



# Implementing the European Health Data Space (EHDS): The role of OMOP & OHDSI in secondary use of health data

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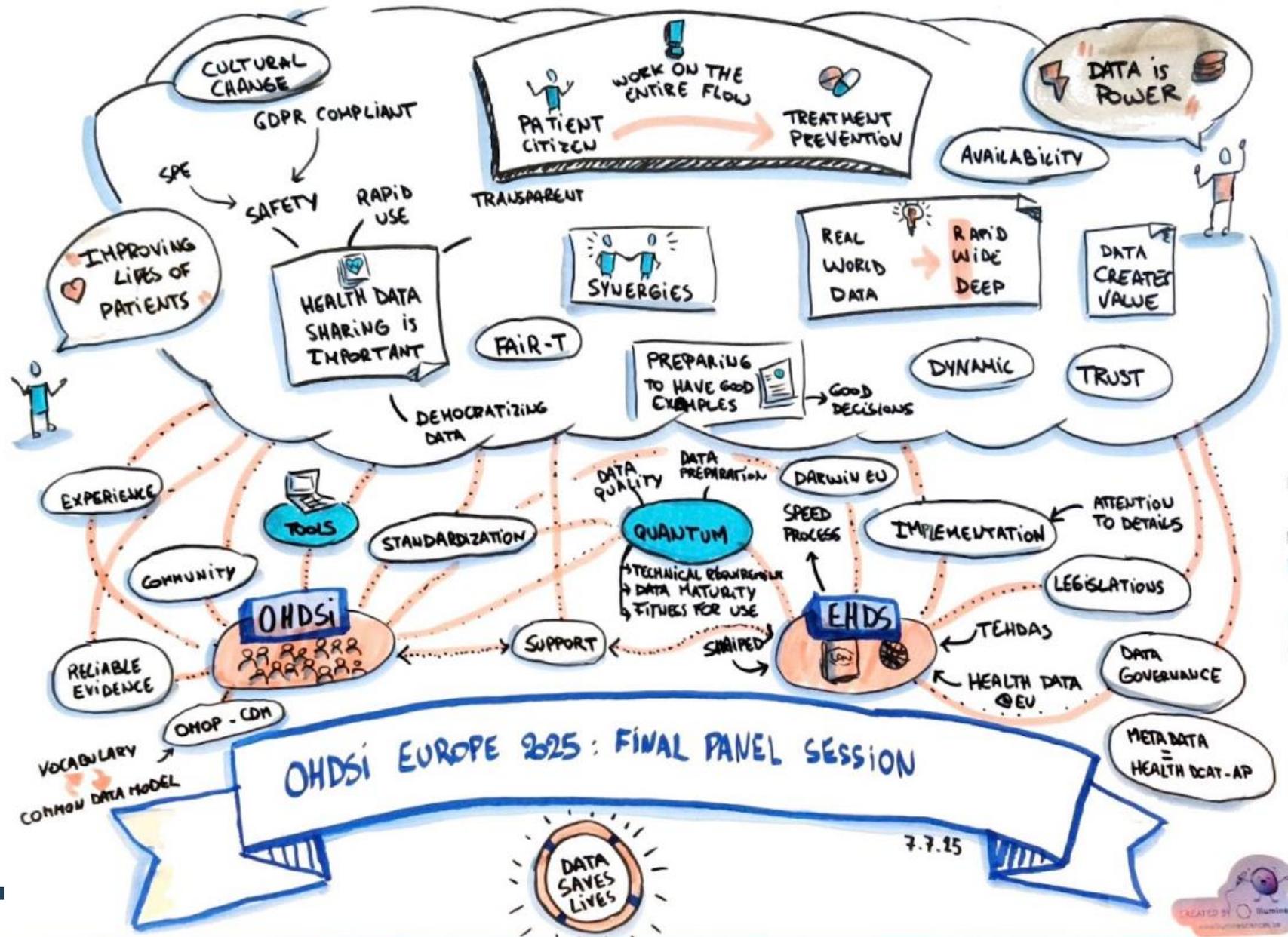


OHDSI Europe Community Call – March 12, 2026

# OHDSI EU Symposium 2025 panel debate



# OHDSI EU Symposium 2025 panel debate





# Goal of this session

- Introduce EHDS for secondary use
- Provide insights on how OMOP CDM and our proven tools and processes can help?
- Your thoughts....



We are drafting a publication about the value of the OMOP CDM and the OHDSI eco-system for operationalising the EHDS.

