

EUROPEAN
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DARWIN EU® update: focus on studies

ENCePP Plenary
22 Nov 2024

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European Medicines Agency, Data Analytics and Methods Taskforce – Real World Evidence

An agency of the European Union



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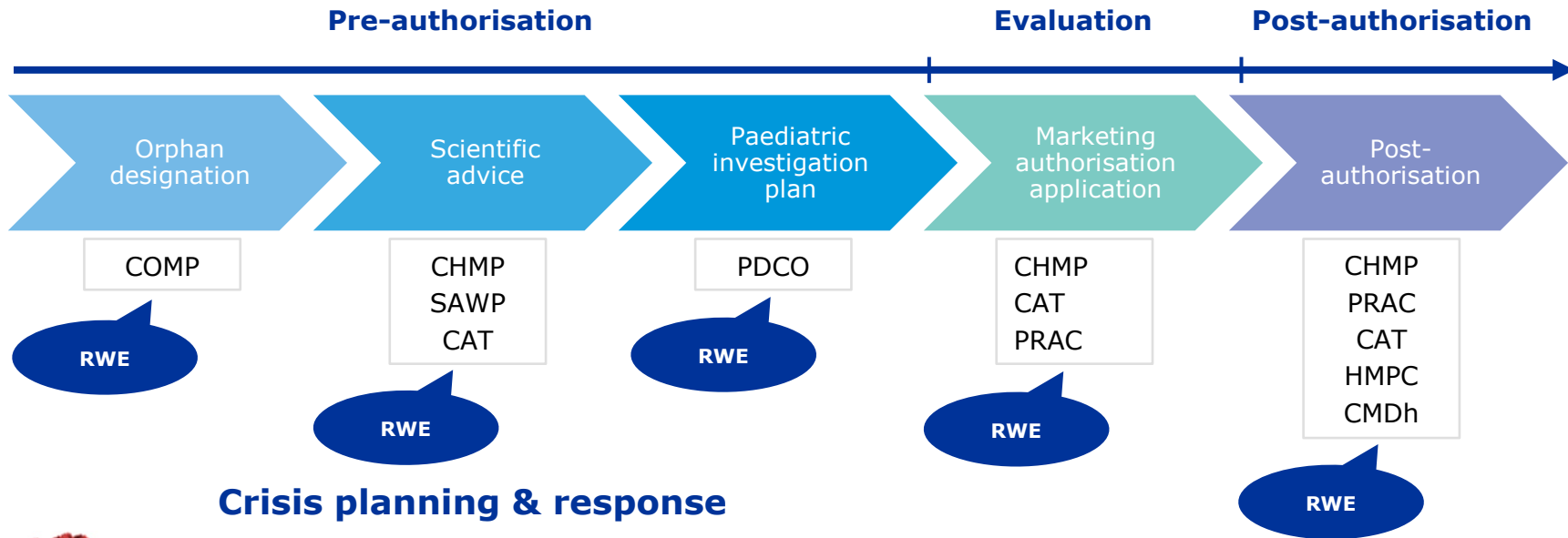
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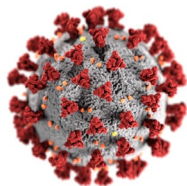
By 2025 the use of Real-World Evidence will have been enabled and the value will have been established across the spectrum of regulatory use cases

- European Medicines Regulatory Network (EMRN) [strategy to 2025](#) -

Demand: RWE use across the medicinal product lifecycle



Crisis planning & response



- Monitoring the use of medicines to predict demand and shortages
- Understanding the disease natural history → development of vaccines and therapeutics
- Provide evidence for repurposing existing medicines
- Monitor the safety and effectiveness of vaccines and therapeutics post-authorisation



