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

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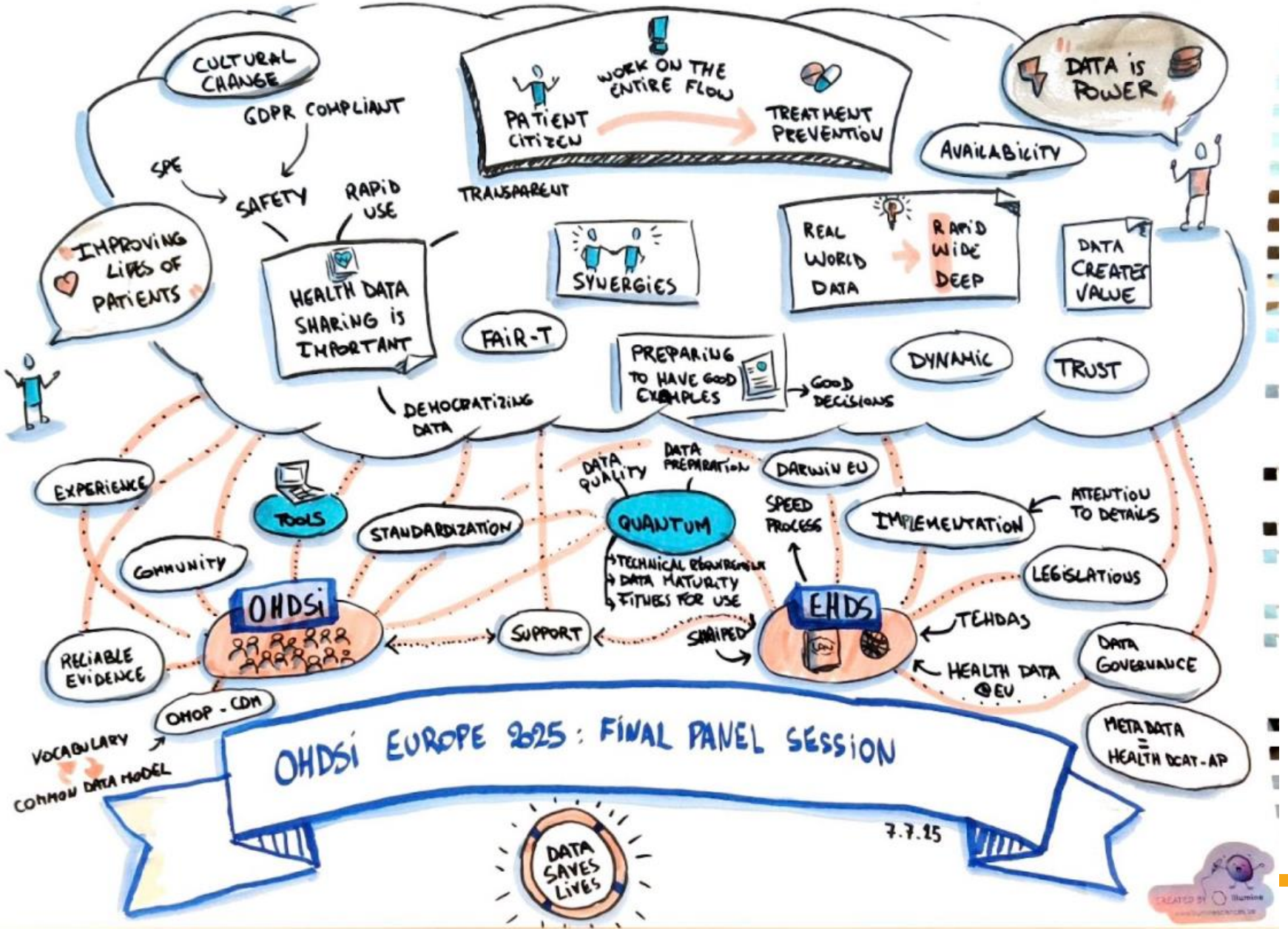
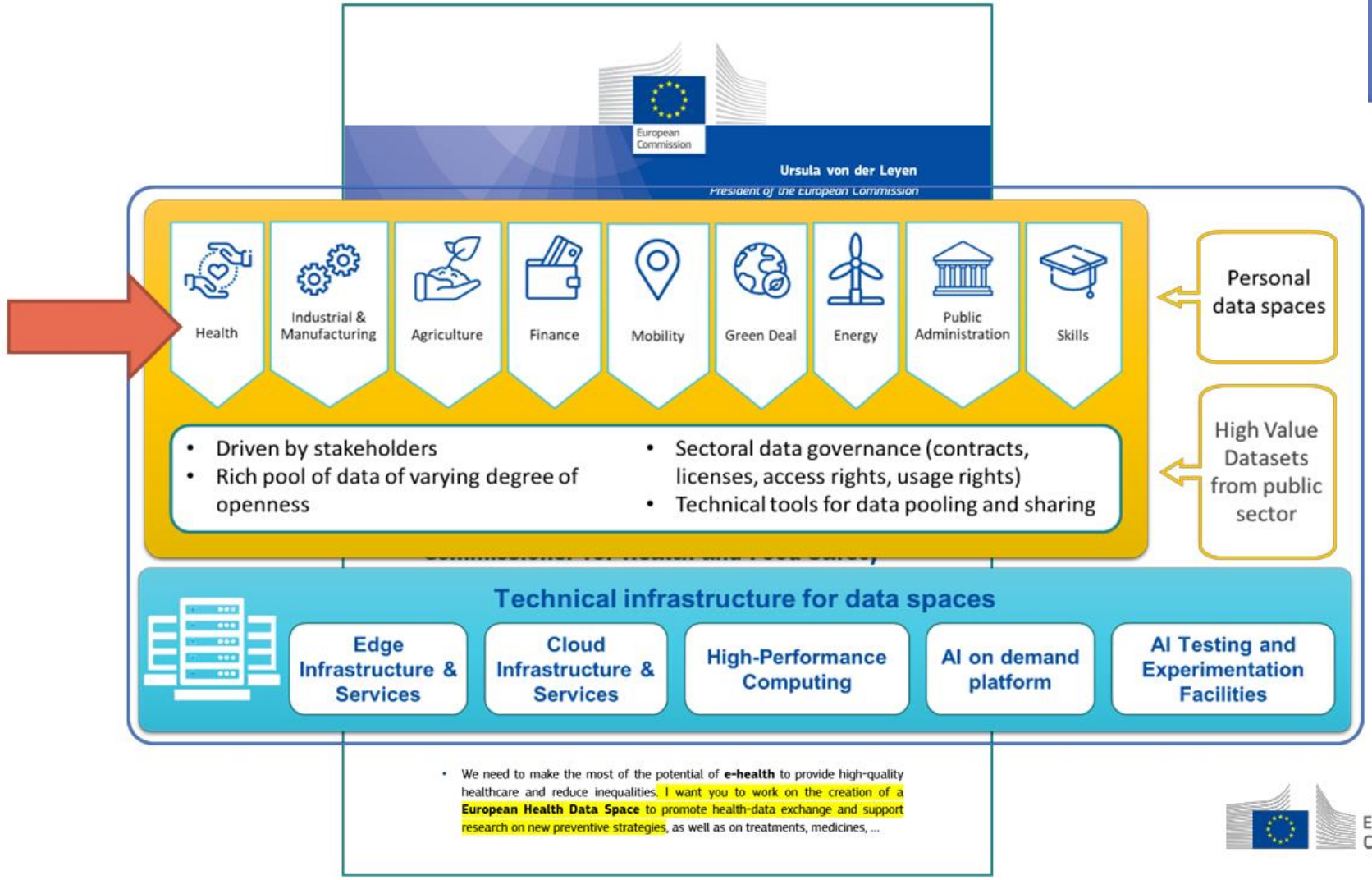


