European OMOP Initiatives

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European Adoption of OMOP

Development of European Networks

End of OMOP Experiment

First OHDSI Symposium/Network Study Published

European Chapter

FDA Adoption

EMA Adoption

First Study

EMA DARWIN

Four Studies

2013

2015

2017

2019

2022

2009

2014

2018

2020/2021

2023

OMOP Experiment #1

Launch of OHDSI

EHDEN Initiation (Europe)

European OHDSI Symposium

OHDSI COVID-19 Study-a-Thon

EU-Chapters

Standard

Innovative Medicines Initiative

Vision

The European Health Data & Evidence Network (EHDEN) aspires to be the trusted observational research ecosystem to enable better health decisions, outcomes and care

Mission

Our mission is to provide a new paradigm for the discover and analysis of health data in Europe, by building a large-scale, federated network of data sources standardized to a common data model
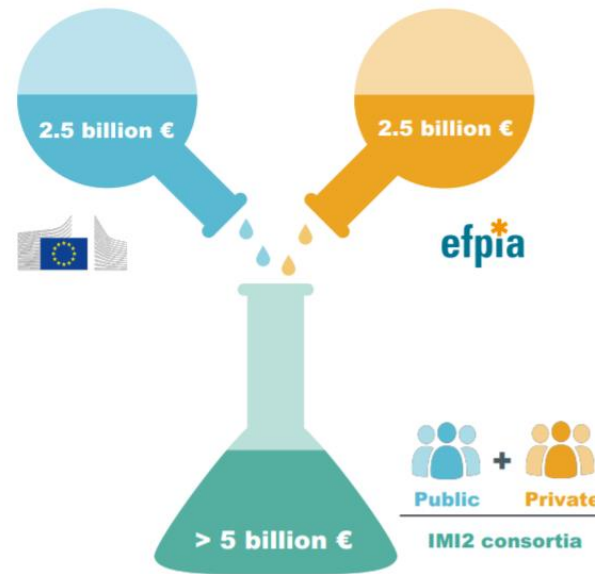
IMI 1 (2008-2014)
2 bn € budget
59 projects

