



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DARWIN EU®

PSC Liver Forum meeting 4 June 2024, Milano, Italy

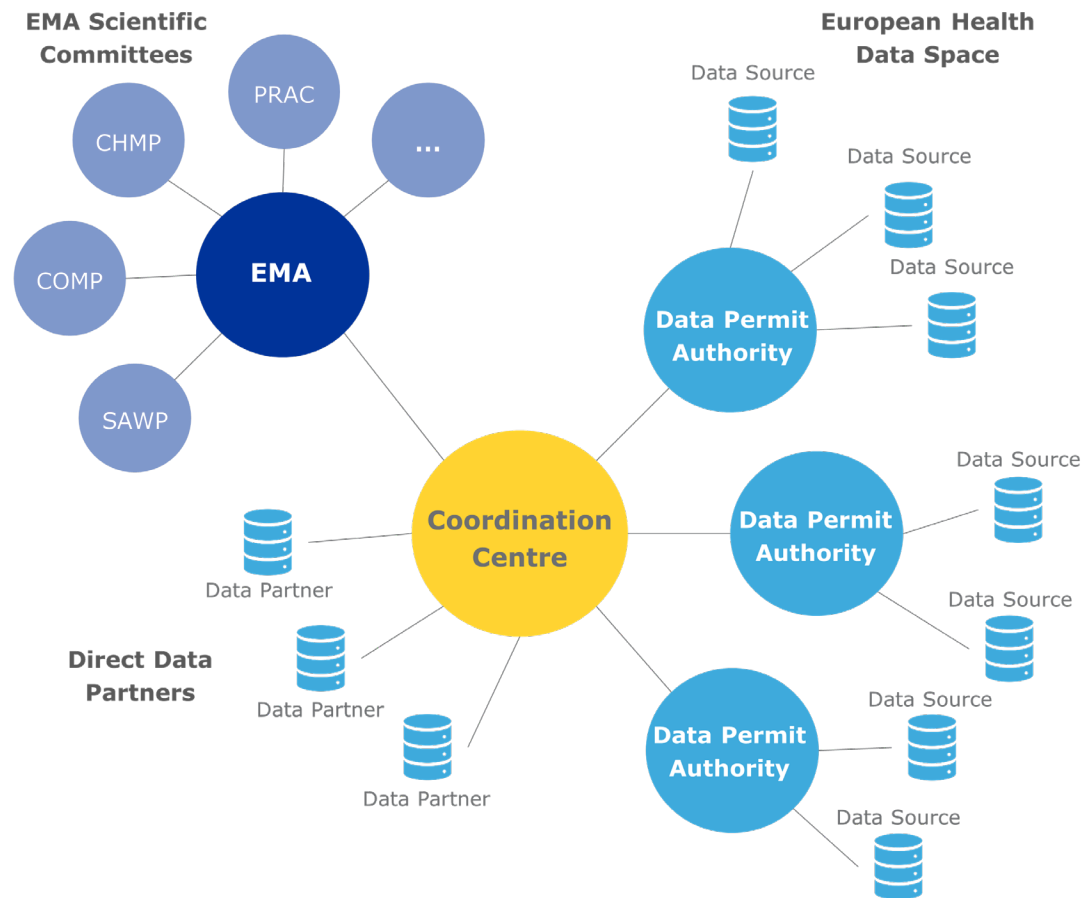
Johannes Taminiau, EMA PDCO HCP member, personal opinion



DARWIN EU® is a federated **network of data, expertise and services** that supports better decision-making throughout the product lifecycle by generating reliable **evidence from real world healthcare data**