Goal of this session

- Introduce EHDS for secundary 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



Brussels, 1 December 2019

European Commission

European Commission Adoption 2024

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

EHDS in a nutshell – what is it about?

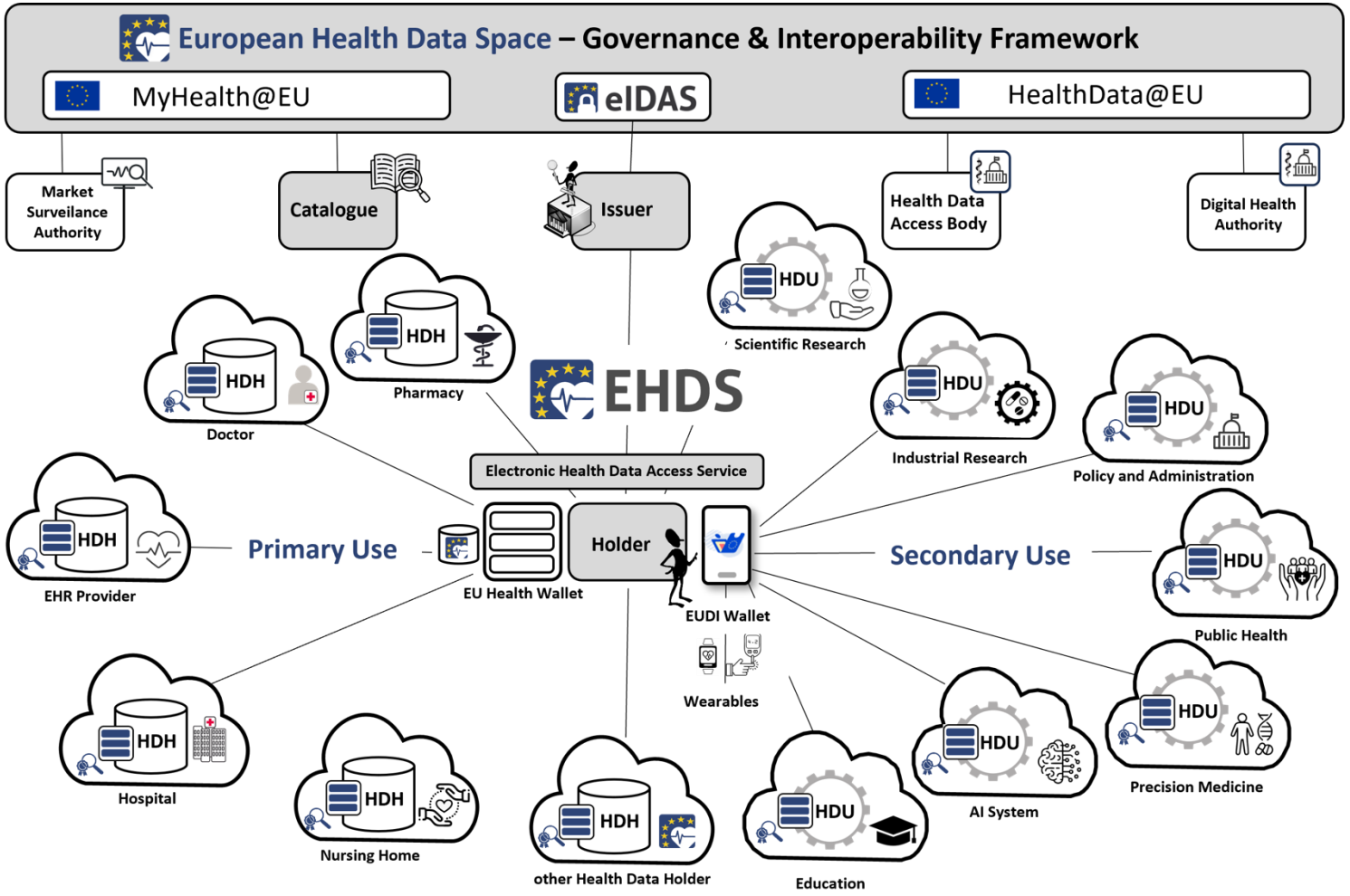
1. **Primary use** = use of data for the delivery of healthcare
   - Improving patients' access to their health data;
   - Ensuring seamless exchanges for continuity of healthcare.