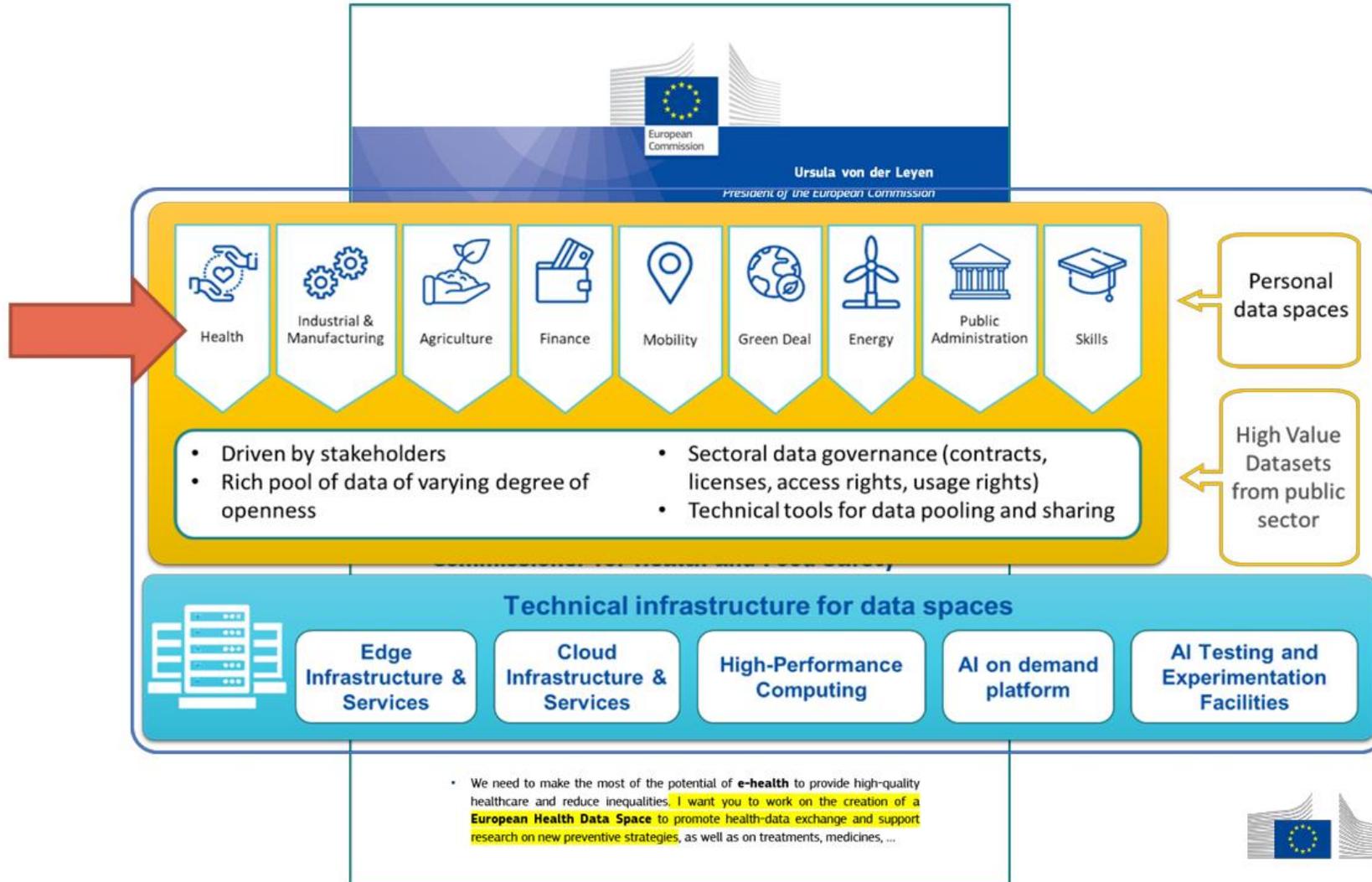
# European Data Spaces



Ursula von der Leyen  
President of the European Commission

Mission letter

Brussels, 1 December 2019





# 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

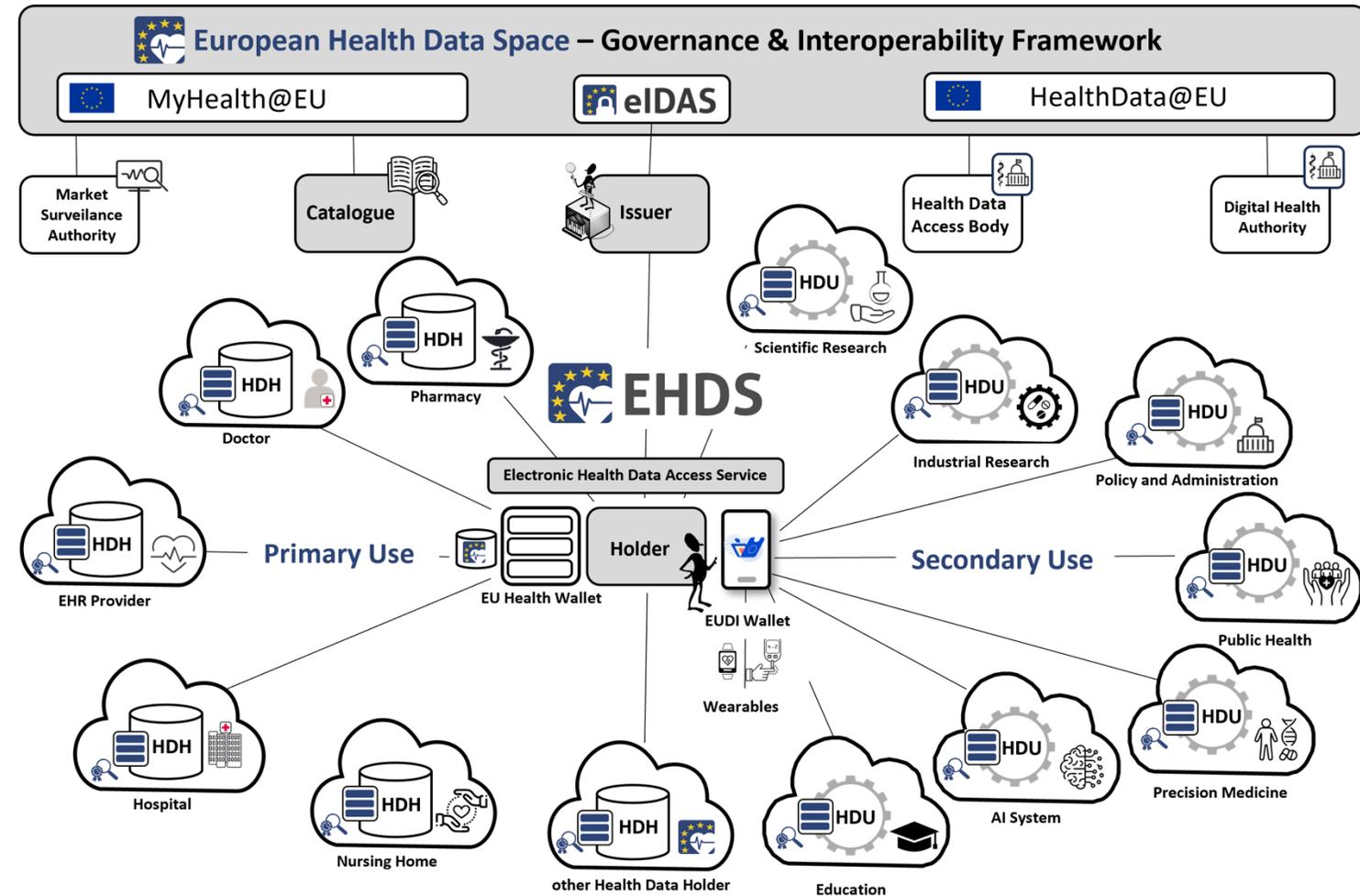
- Making data available for research, policy-making etc. in a safe and secure way.

