



# European Health Data Space

*Harnessing the power of health data for people and innovation*

MII Symposium  
*10/12/2024*

*EC – SANTE C1*



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**



**air-conditioning COVID-19: first**

... in closed spaces; ... ating, ventilation and air- ... asing potential airborne

... nsidered to reduce potential COVID-19 sources in closed spaces; ... naturally ventilated closed spaces;

... g (HVAC) systems in closed spaces in

... c of SARS-CoV-2 transmission in

... national guidance; and ... f COVID-19 based on an inquiry sent ... and NFPs for Influenza and other

... U/EEA) and the United Kingdom (UK).

... tilation and air-conditioning systems in

Personal data spaces

High Value Datasets from public sector

Testing and experimentation facilities

# Context and content

*What is it about ?*

# EHDS – what is it about?

## Primary use of electronic health data

= use of data for the delivery of healthcare

*Improving patients' rights regarding their health data;*

*Ensuring seamless exchanges for the continuity of healthcare.*

## Secondary use of electronic health data

= re-use of data for research and public interest purposes

*Making data available for research, policy-making etc. in a safe and secure way.*

## Requirements for electronic health record (EHR) systems

*Creating a single market for electronic health records systems, supporting both primary and secondary use.*



# Secondary use in a nutshell

Common European rules on who has to make which data available for which purposes and under which conditions

## How ?

A mandatory connexion of all MS to a common infrastructure

Data catalogues of available datasets

Permits for data use, common safeguards

# 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.



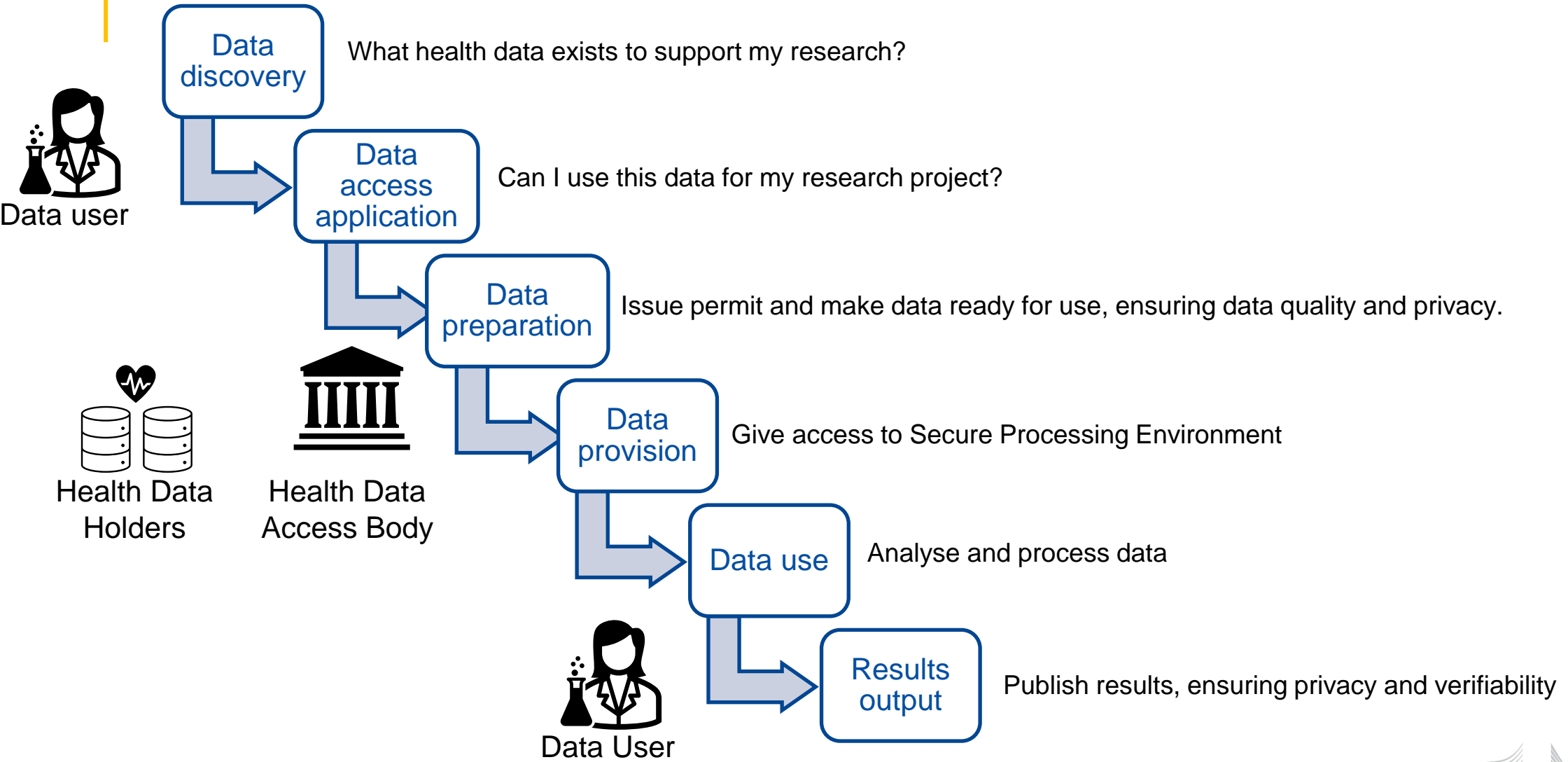
human **genetic, epigenomic and genomic** data;  
other **human molecular** data such as proteomic  
transcriptomic, metabolomic, lipidomic and other  
omic data;

