DARWIN EU®

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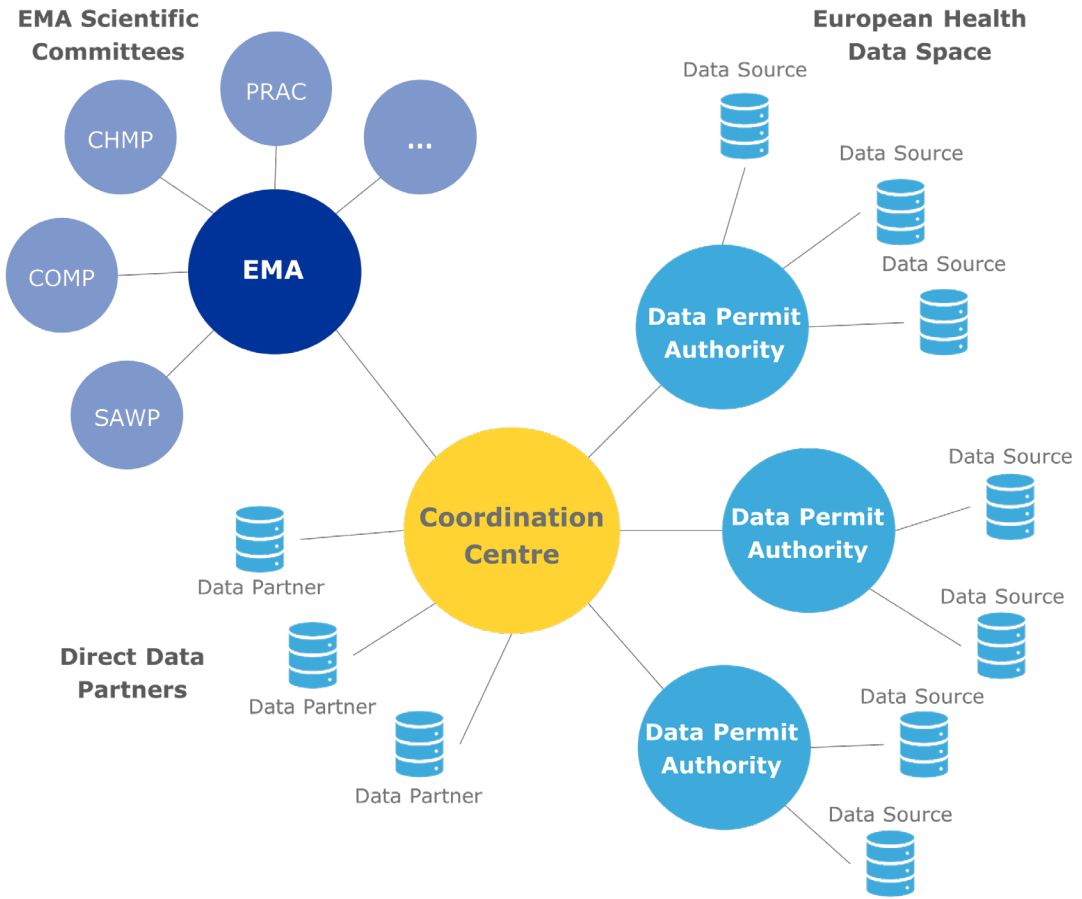
Johannes Taminiau, EMA PDCO HCP member, personal opinion

