

European Health Data Space (EHDS)

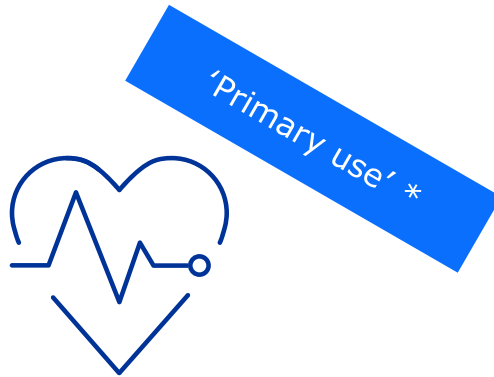
Regulation (EU) 2025/327

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Head of Transparency

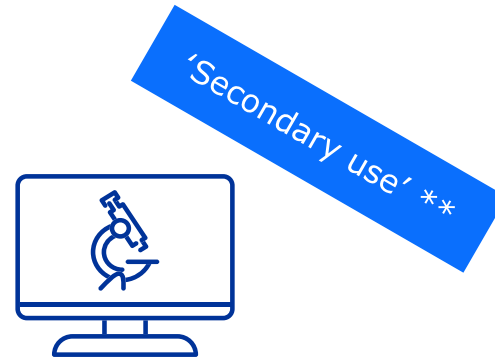
PCWP 30 June 2026



EHDS aim



Empower individuals
to freely access and manage
their electronic health data,
while also enabling secure sharing of
such data with HCPs across the EU



**Enable access and reuse of
electronic health data**
for research, innovation and
regulatory activities
in safe and secure way



Create a single market
for electronic health records systems,
supporting
both primary and secondary use

* Use of data for the delivery of healthcare

** Use of data for research and public interest purposes

EHDS key concepts and actors



Data user

Any natural or legal **person allowed to request access** to electronic health data through EHDS for certain purposes



Data holder

Any natural or legal **person holding non-anonymised electronic health data**, which it has a right or obligation to process in its capacity as a controller, or anonymized electronic health data



Health Data Access Body

Public bodies established by MSs and EC **to oversee and facilitate data access** through EHDS



Data permit

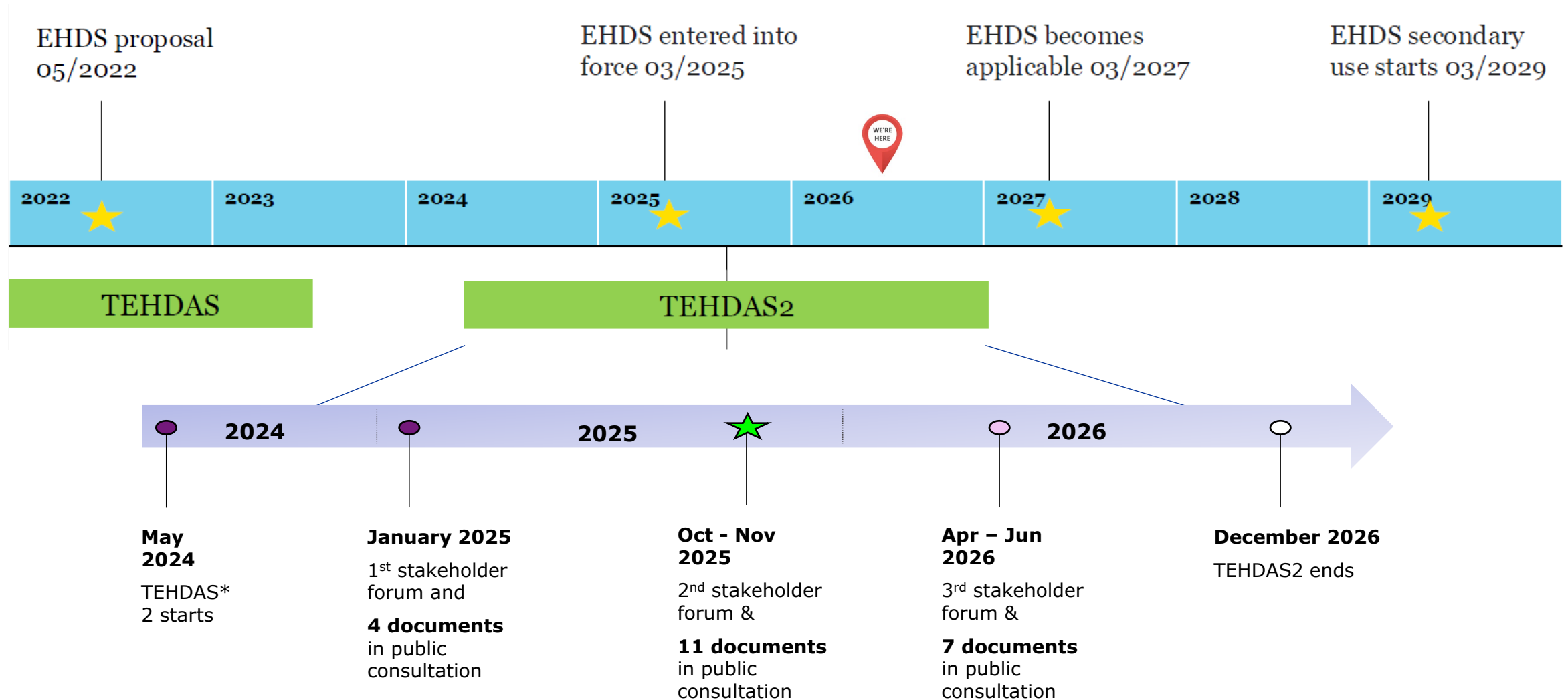
Administrative decision issued by a health data access body to a data user **to access and process specified electronic health data**