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



# User journey



# Safeguards

## Secure Processing Environment (SPE)



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

State-of-the-art measures to prevent unauthorized 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 organizational measures to protect intellectual property and personal data.

Obligations to **inform individuals about data use** and their rights under data protection laws.

**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*

## Allowed and prohibited purposes

Data can be used for public health, scientific research, healthcare delivery improvement, etc.

**Prohibited uses** include decisions detrimental to individuals, marketing, and creating addictive or harmful products/services.

## Data Minimization and Purpose Limitation

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

Pseudonymized data provided unless anonymized data suffices, with strict controls on de-identification.



# What's in it for *data users* ?

## Increased data discoverability

- Access to a rich, diverse, and high-quality dataset that supports research and public health actions.
- A single platform / EU catalogue

## A streamlined procedure to access data across EU

- Single application form
- Single permit template
- Fees determination based on the complexity and duration of data access.
- Timely access



## European data

data.europa.eu The official portal for European data

Home Data Academy Community Publications Documentation

Home > Datasets

### Datasets

Data scope <sup>Ⓢ</sup>  
- Any -

Provenance <sup>Ⓢ</sup>  
- Any -

Publisher <sup>Ⓢ</sup>

Search

Datasets found (1 729 857)

**Bornes de Recharge pour Véhicules Électriq**  
Data Bornes de Recharge pour Véhicules Électriques Wattzhub

## Obligations

- **Approved Purposes:** Use data only for the purposes defined in the data permit
- **Data Protection:** Process data in secure environments, ensuring privacy and protection (anonymization/pseudonymization)
- Strictly adhere to **security and ethical standards**, and avoid any re-identification attempts.
- **Transparency:** Publish results in a way that contributes to public knowledge while respecting privacy rules.

# What's in it for *data holders* ?

## OBLIGATIONS

### Dataset description

- communicate to the HDAB a description of their datasets
- accurate and kept up to date
- Compliant with **EHDS metadata standards**
- + **data quality and utility label**

### Make data available

- upon request of the HDAB - according to a data access
- Timely provision : within a reasonable time frame (3 months )

### Respect obligations towards natural persons



## Benefits

- Contribution to advancing public health and research
- **Recognition** and potential collaborations within the EHDS network.
- Participation in building a resilient European health system.

