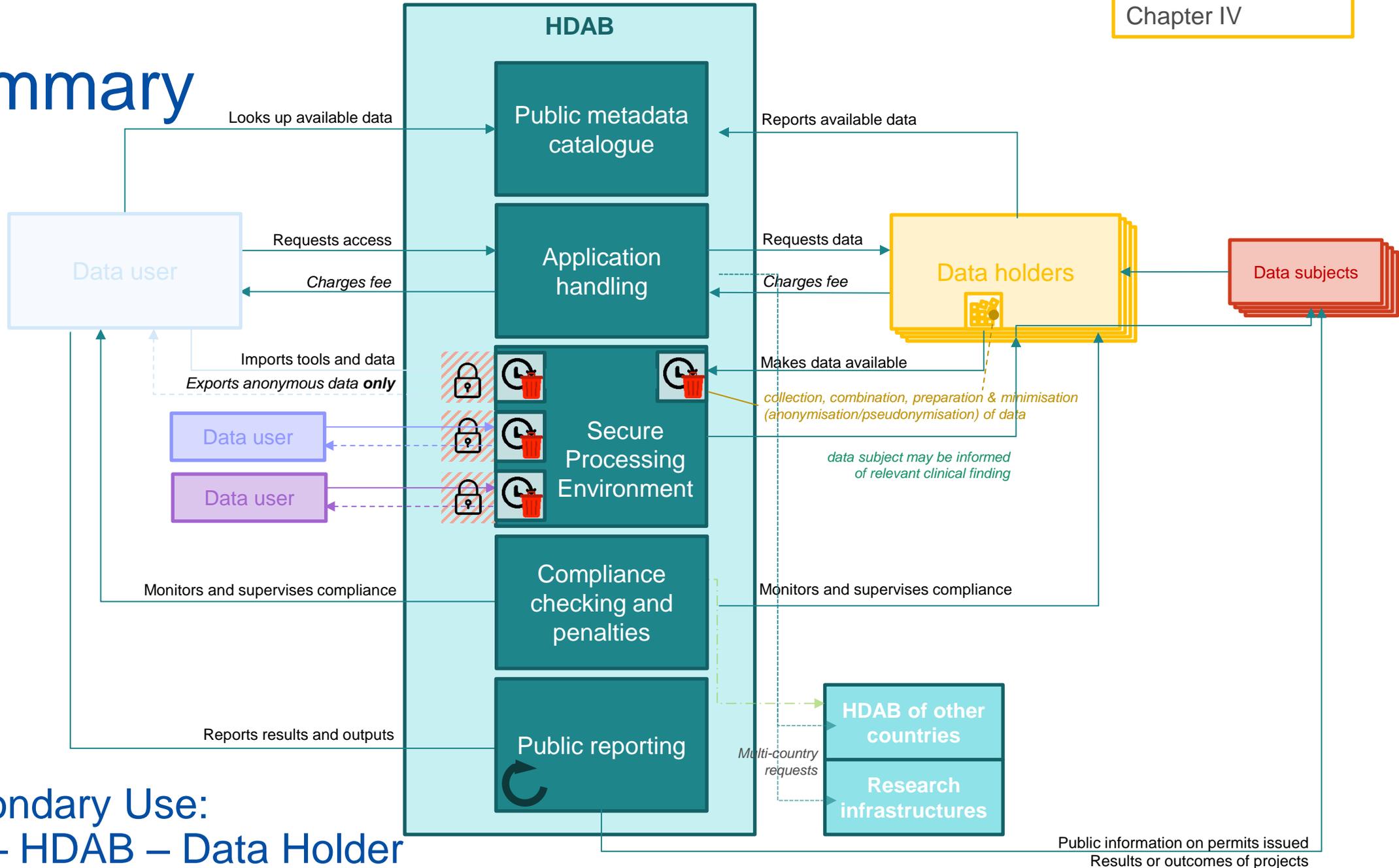
### Mechanism to make data available

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

# 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

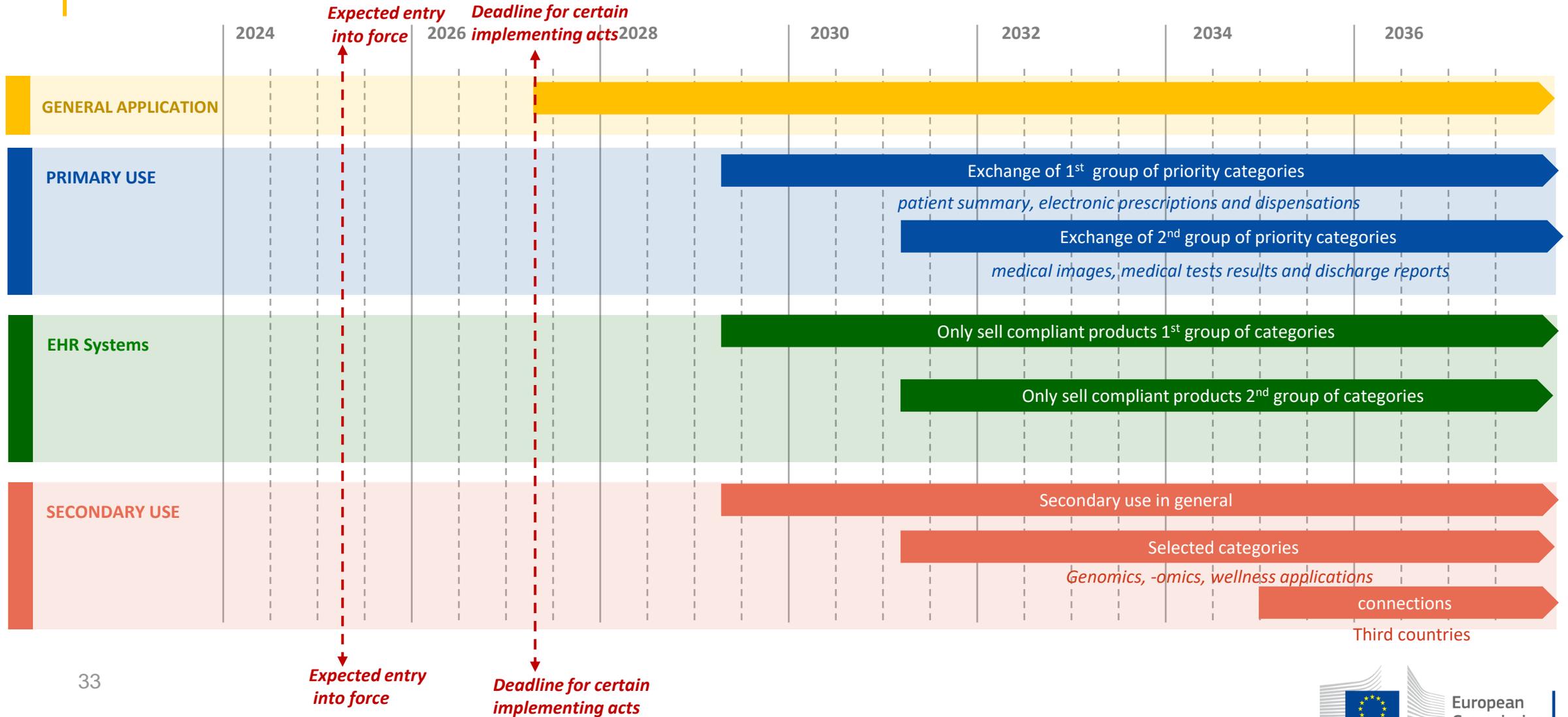
## What does HD@EU actually do?

- 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, EHMSEG, Community of practice...

# Thank you!

# Questions? Answers!



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