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)

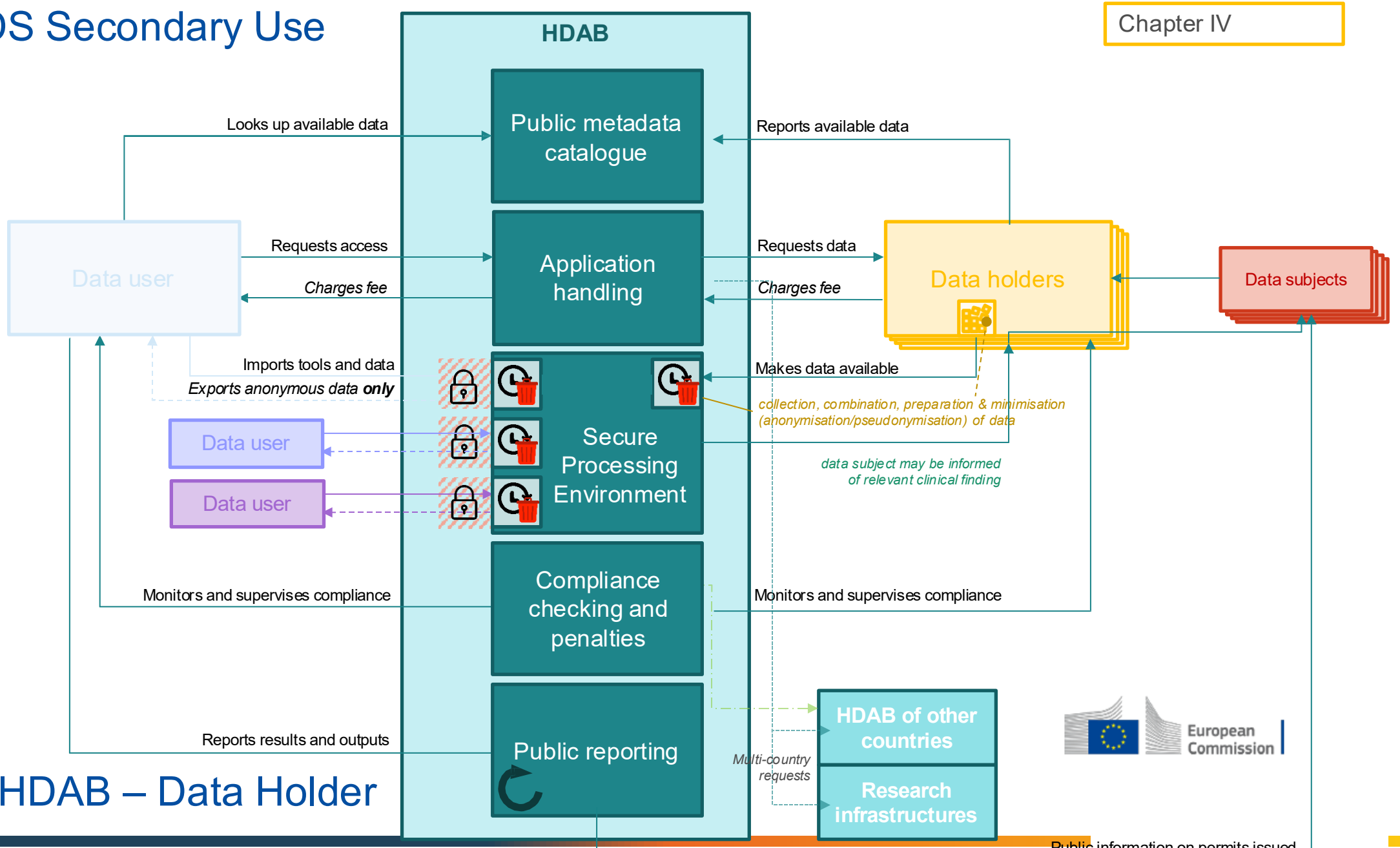
- Health Data Holders (HDH) have a **legal obligation** to make health data available for Health Data Users (HDU).
- Intended to **unlock** data for research, public health, regulatory decision-making
- **Not mandatory** to get access to data!
- ***Technology-neutral*** → risks *fragmented national implementations*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



