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**
- **EMA Adoption**
- **EMA DARWIN**
- **FDA Adoption**
- **European OHDSI Symposium**
- **EHDEN Initiation (Europe)**
- **OHDSI COVID-19 Study-a-Thon**
- **EU-Chapters**

**Timeline**:
- 2009: OMOP Experiment #1
- 2013: End of OMOP Experiment
- 2014: Launch of OHDSI
- 2015: First OHDSI Symposium/Network Study Published
- 2017: European Chapter
- 2019: EMA Adoption
- 2018: EMA DARWIN
- 2022: OHDSI COVID-19 Study-a-Thon
- 2023: Standard
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.

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.
PIioneer 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.

https://doi.org/10.1038/s41585-020-0324-x
Validation through EMA

Consistency between source and CDM data

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

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 **Data Analysis and Real World Interrogation Network** (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**

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**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**

- **DIGital Institute for Cancer Outcomes Research (DIGICORE)**
  - Pan-EU research collaboration to study cancer outcomes, capitalizing on increase in precision oncology

**Benefits and rationale**

- **For Cancer Centres**, interoperability of cancer data across sites for improved, lower cost 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)**
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)
- Leeds (Geoff Hall)
- Maastricht (Andre Dekker)
- Oslo (Åslaug Helland)
- St Luc (Cédric Van Marcke)
- San Raffaele (Giovanni Tonon)
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.
Thank you!
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