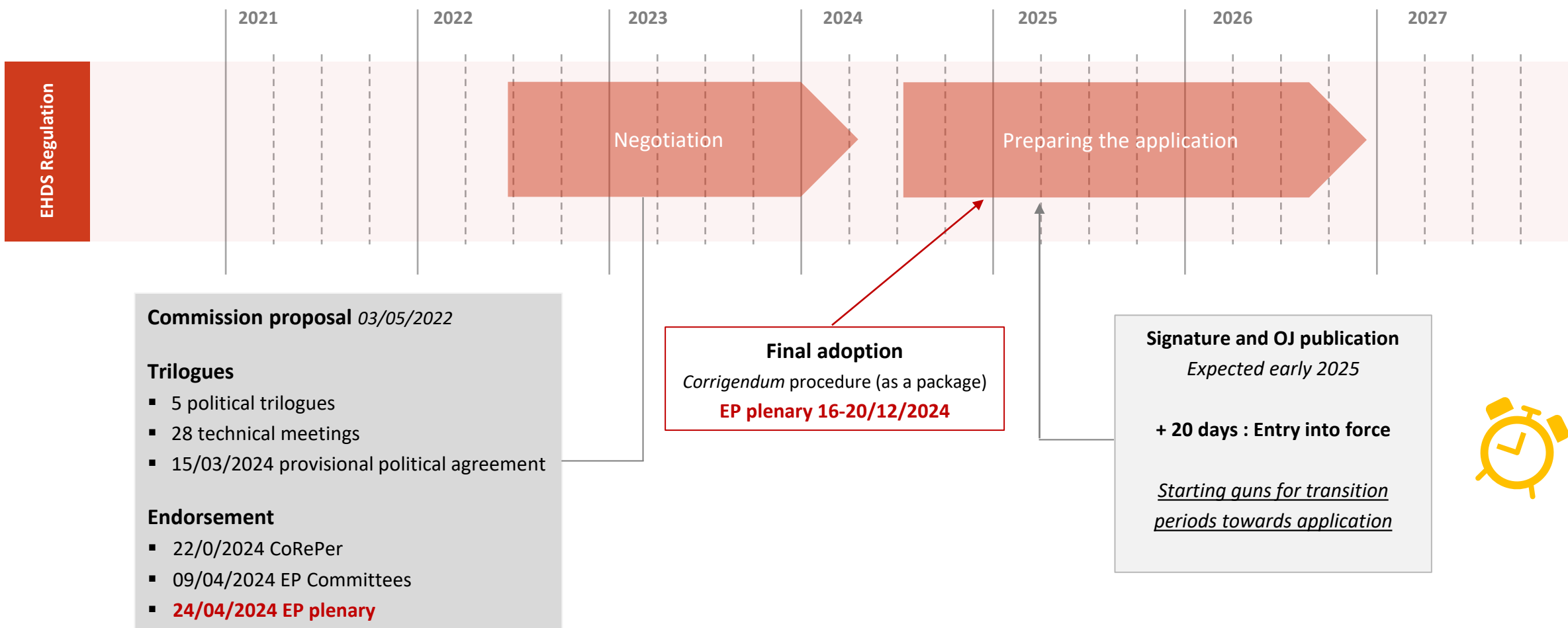
## Protection

- **Charge fees**
- Protection of **trade secrets and IP rights**

Next steps..