## 3. Requirements for **electronic health record (EHR)** systems

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

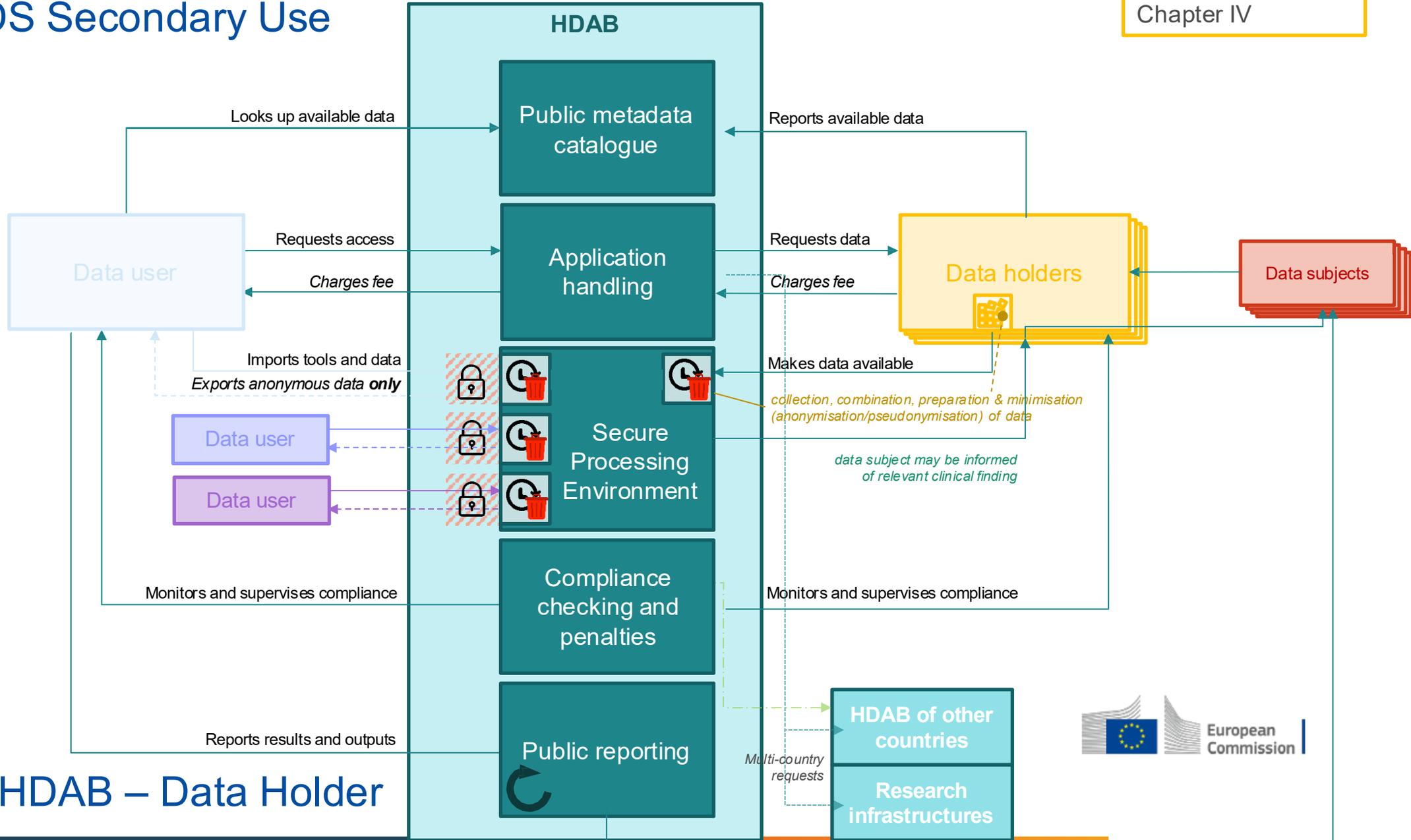
# The European Health Data Space (EHDS)

- Health Data Holders (HDH) have a **legal obligation** to make health data available for Health Data Users (HDU).
- Intended to **unlock** data for research, public health, regulatory decision-making
- **Not mandatory** to get access to data!
- **Technology-neutral** → risks *fragmented national implementations*
- Huge **opportunity** for OMOP/OHDSI to support EHDS implementation





# EHDS Secondary Use



## Data User – HDAB – Data Holder





# Towards European Health Data Space (THEEDAS)



<https://tehdas.eu/>

Search

[Project](#) [Public consultations](#) [Updates](#) [Events](#) [Get involved](#) [Results](#)

## Public consultations

Public consultations are a core part of the TEHDAS2 work.

All TEHDAS2 draft guidelines and technical specifications are published for public consultation to help ensure that the final outputs meet the needs of citizens, health professionals and regulators.

The public consultations are carried out in three waves: January-February 2025, September-November 2025 and May-June 2026. After each consultation, the authors review the feedback received and use it to finalise the documents. The finalised documents include a summary of the comments submitted and how the feedback was processed. The final deliverables are published on the [Results page](#).