IMI 2 (2014-2024)
3.3 bn € budget
More ambitious, more open & greater scope

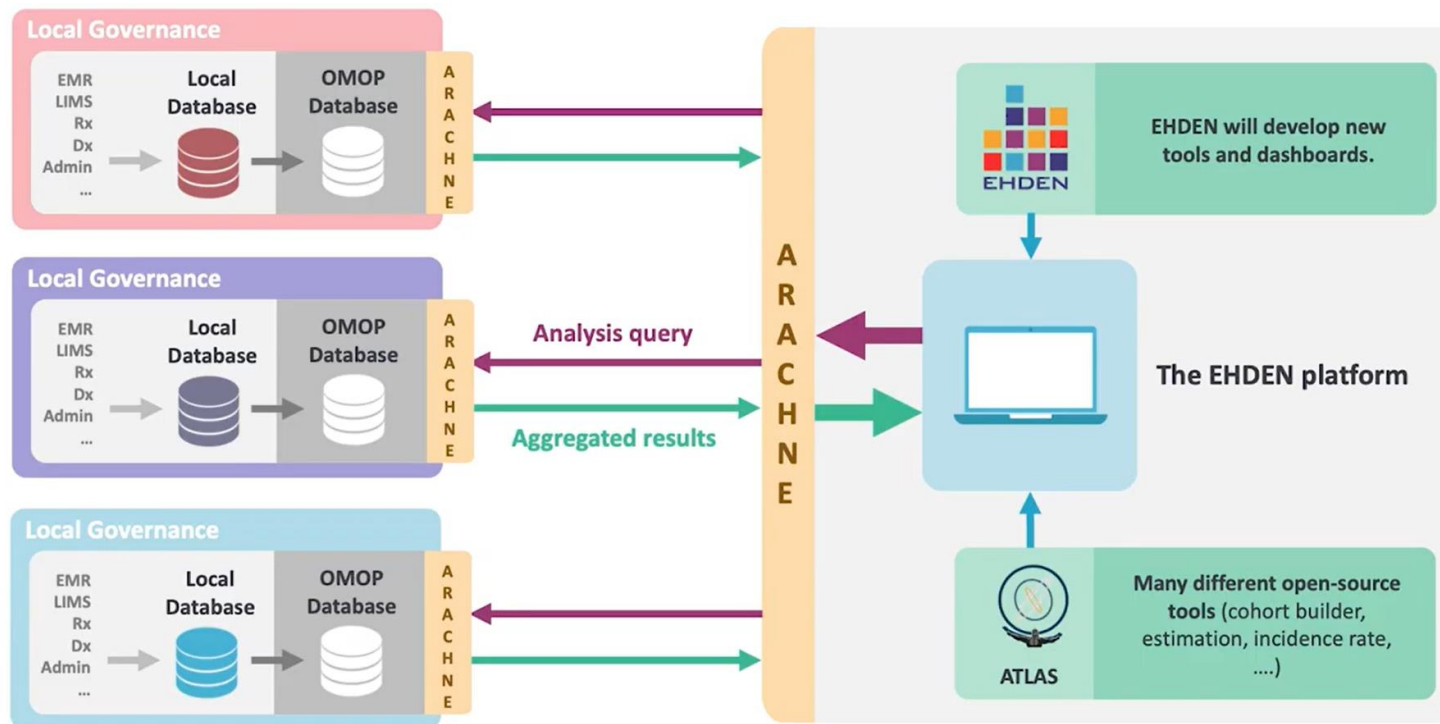### EHDEN Project Facts

Start date: 1st Nov 2018
End date: 30th Apr 2024
Total duration: 66 months

Total budget: 28,917,357€
IMI2 Funding: 14,105,750€
EFPIA contribution: 14,811,607€

=> 187 institutions have joined the network

EHDEN Network

EHDEN is an important data node in the OMOP collaboration

- **EHDEN** represents the OMOP community in **Europe** and is beginning to run studies which can also be **industry-sponsored studies**

- The network today has over **187 data** partners from **29 different countries in Europe**

- Some of the data partners have already completed **data conversion to OMOP**, which makes the EHDEN network a good partner for conducting studies