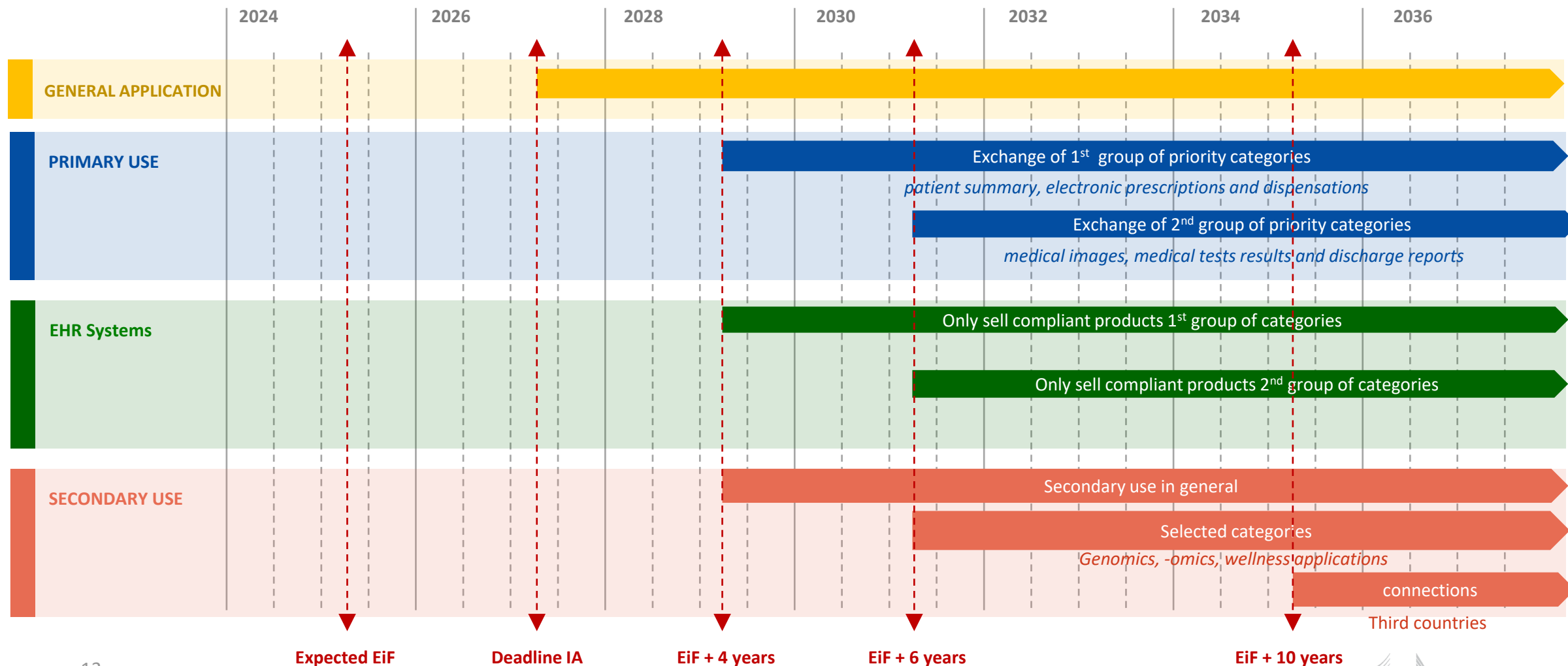
# EHDS2 – Legislative process

Timelines are indicative.



# EHDS – Overall timeline for application

Timelines are indicative.



# Implementing and Delegated Acts

- Many details to be spelled out in implementing or delegated acts, informed by supporting actions
- Numerous empowerments for COM:
  - Primary use: 13 implementing acts (of which 3 with deadline), 1 delegated act
  - EHR systems: 4 implementing acts (of which 1 with deadline) , 1 delegated act
  - **Secondary use: 13 implementing acts (of which 5 with deadline), 2 delegated acts**
  - Others/Governance: 1 implementing acts

# Implementing and Delegated Acts

## Implementing acts

1. Principles for fees policies
2. Architecture of IT tool for transparency on enforcement measures
3. **Templates for applications, requests, decisions**
4. EHDS logo
5. **Requirements for SPEs**
6. Template controller-processor agreements
7. Connecting third countries
8. **Requirements and specs for HealthData@EU**

9. Decisions to let authorised participants join
10. **Elements to be provided for data catalogue**
11. **Details for data quality and utility label**
12. High impact datasets
13. Reciprocity decisions