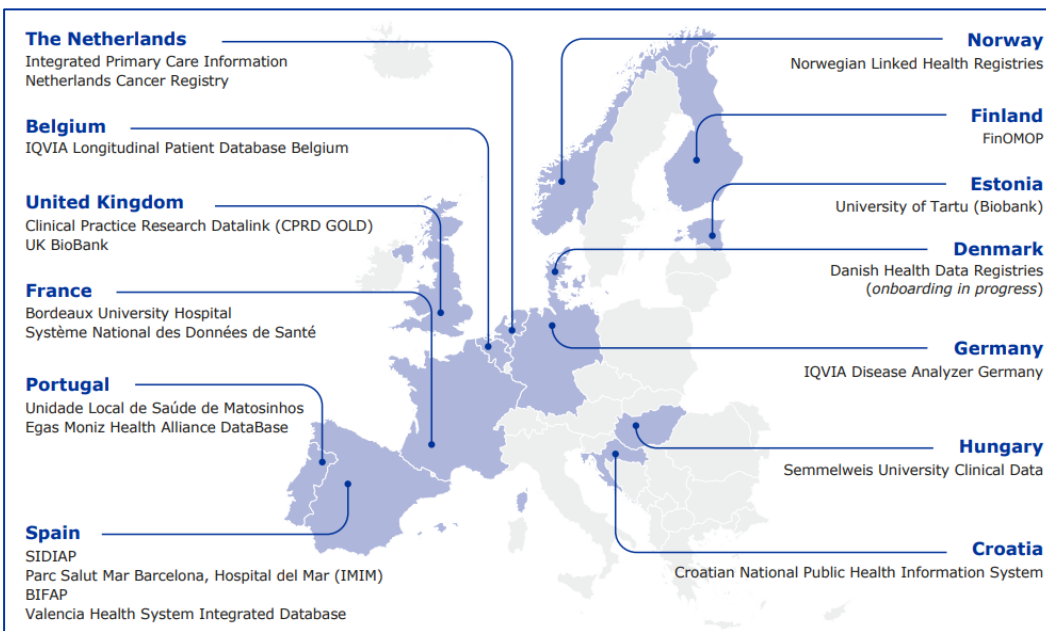
FEDERATED NETWORK PRINCIPLES

- Data stays **local**
- **Use of OMOP Common Data Model** (where applicable) to perform studies in a timely manner and increase consistency of results. (Observational Medical Outcomes Partnership)



DARWIN EU – two years of experience

- DARWIN EU [news announcement](#) & [infographic](#): 2 years establishment completed



DARWIN EU®: Making health data count

DARWIN EU® (Data Analysis and Real-World Interrogation Network) generates real-world evidence (RWE) to support EMA committees and national regulators in the EU in making more data-driven decisions on medicines. RWE comes from the analysis of real-world data, health data collected in routine care settings. It complements data from clinical trials.



How do we use data for the benefit of patients?

Collecting data

Doctors, pharmacists, researchers and other bodies collect data about patients' health and experience when delivering care. The data come in different formats.



Data partners

DARWIN EU® data partners hold or access data through hospitals, registries, insurance claims, biobanks and other sources.

Common data model

A common data model (OMOP) transforms all data into the same format to be analysed using the same analytical code.



Compiling reports

Experts use standardised analytical methods to produce study reports based on the data analysis.



Decision-making

EMA committees and EU regulators use the RWE reports generated to complement other evidence when assessing medicines.



Data-driven regulation

More data-driven regulation will help to deliver safer and more effective medicines to patients.