- 1. DRAFT GUIDELINE FOR HEALTH DATA ACCESS BODIES ON FEES RELATED TO THE EHDS REGULATION** ([Click to view](#))
- 2. DRAFT GUIDELINE FOR HEALTH DATA ACCESS BODIES ON PENALTIES FOR NON-COMPLIANCE RELATED TO THE EHDS REGULATION** ([Click to view](#))
- 3. DRAFT GUIDELINE FOR HEALTH DATA ACCESS BODIES ON MINIMUM CATEGORIES AND LIMITATIONS ON THE REUSE OF HEALTH DATA** ([Click to view](#))
- 4. DRAFT GUIDELINE FOR DATA HOLDERS ON MAKING PERSONAL AND NON-PERSONAL ELECTRONIC HEALTH DATA AVAILABLE FOR REUSE** ([Click to view](#))
- 5. DRAFT GUIDELINE FOR HEALTH DATA ACCESS BODIES ON THE PROCEDURES AND FORMATS FOR DATA ACCESS** ([Click to view](#))
- 6. DATA ACCESS APPLICATION MANAGEMENT SYSTEM (DAAMS) – DRAFT TECHNICAL SPECIFICATION FOR HEALTH DATA ACCESS BODIES** ([Click to view](#))
- 7. DRAFT GUIDELINE FOR HEALTH DATA ACCESS BODIES ON DATA MINIMISATION, PSEUDONYMISATION, ANONYMISATION AND SYNTHETIC DATA** ([Click to view](#))
- 8. DRAFT TECHNICAL SPECIFICATION FOR HEALTH DATA ACCESS BODIES ON THE IMPLEMENTATION OF THE COMMON IT INFRASTRUCTURE** ([Click to view](#))



## HealthData@EU Pilot

Piloting a european infrastructure for the secondary use of health data

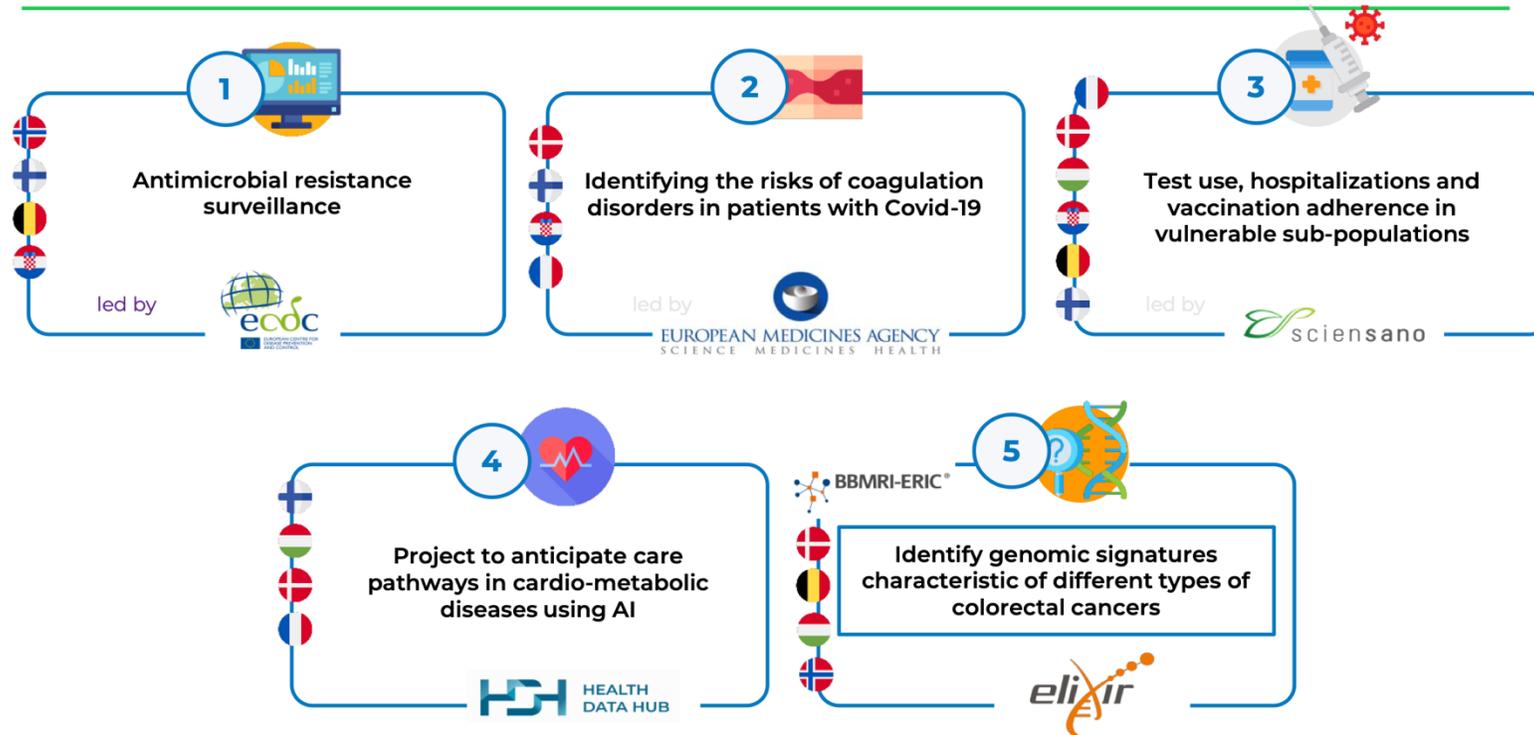
PARTNER



# EHDS

HealthData@EU Pilot

## 5 concrete research use cases to demonstrate the feasibility and added value of European research projects



# Use case factsheet

## Use case leader



## Research teams

- DARWIN EU
- Denmark Health Data Authority, DK
- Health Data Hub, FR
- Croatian Institute for Public Health, HR
- Finnish Institute for Health and Welfare (THL), FI

## National nodes

Findata, FI      HDH, FR

DHDA DK      CIPH, HR

DARWIN EU network

## Stakeholders

The Use case will aim to address 5 research questions of growing complexity: estimate the incidence of venous and arterial thromboembolic events among 1/the general population; 2/patients with COVID-19; 3/patients with SARS-CoV-2 vaccination ; estimate 4/the impact of clinical risk factors and prior SARS-CoV-2 vaccination on the incidence of venous and arterial thromboembolic events among patients with COVID-19 and worsening of COVID-19, as well as 5/ the incidence rate ratios for such events among patients with COVID-19 during the period when Omicron was the dominant variant and people vaccinated against SARS-CoV-2, compared to background rates as estimated in objectives. 1, 2 and 3.