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**

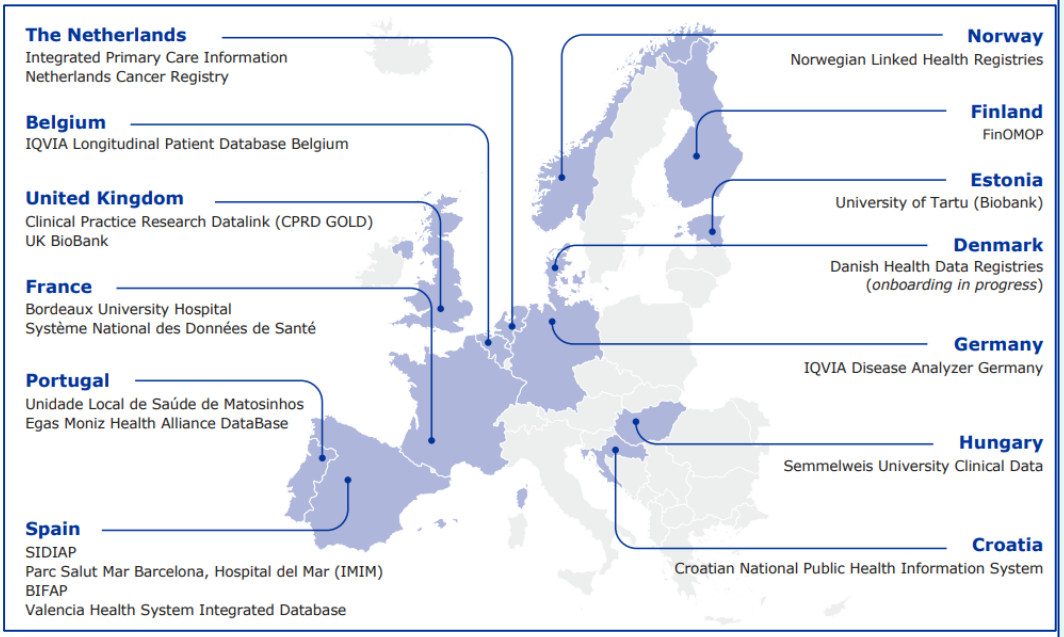


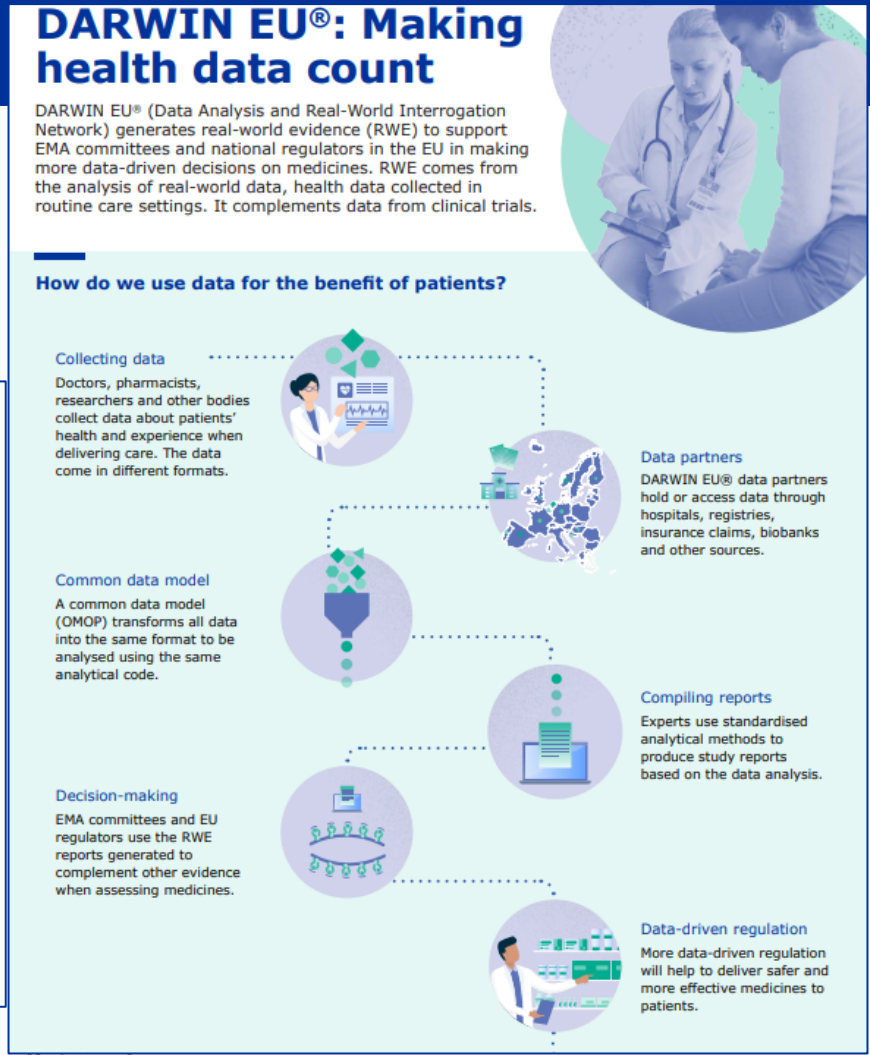
FEDERATED NETWORK PRINCIPLES

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

DARWIN EU – two years of experience

- DARWIN EU news announcement & infographic: 2 years establishment completed



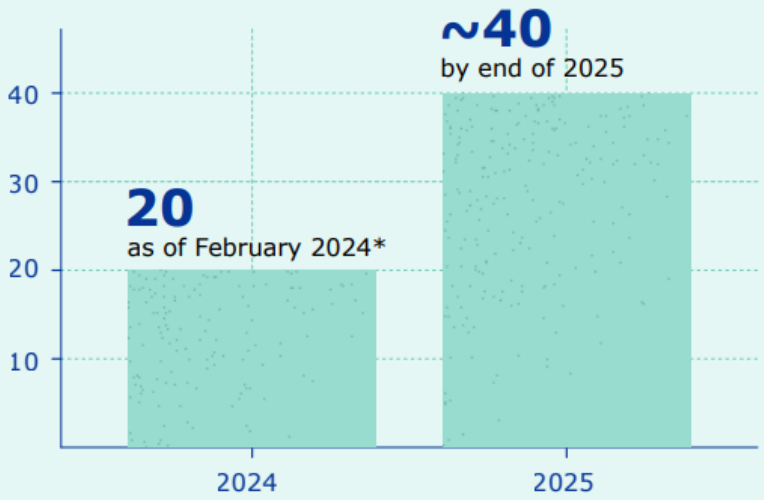


Network and study metrics

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



Access to data from
~130 million
patients in Europe, in 2024

140+
studies delivered per year from 2025