PIONEER

Part of the Innovative Medicine Initiative's (IMI's) "Big Data for Better Outcomes" (BD4BO) umbrella programme
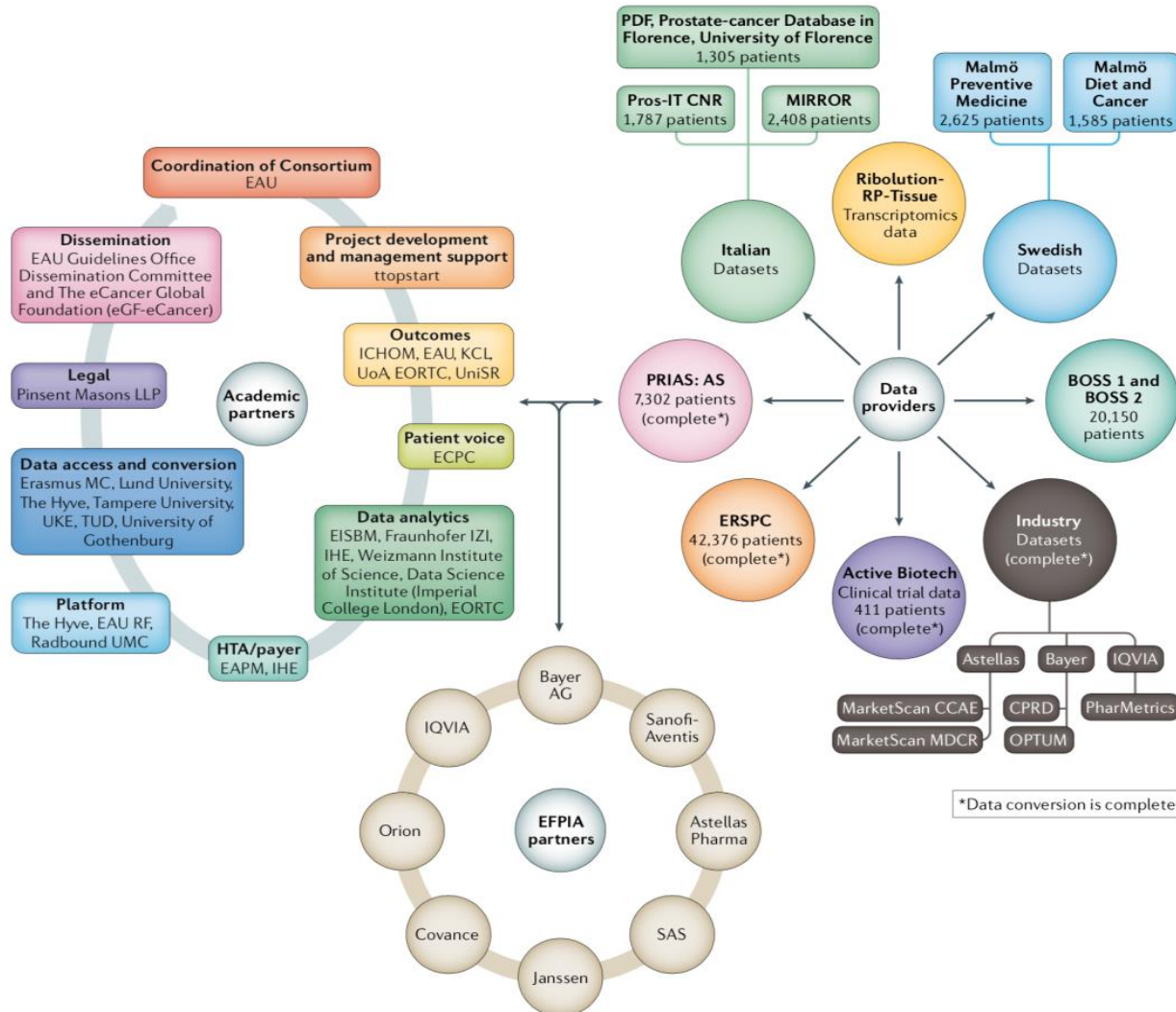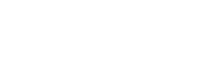

PIONEER is:

- A network of **32 public and private stakeholders** across **9 countries**

- who collaborate closely with internal and external **data providers**

- to build a prostate cancer **Big Data platform.**

Omar et al., Nat. Rev. Urology, 2020. Jun;17(6):351-361.
https://doi.org/10.1038/s41585-020-0324-x

PIONEER Consortium

Validation through EMA

Consistency between source and CDM data

> Clin Pharmacol Ther. 2020 Apr;107(4):915-925. doi: 10.1002/cpt.1785. Epub 2020 Mar 2.

Can We Rely on Results From IQVIA Medical Research Data UK Converted to the Observational Medical Outcome Partnership Common Data Model?: A Validation Study Based on Prescribing Codeine in Children

Gianmario Candore [1], Karin Hedenmalm [1], Jim Slattery [2], Alison Cave [2], Xavier Kurz [2], Peter Arlett [2]

Affiliations — collapse

Affiliations

1 Business Data Department, European Medicines Agency, Amsterdam, The Netherlands.
2 Pharmacovigilance and Epidemiology Department, European Medicines Agency, Amsterdam, The Netherlands.