## Objectives

## Data

- Coagulopathy related events
- Use of thrombotic agents
- Risk factors
- Vaccination
- Covid-19 worsening

Each of the nodes participating in the project will be expected to select the research questions outlined above. Based on the questions and variables defined the protocol, data analysis will be conducted on both native data and OMOP data. Data analysis will focus on the following aspects:

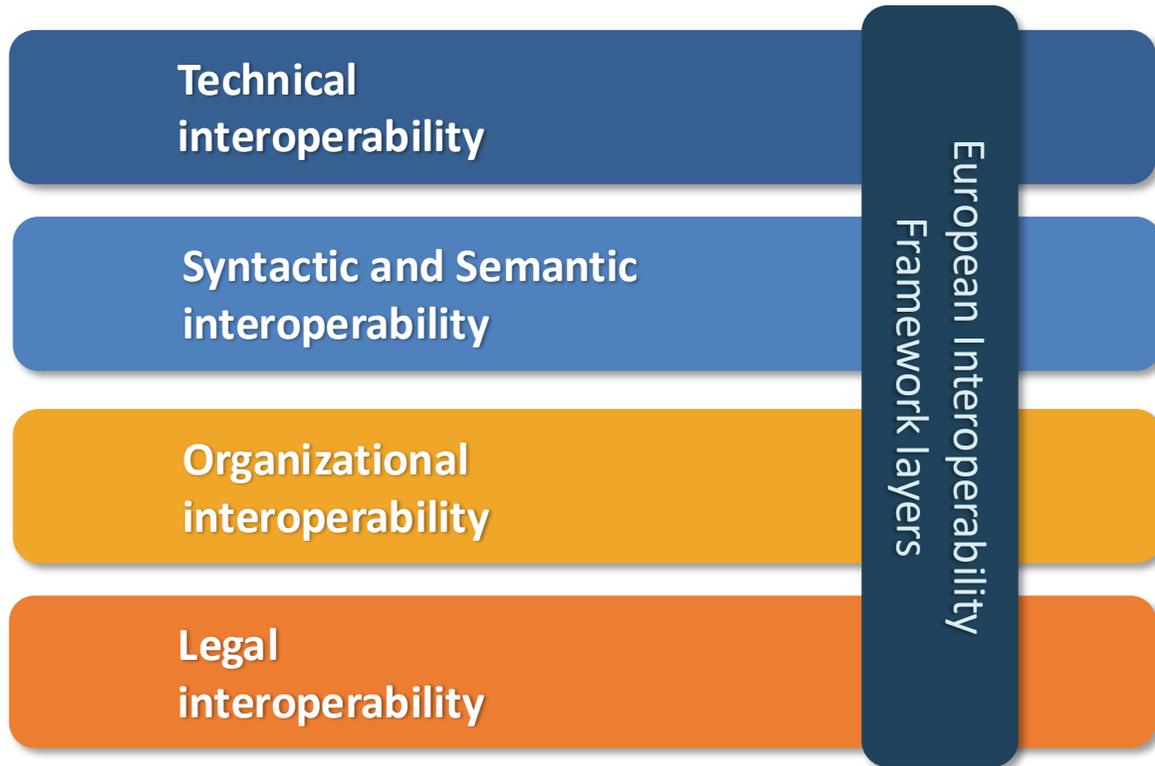
- Descriptive statistics of the observed characteristics of each population study;
- Incidence of study outcome (venous thromboembolic events, arterial thromboembolic events, cardiovascular events)
- Assessment of the impact of identified risk factors
- Assessment of the risk of Covid-19 worsening
- Contextualisation of incidence rate of thromboembolic events.

Output: aggregated results from each node that can then be pooled together or do comparative analysis between nodes.



## Research approach

# Need for interoperability on all layers



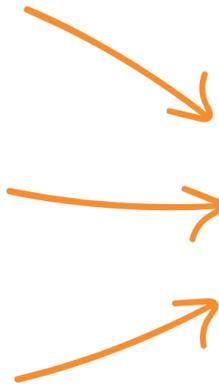
- EHDS ensures **legal interoperability** (access & governance)
- But does **not** specify technical standards
  - *Member States might implement incompatible data models*
  - *Cross-border evidence generation becomes difficult*

*Without a shared technical & analytical representation we cannot make the necessary paradigm shift*

# Two operational models under EHDS both need interoperability of data and tools

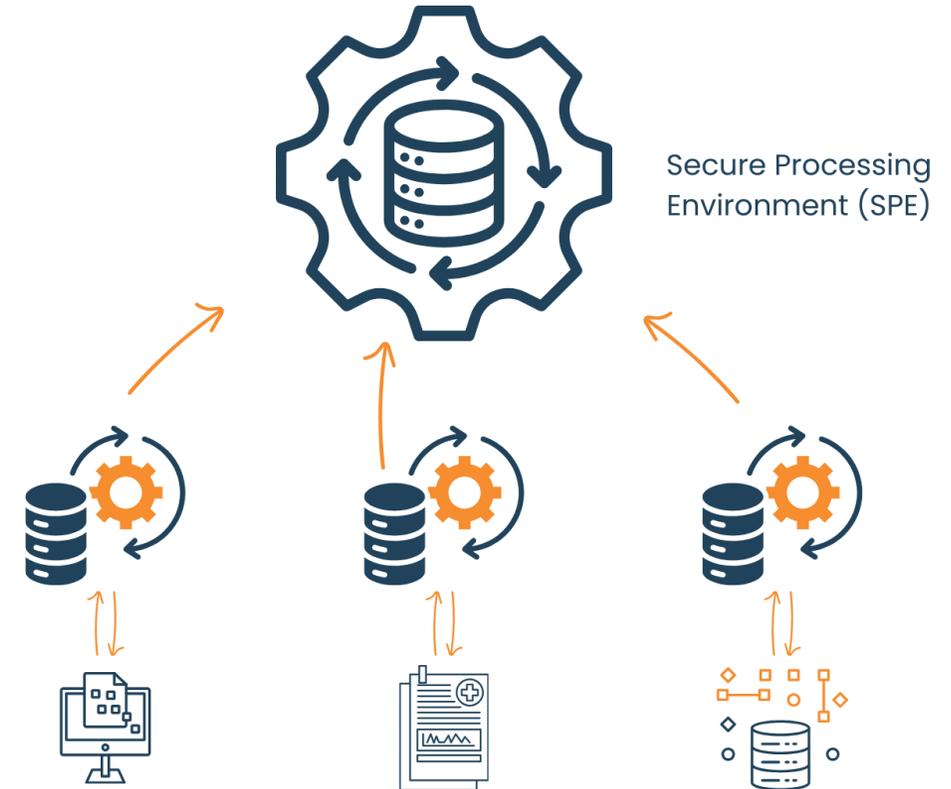
**Upload approach:**  
raw subsets into SPE