* 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

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

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

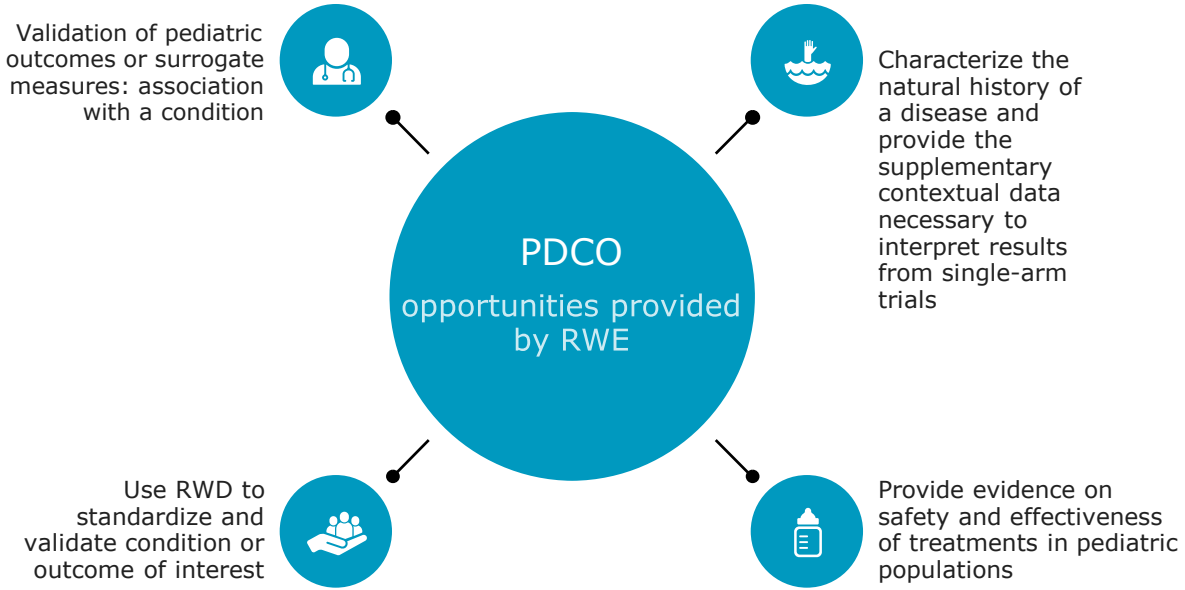
NCA
OTS

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

PDCO
OTS

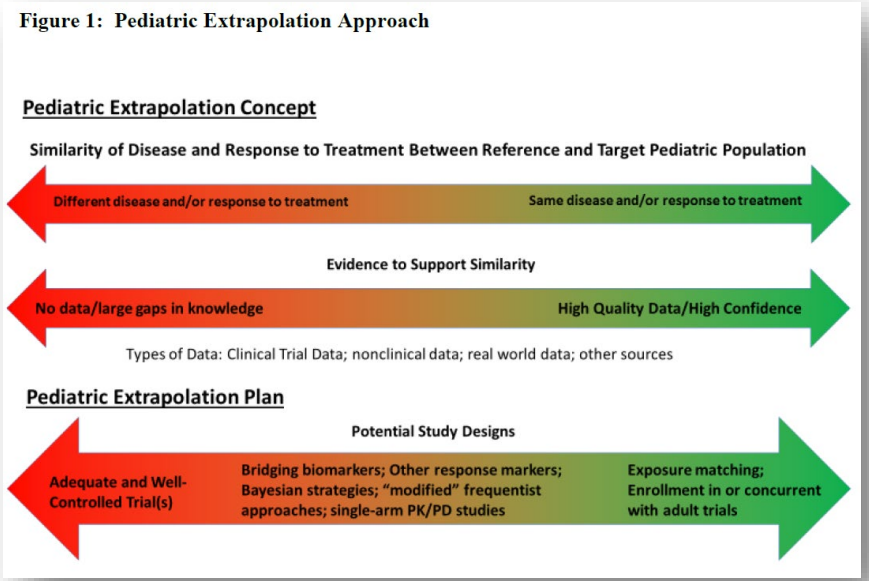
OTS = off-the-shelf study | **completed**

Better get smart about it, quick!



RWE in paediatric research

Paediatric extrapolation framework & how RWE could support



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