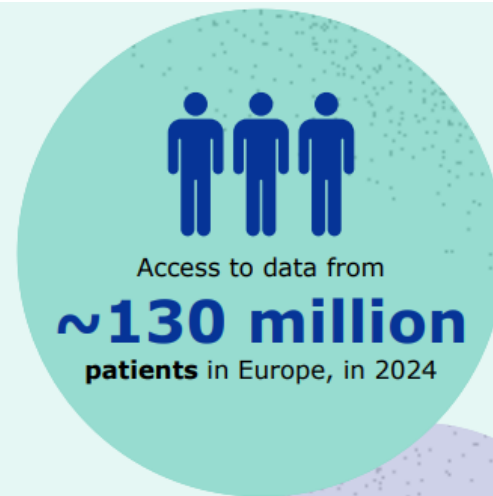
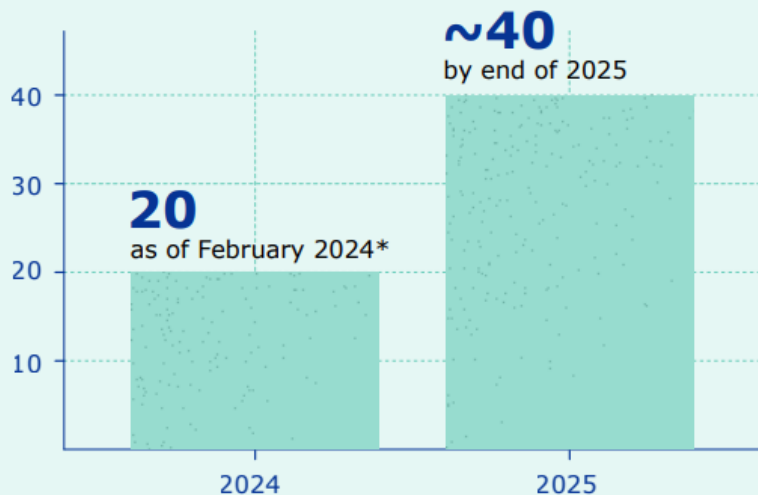


Network and study metrics

Key figures

Since 2022, 20 data partners have been onboarded. In 2024 and 2025, additional ten data partners per year will join the network.

Data partners



3 * in 13 European countries



Use cases: How RWE can support decision-making?

1

Understand the clinical context

✓ Disease epidemiology

✓ Clinical management

✓ Drug utilisation

2

Support the planning and validity of studies

✓ Design and feasibility of studies

✓ Representativeness and validity of completed studies

3

Investigate associations and impact

✓ (Comparative) Effectiveness and safety studies

Impact of regulatory actions

Examples of recently completed studies

1 Understand the clinical context

2 Support the planning and validity

3 Investigate associations and impact

a. Background all-cause **mortality rates in patients with severe asthma aged ≥ 12 years old**
[[EUPAS103936](#)]

CHMP
Complex

b. Drug utilisation study on co-prescribing of **endothelin receptor antagonists (ERAs) and phosphodiesterate-5 inhibitors (PDE-5is)** in pulmonary arterial hypertension.
[[EUPAS106052](#)]

CHMP
OTS

f. **EHDS** coagulopathy in COVID-19 patents

EC / EHDS
Complex

h. Age-specific incidence rates of **RSV-related disease** in Europe
[[EUPAS107708](#)]

ECDC
OTS

i. Use of antivirals for the treatment of chronic **hepatitis B and C.**
[[EUPAS107650](#)]

ECDC
OTS

j. **Natural history** of **dermatomyositis (DM)** and **polymyositis (PM)** in adults and paediatric populations
[[EUPAS107454](#)]

PDCO
OTS

e. Drug utilisation study of **medicines with prokinetic properties** in children and adults diagnosed with gastroparesis

NCA
OTS

k. Treatment patterns of drugs used in adult and paediatric population with **lupus**
[[EUPAS106436](#)]