PMID: 31956997   DOI: 10.1002/cpt.1785
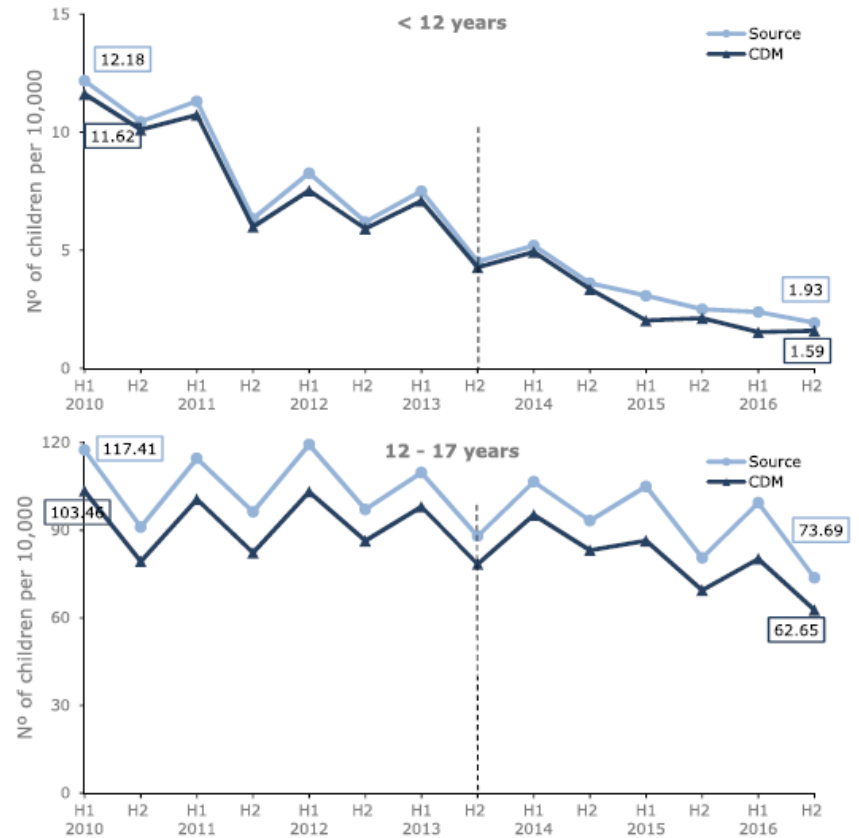
Figure 1-2: Six-monthly prevalence (per 10,000) of codeine prescribing for pain in 0–17 years
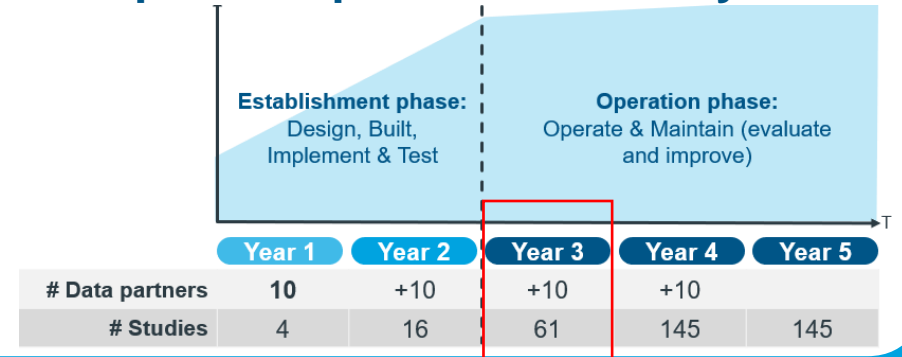
The **D**ata **A**nalysis and **R**eal **W**orld Interrogation **N**etwork (DARWIN EU)

Providing timely and reliable evidence on the use, safety and effectiveness of medicines for human use, including vaccines, from real world healthcare databases across the EU

Overview of DARWIN EU Timelines

- 2021: Project initiation
- 2022: DARWIN EU establishment
- 2023: Developing and using DARWIN EU
- 2024: Full operation mode
- 2025: Leverage the EU Health Data Space

Expected operations over 5 years

Establishment phase: Design, Built, Implement & Test

Operation phase: Operate & Maintain (evaluate and improve)

	Year 1	Year 2	Year 3	Year 4	Year 5
# Data partners	10	+10	+10	+10	
# Studies	4	16	61	145	145