https://www.ehds.io/

EHDS Secondary Use

Chapter IV



Data User – HDAB – Data Holder

Public information on permits issued
Results or outcomes of projects

Towards European Health Data Space (THEDAS)

https://tehdas.eu/

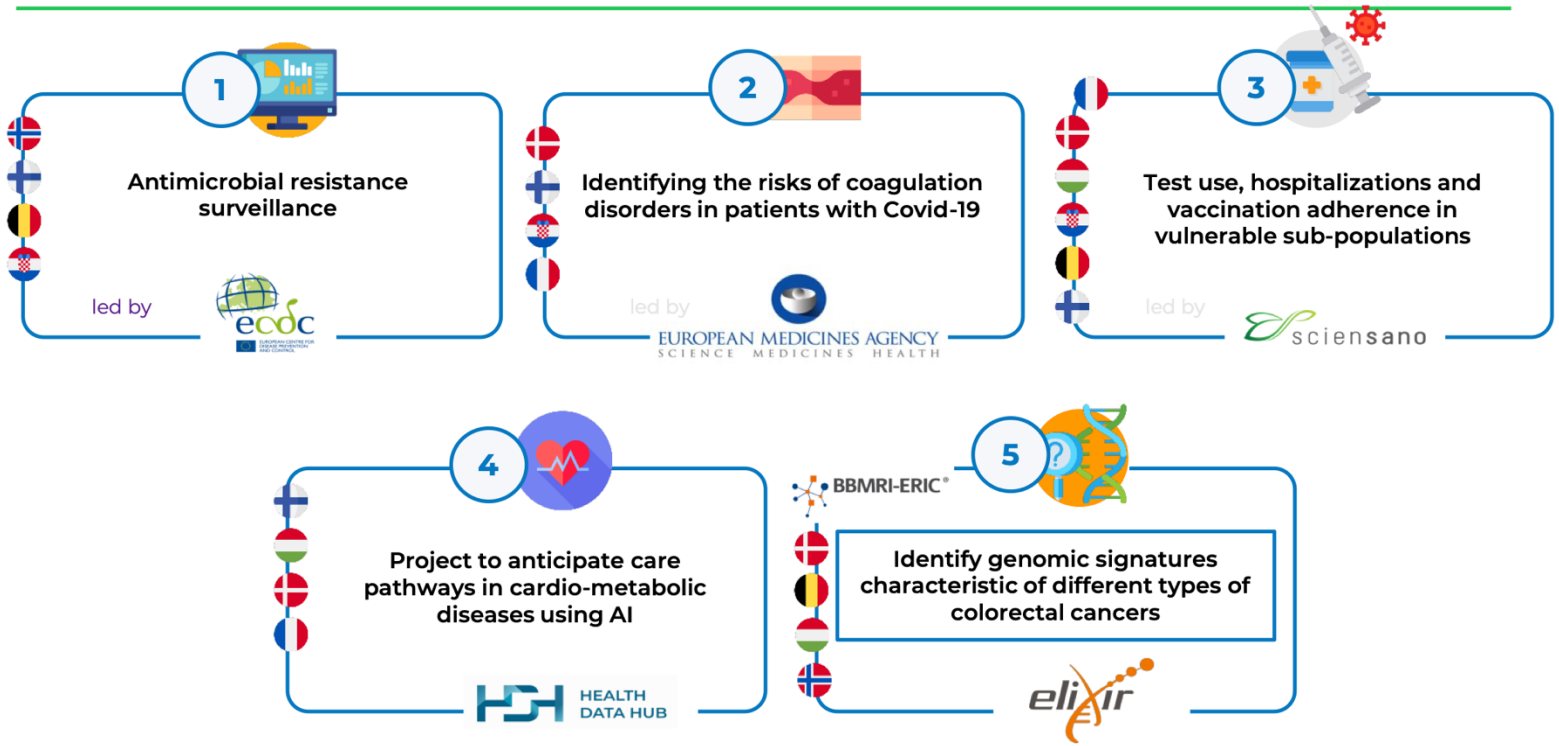
HealthData@EU Pilot

Piloting a europeean infrastructure for the secondary use of health data

PARTAGER

EHDS
HealthData@EU Pilot

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



EHDS
HealthData@EU Pilot

Use case factsheet

Use case leader

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Stakeholders

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

Objectives

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.