PDCO
OTS

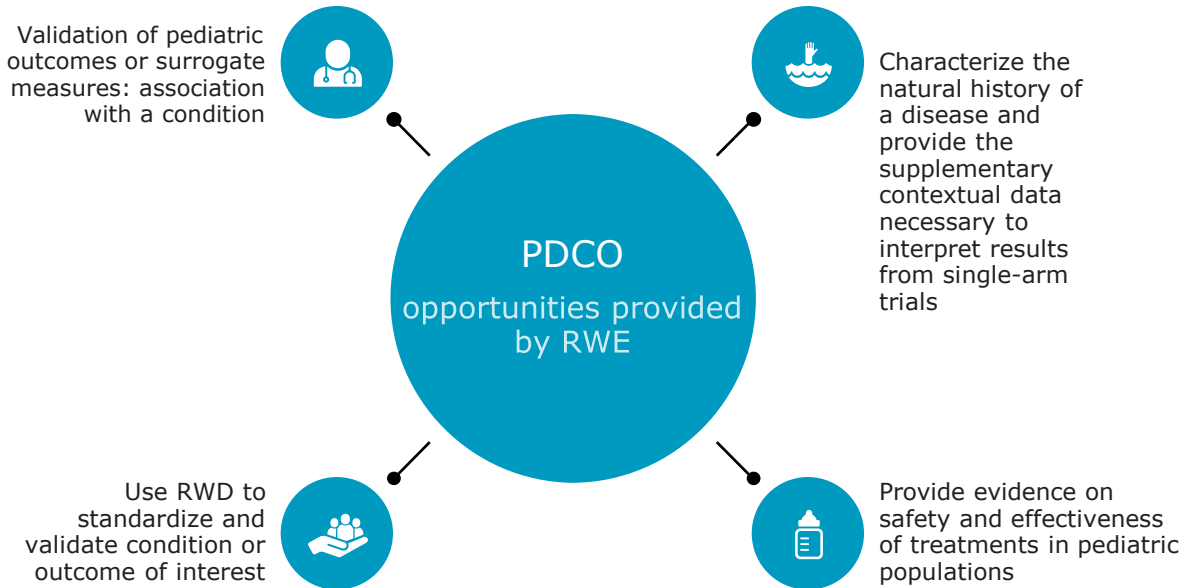
d. Drug utilisation study of prescription **opioids.**
[[EUPAS105641](#)]

PRAC
OTS

g. **Multiple myeloma:** patient characterisation, treatments and survival in the period 2012-2022
[[EUPAS105033](#)]

HTA / Payers
OTS

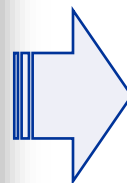
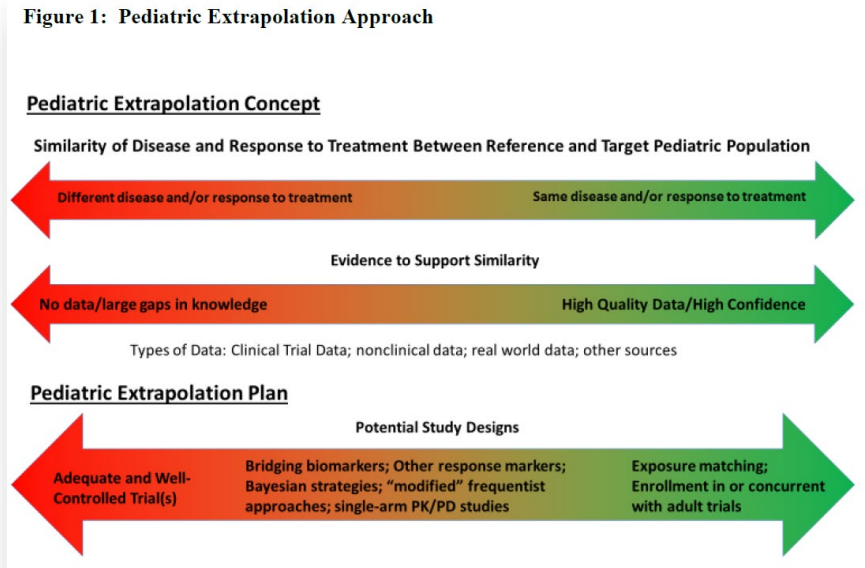
Better get smart about it, quick!



RWE in paediatric research

Paediatric extrapolation framework & how RWE could support

Figure 1: Paediatric Extrapolation Approach



1. Key areas of paediatric extrapolation and how they might map to RWE research questions
 - **Disease similarity**
 - **Response to treatment**
 - **Pharmacology**
2. The type of evidence that could be generated