Secure processing environment

Specialised infrastructure, offered by health data access body, **to enable safe access and use** of electronic health data

EHDS timelines



TEHDAS2 public consultations

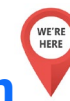
1st public consultation (completed)

- **M5.1** Guideline for data holders on data description
- **M5.3** Technical specification on national metadata catalogue
- **M6.2** Guideline for data users on good application and access practice
- **M7.1** Guideline on how to use data in SPE

2nd public consultation (completed)

- **M4.1** Guideline for HDABs on fees and penalties for non-compliance
- **M5.2** Guideline for HDABs on minimum categories and limitations on the reuse of health data
- **M6.1** Guideline for health data holders on making personal and non-personal electronic health data available for reuse.
- **D6.3** Guideline for HDABs on procedures and formats for data access
- **D6.3** Technical specifications for DAAMS
- **M7.2** Guideline on Data Minimisation, Pseudonymisation, Anonymisation & Synthetic Data
- **M7.3** Technical specifications for HDABs on the implementation of the common IT infrastructure
- **M7.4** Technical, functional and security specifications of SPEs
- **M8.1** Guideline for HDABs on “How to implement opt-out from secondary use of electronic health data”
- **M8.2** Guideline for HDABs on implementing the obligation of notifying the natural person on a significant finding from the secondary use of health data

3rd public consultation (ongoing)



- **M4.2** Guideline on a framework for collaboration
- **M4.3** Guideline for HDABs on international and third country access and transfer of electronic health data
- **M5.4** Guideline for data enrichment
- **M5.5** Guideline for data users navigating the catalogue Guideline for HDABs on informing natural persons about the use of health data – “Citizen Information Point”
- **M7.5** Guideline on linkage of health datasets
- **M8.3** Guideline for HDABs on informing natural persons about the use of health data
- **M8.4** Guideline for data users on handling research outcomes

Preparing for EHDS implementation

- An internal EHDS working group to co-ordinate implementation of EHDS requirements
- Engaging with EC and contribute to the preparation for implementing acts and guidelines
 - ❑ Represent EMA in EHDS-related engagements with EC (e.g. ISCG, TEDHAS2...)
 - ❑ Review of EHDS Board guidelines, draft implementing acts...
 - ❑ Actively contribute to EHDS-supporting projects, joint actions, EC implementation activities
- Developing an EMA Roadmap for implementation of EHDS
- Preparing a metadata catalogue of health data
- Identifying potential synergies with PMS, DARWIN...



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Thank you

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