Data

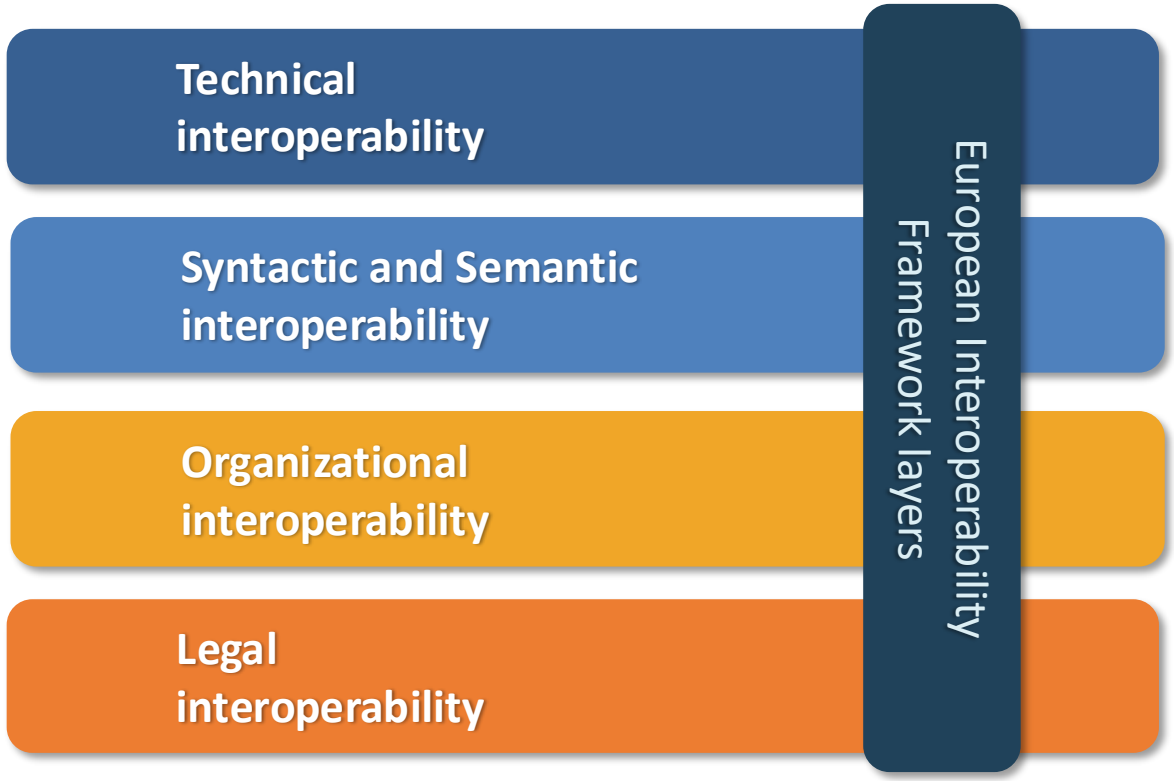
- Coagulopathy related events
- Use of thrombotic agents
- Risk factors
- Vaccination
- Covid-19 worsening

Research approach

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.

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

Need for interoperability on all layers



- EHDS ensures **legal interoperability** (access & governance)
- But does **not** specify technical standards

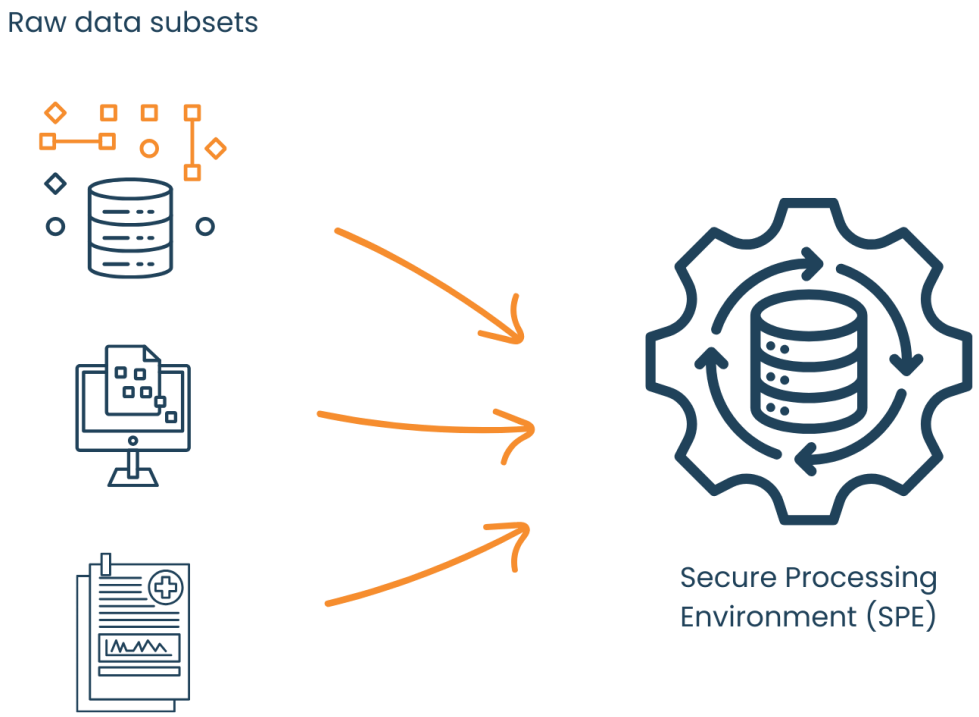
  → *Member States might implement incompatible data models*