Raw data subsets



Secure Processing Environment (SPE)

**Federated model:** preprocessing & analyses run locally, aggregated results shared





# We are already executing studies at scale in Europe following EHDS principles



The Lancet Public Health  
Volume 10, Issue 10, October 2025, Pages e835-e847

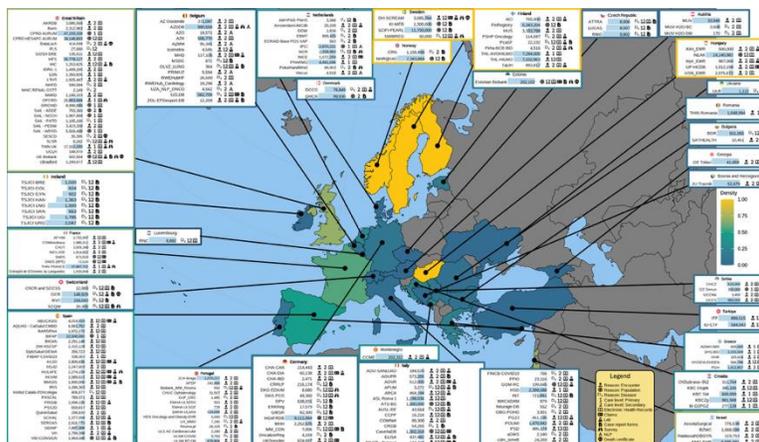


## Articles

### Changes in use and utilisation patterns of drugs with reported shortages between 2010 and 2024 in Europe and North America: a network cohort study

Marta Pineda-Moncusí PhD<sup>a</sup>, Alexandros Rekkas PhD<sup>b</sup>, Álvaro Martínez Pérez BSc<sup>c</sup>, Angela Leis PhD<sup>e</sup>, Carlos Lopez Gomez MSc<sup>d</sup>, Eric Fey PhD<sup>f</sup>, Erwin Bruninx MD<sup>g</sup>, Filip Maljković MScEE<sup>h</sup>, Francisco Sánchez-Sáez PhD<sup>i,j</sup>, Jordi Rodeiro-Boliart MSc<sup>k</sup>, Loretta Zsuzsa Kiss MD, PhD<sup>l</sup>, Michael Franz MSc<sup>m</sup>, Miguel-Angel Mayer PhD<sup>e,n</sup>, Neva Eleangovan MSc<sup>o</sup>, Pau Pericàs Pulido MD<sup>p</sup>, Pantelis Natsiavas PhD<sup>q</sup>, Selçuk Şen MD<sup>r</sup>, Steven Cooper PhD<sup>s</sup>, Sulev Reisberg PhD<sup>t,u</sup>, Katrin Manlik MSc<sup>v</sup>, Prof David Brendan Price PhD<sup>o,w</sup>, Luca Moscetti MD<sup>x</sup>, Manon Merkelbach MSc<sup>y</sup>, Mina Tadrous PhD<sup>z</sup>, Nadav Rappoport PhD<sup>aa</sup>, Ravinder Claire PhD<sup>ab</sup>, Salvador Garcia-Torrens MSc<sup>ac</sup>, Prof Daniel Prieto-Alhambra PhD<sup>a,ad</sup>, Prof Peter R Rijnbeek PhD<sup>ad</sup>, Theresa Burkard PhD<sup>a</sup> on behalf of the Drug Shortages EHDEN Study Group

Marta Pineda-Moncusí<sup>ae</sup>, Alexandros Rekkas<sup>af</sup>, Álvaro Martínez Pérez<sup>ag</sup>, Angela Leis<sup>ah</sup>, Carlos López Gómez<sup>ai</sup>, Eric Fey<sup>aj</sup>, Erwin Bruninx<sup>ak</sup>, Filip Maljković<sup>al</sup>, Francisco Sánchez-Sáez<sup>am,an</sup>, Jordi Rodeiro<sup>ao</sup>, Loretta Zsuzsa Kiss<sup>ap</sup>, Michael Franz<sup>aq</sup>, Miguel-Angel Mayer<sup>ar,as</sup>, Neva Eleangovan<sup>at</sup>, Pau Pericàs Pulido<sup>au</sup>, Pantelis Natsiavas<sup>av</sup>, Selçuk Şen<sup>aw</sup>, Steven Cooper<sup>ax</sup>, Sulev Reisberg<sup>ay,az</sup>, Katrin Manlik<sup>ba</sup>, Beatriz del Pino<sup>bb</sup>, Albert Prats Uribe<sup>bc</sup>, Ali Yağız Üresin<sup>bd</sup>, Ana Danilović Bastić<sup>be</sup>, Ana Maria Rodrigues<sup>bf,bg,bh</sup>, Ânaela Afonso<sup>bi</sup>, Anna Palomar-Cros<sup>bj</sup>, Annelies Verbiest<sup>bk,bl</sup>, Antonella Delmestri<sup>bm</sup>



18 National Nodes

Large number of European Projects

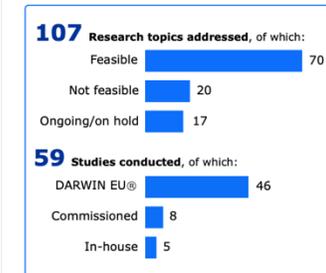
## The reports

EMA regularly reports on the progress made on RWD studies to support regulatory decision making. The latest report covers the period from 8 February 2024 to 7 February 2025, which corresponds to the third year of DARWIN EU®.