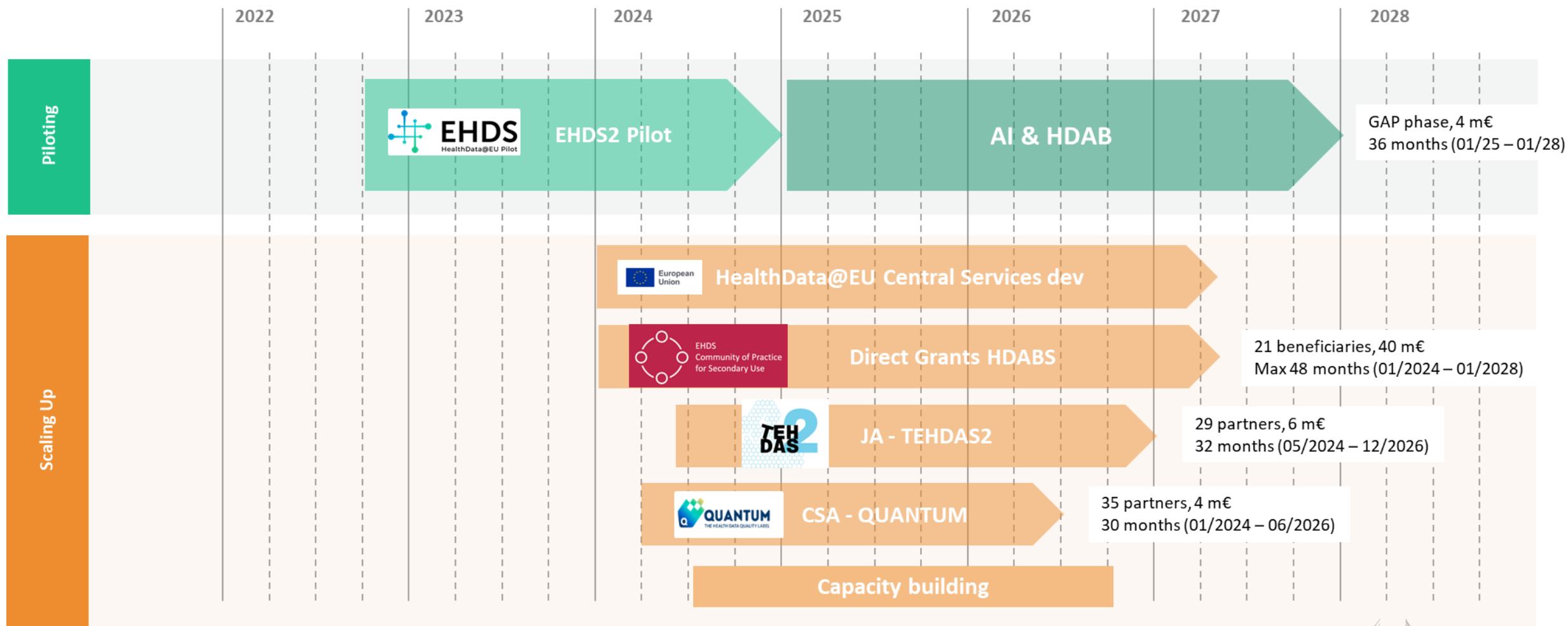
## Delegated acts

1. *Changing data quality and utility label elements*
2. *DGA protective measures for third-country transfers of non-personal data*

**Bold** = deadline for adoption by EiF + 2 years

# EHDS2 – Supporting actions

Timelines are indicative.

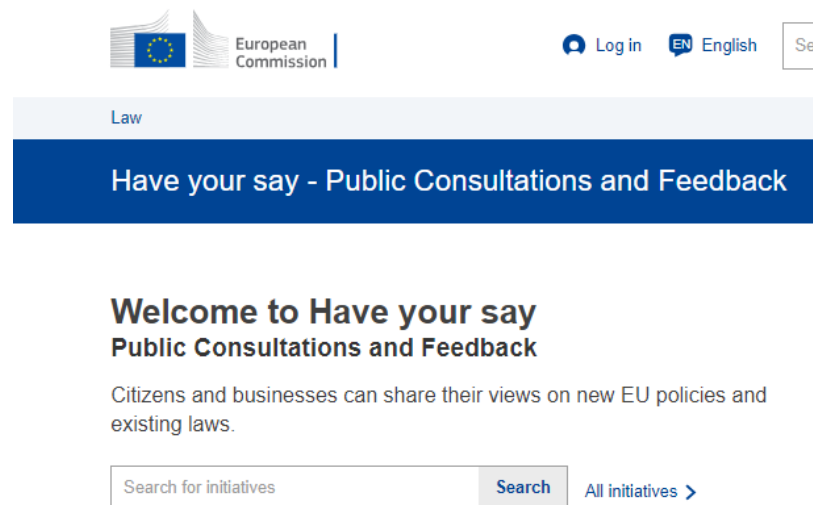


# How to participate ?

# How can you make your voice heard?

## TEHDAS2

- Public consultation on all milestones (three waves)
- External advisory board** with stakeholder representatives (closed)
- Save the date: Open **TEHDAS2 stakeholder forum** (hybrid) on 31/01/25
- Two others stakeholder forum aligned with the public consultations



### Implementing/delegated acts

- standard better regulation rules apply
- Expect 4-week public consultations

# How can you learn more ?

## ▪ European Commission

- Publication of a [Q&A document](#) Q1 2025
- Series of 3 x 90 min [webinars](#) Q1 2025 to understand the regulation, opportunity to ask questions



# Thank you



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