  → *Cross-border evidence generation becomes difficult*

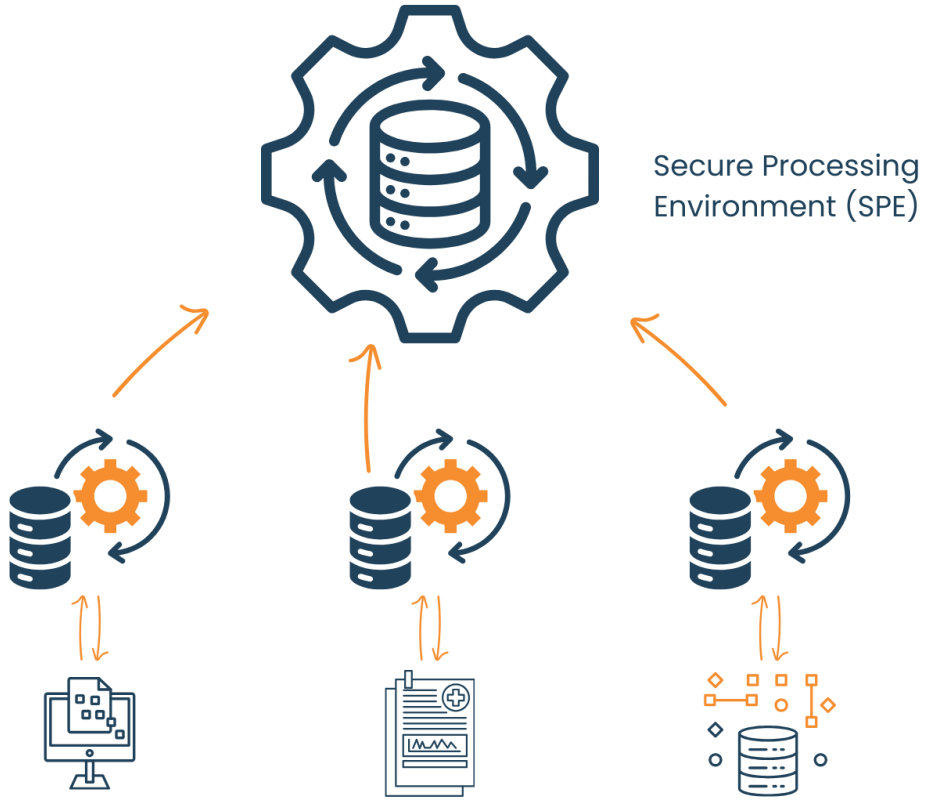
Without a shared technical & analytical representation we cannot make the necessary paradigm shift

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

Upload approach:
raw subsets into SPE



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



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

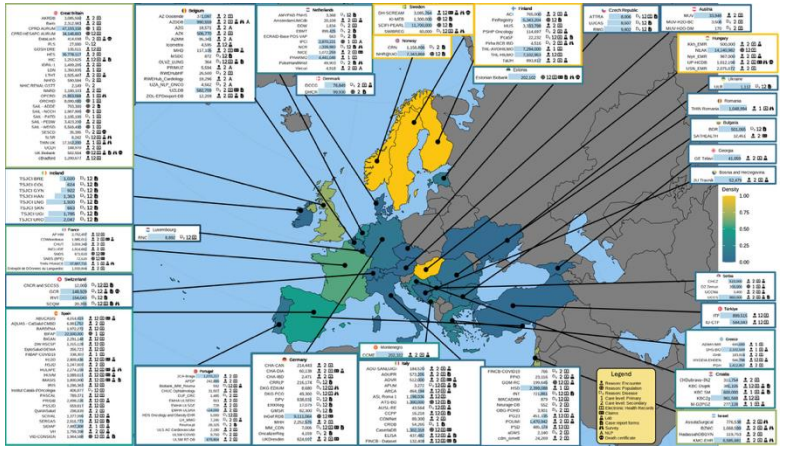
The Lancet Public Health
Volume 10, Issue 10, October 2025, Pages e835-e847