IQVIA Sources of Data

- IQVIA Longitudinal Patient Database (LPD) Belgium
- IQVIA Disease Analyser (DA) Germany
- *Other OMOP databases**
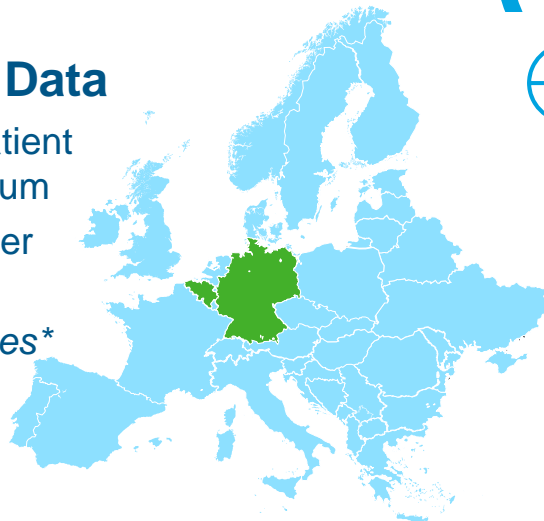
Scientific Questions

- Prevalence of Rare Blood Cancers in EU
- Drug Utilisation of valproate-containing products
- Severe Asthma
- Drug utilisation in patients with depression
- Monitoring prescription of medicines for public health emergencies at risk of shortages

IQVIA helped create DIGICORE in 2020, an international public private partnership to transform **and digitise** precision oncology outcomes research

Members

Academic cancer centres

unicancer

ALLIANCE AGAINST CANCER

Individual cancer centers

Industry

IQVIA

illumina®

DIGital Institute for Cancer Outcomes Research (DIGICORE)

Pan-EU research collaboration to study cancer outcomes, capitalizing on increase in **precision oncology**

Independent European Economic Interest Group (like OECI) with 40 cancer centres today in 17 countries
Founded in 2020

Benefits and rationale

- For **Cancer Centres**, interoperability of cancer data across sites for improved, lower cot translational research

- For **Patients,** broader trial access and in future better outcomes

- For **Industrial Partners:** drive commercial multi – centre, international RWE projects in precision oncology and drive precision trial recruitment

- Grow **clinical evidence base for molecular diagnostic tests** in improving outcomes and accelerate test reimbursement for all vendors

DigiCore - Homepage (digicore-cancer.eu)

IQVIA

DIGICORE launches Digital Oncology Network for Europe (DIGIONE)

Scalable federated approach to digital cancer care quality management – 6 centre pilot

1. Define a **scalable common international minimum dataset for precision oncology**, building from French OSIRIS dataset

2. Achieve **interoperability and high data quality** on that dataset between 6 centres across Europe under GDPR using Cancer OMOP

3. Establish a **federated network between those centres** to allow complex statistics such as risk adjusted Kaplan Meier curves, with appropriate information governance and contracting

4. Work out how to **scale up digitally less mature hospitals** with a **variety of technologies and vendors** in DIGICORE's learning-by-doing community

16 sites applied → 6 centres (with leading KOLs) won	
▪ Frankfurt (Janne Vehreschild)	▪ Oslo (Åslaug Helland)
▪ Leeds (Geoff Hall)	▪ St Luc (Cédric Van Marcke)
▪ Maastricht (Andre Dekker)	▪ San Raffaele (Giovanni Tonon)

IQVIA

Key takeaways

Thank you for your attendance

01   **EHDEN** a large-scale, federated network of data sources standardized to a common data model and trusted observational research ecosystem

02   **PIONEER** a central and federated state-of-the-art Big Data analytic platform for prostate cancer

03   **DARWIN** a real-world evidence from across Europe on diseases, populations and the uses and performance of medicines

04   **Digicore** a pan-EU research collaboration to study cancer outcomes, capitalizing on increase in precision oncology

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Thank you!

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