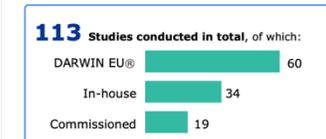
The reports are available on the [EMA website](#).

## EMA-led RWD studies

From latest reporting period (February 2024 - February 2025):



Since start of the reviews (September 2021):



Research topics requested by: EMA committees, Working Parties and internal functions, European Centre for Disease Prevention and Control, Health Technology Assessment bodies/payers and European Commission.

Procedures covered: safety signals assessment, periodic safety update report single assessments and applications for paediatric investigation plans.

Other studies: vaccine safety and effectiveness monitoring, shortage prevention and crisis preparedness, EMA geriatric strategy and methodological studies.

## Highlights of the latest report

- DARWIN EU® expanded to 30 data partners, with access to data from around 180 million patients from 16 European countries.
- 59 studies were conducted representing a 47.5% increase compared to the previous reporting period.
- The proportion of feasible studies addressing initial requests increased from the previous reporting period (78% vs. 60%).
- The median study duration for DARWIN EU studies is now 4 months from protocol approval to study results.

## Recommendations for enabling the use of RWE

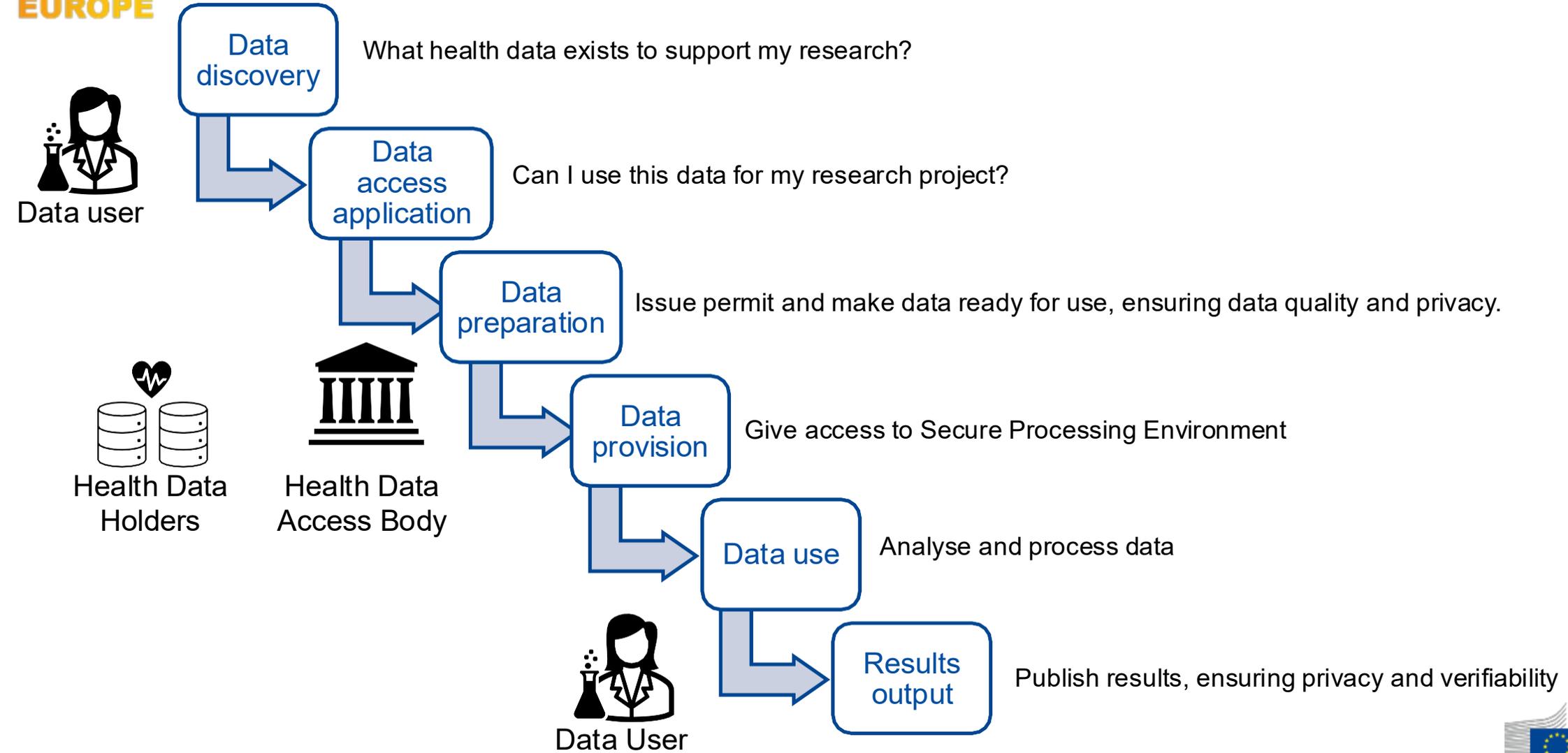
A set of recommendations was developed to address identified opportunities and challenges. The third report reflects on the progress made in implementing them, with a list of further actions.