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

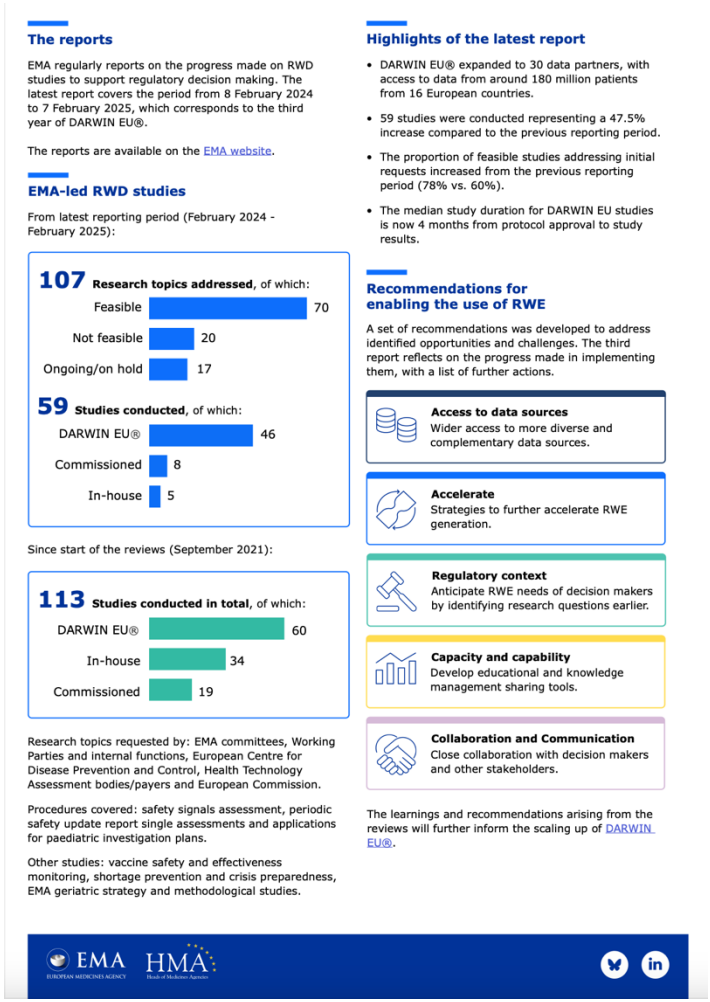
Marta Pineda-Moncusí PhD [a], Alexandros Rekkas PhD [b], Álvaro Martínez Pérez BSc [c], Angela Leis PhD [e], Carlos Lopez Gomez MSc [d], Eric Fey PhD [f], Erwin Bruninx MD [g], Filip Maljković MScEE [h], Francisco Sánchez-Sáez PhD [i j], Jordi Rodeiro-Boliart MSc [k], Loretta Zsuzsa Kiss MD, PhD [l],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

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

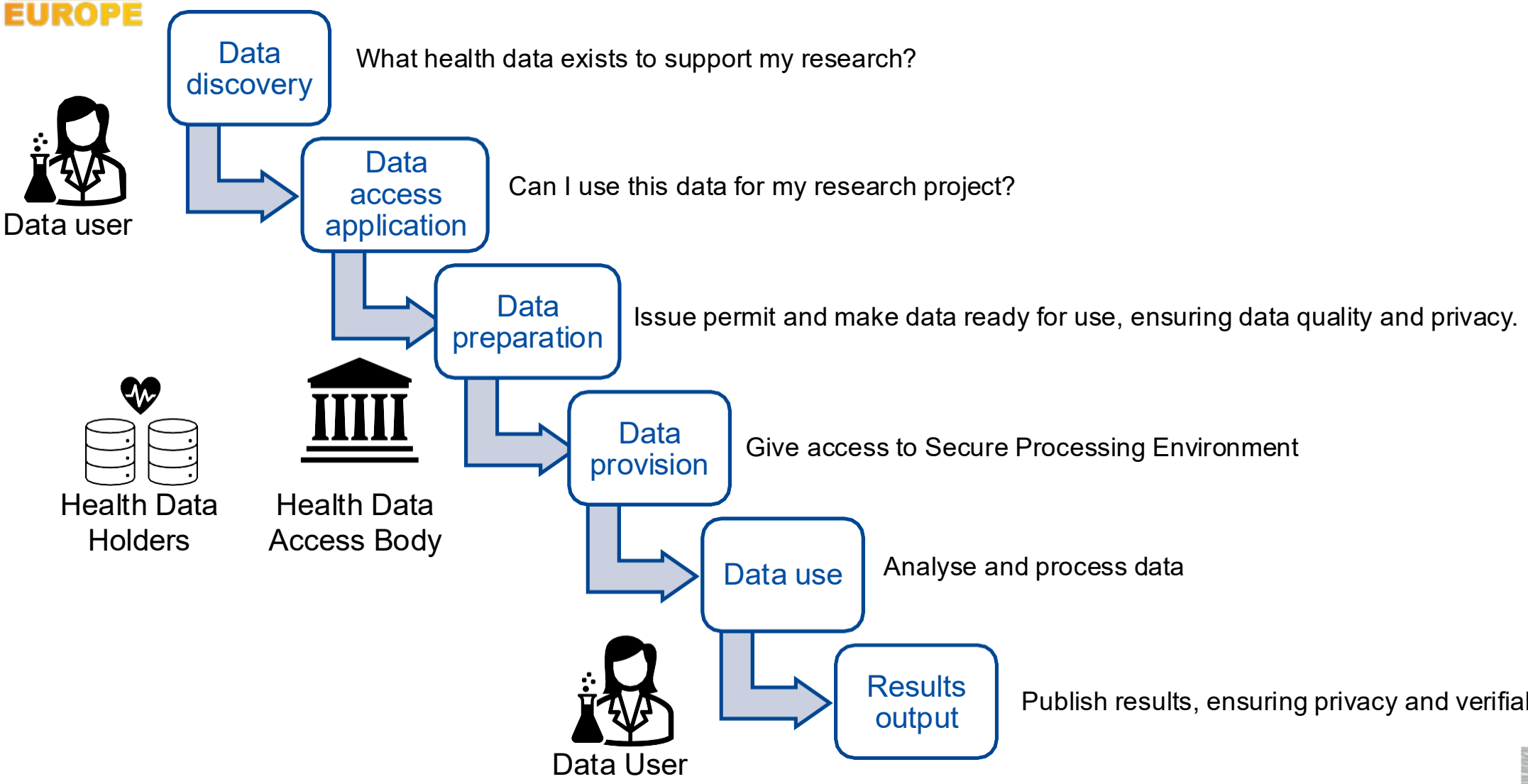


18 National Nodes

Large number of European Projects



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

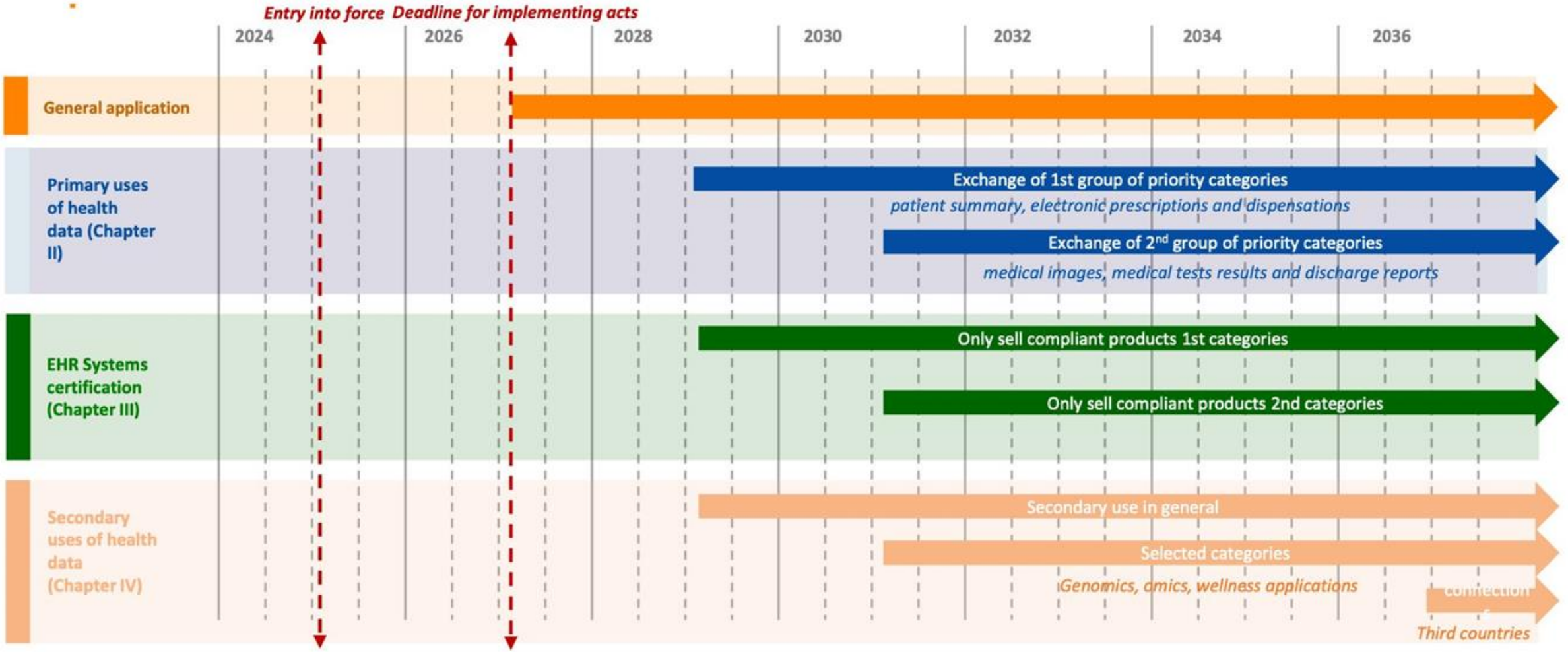
What OHDSI can offer member states & HDABs

- **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

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

HOW DO YOU THINK EHDS CAN HELP OHDSI?