- Access to data sources**  
Wider access to more diverse and complementary data sources.
- Accelerate**  
Strategies to further accelerate RWE generation.
- Regulatory context**  
Anticipate RWE needs of decision makers by identifying research questions earlier.
- Capacity and capability**  
Develop educational and knowledge management sharing tools.
- Collaboration and Communication**  
Close collaboration with decision makers and other stakeholders.

The learnings and recommendations arising from the reviews will further inform the scaling up of DARWIN EU®.



# How can we help in the User journey?



# Where can we add value?



# Where can we add value?



## Exploration Phase

- Data Quality Label can benefit from automated QA (fit-for-use)
- Data Diagnostics via large-scale dashboards and feasibility analytics (fit-for-purpose)
- Meta Data available for many data sources

# Where can we add value?



## **Initiation Phase**

- Setup of necessary infrastructure, e.g. SPE used in DARWIN EU (anDREa), collaborative space, code repositories, service desk, etc.
- Expertise in Framework Contracts and Work Orders

# Where can we add value?



## **Implementation Phase**

- Many standard analytics, e.g. HADES, that can be applied centrally or in federated approach.
- Standardized Study Code Repositories
- Study Protocol Templates
- Cohort Diagnostics and Phenotyping tools and processes
- Expertise with Governance Board Approval steps

# Where can we add value?



## Execution Phase

- Processes and tools for sharing common analytics
- Reproducible federated or central execution mechanism
- Processes for user support
- Tools for sharing aggregated results after local approval.

# Where can we add value?



## **Dissemination Phase**

- Quality Assessment processes
- Standardized dashboards for large scale evidence dissemination
- Supporting tools for automatic report generation

# What OHDSI can offer member states & HDABs

- **Proven expertise** in large-scale evidence generation
- **A very large network** of data sources in one CDM and semantic layer
- **Analytical tools** for every study design
- **Capacity building** via National Nodes, and training programs.
- ...

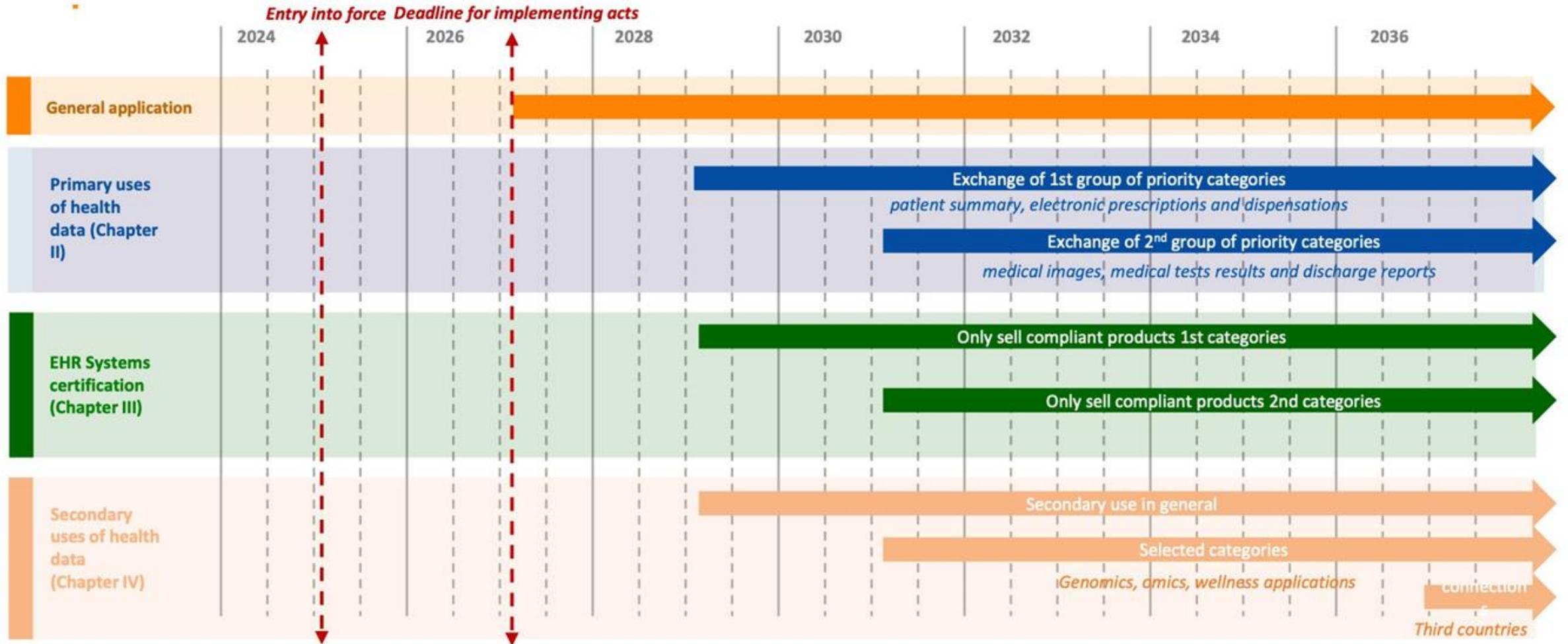




# What can EHDS offer OHDSI?

- A push to improve interoperability of data.
- FAIR data, tools, and results.
- A Technical Platform that supports OMOP CDM studies and federated execution.
- Access to more linked data.
- Streamlined governance procedure across Europe.
- More service providers that can help with ETL and QA.
- More data users with OMOP CDM Expertise.
- ....

# Implementation of EHDS regulation



# Call-to-action

*EHDS provides the mandate - OHDSI provides the methods.*

Let's:

1. Align national implementations on OMOP & use of OHDSI tools;
2. Engage with HDABs in Europe;
3. Expand the data network!
4. Demonstrate how to scale real world evidence generation as community.



# Q&A

[p.rijnbeek@erasmusmc.nl](mailto:p.rijnbeek@erasmusmc.nl)



HOW DO YOU THINK OHDSI COULD  
CONTRIBUTE TO THE EHDS  
IMPLEMENTATION?



HOW DO YOU THINK EHDS CAN HELP  
OHDSI?