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

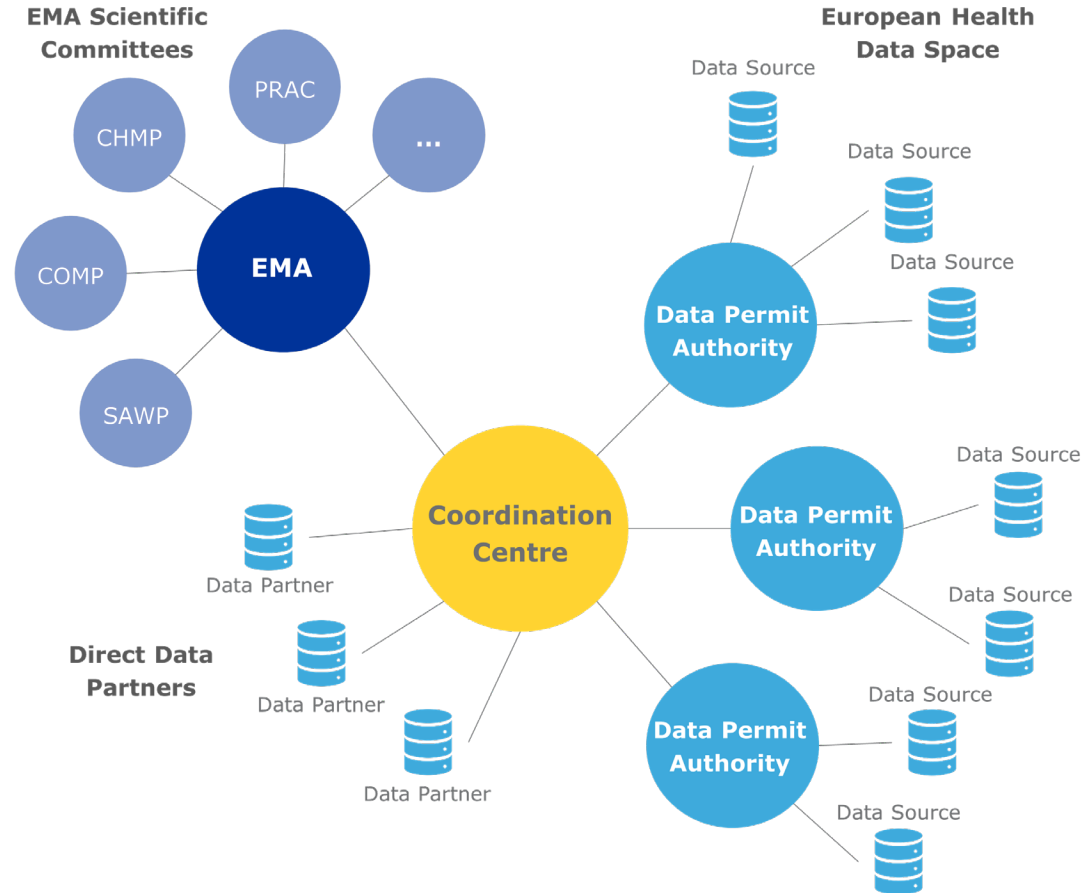
3

Investigate associations and impact

✓ (Comparative) Effectiveness and safety studies

Impact of regulatory actions

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



Off-the-shelf studies

These are mainly characterisation questions that can be executed with a generic protocol. This includes disease epidemiology, for example the estimation of the prevalence, incidence of health outcomes in defined time periods and population groups, or drug utilization studies at the population or patient level.

+ Patient-level characterisation

+ Patient-level DUS analyses

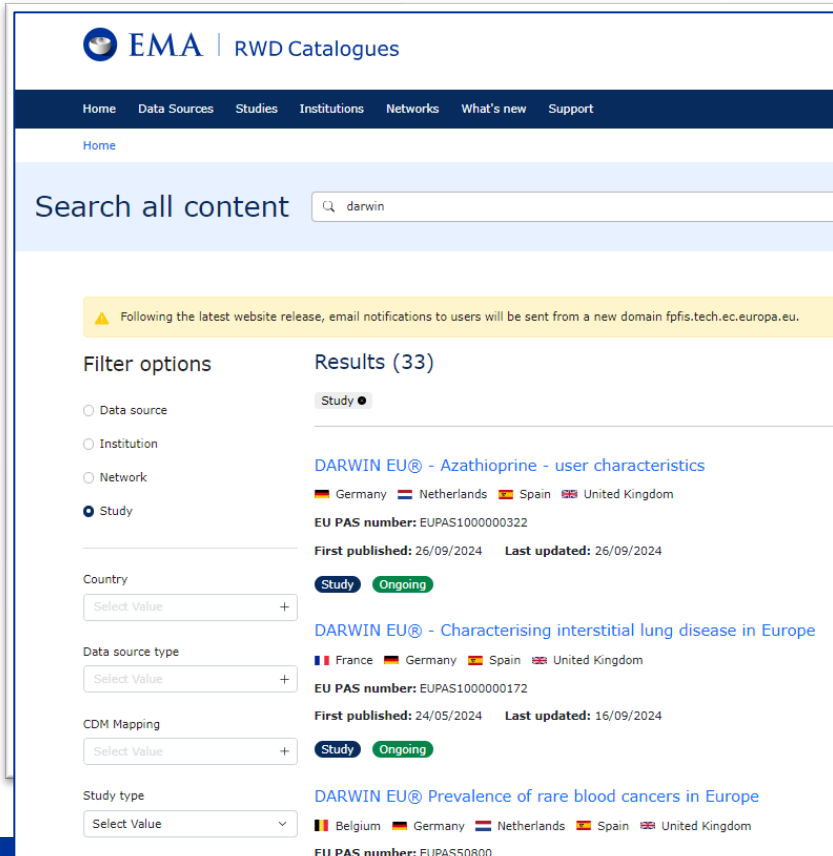
Cohort of newly diagnosed patients or new users of a medicine followed over time. Studies used to characterise disease, patients or use of medicines

+ Population-level DUS analyses

+ Population-level descriptive epidemiology

Used for incidence/prevalence studies. All subjects in the database are eligible based on minimal inclusion criteria.

Study protocols and reports made public



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Study

DARWIN EU® - Azathioprine - user characteristics

Germany Netherlands Spain United Kingdom

EU PAS number: EUPAS1000000322

First published: 26/09/2024 **Last updated:** 26/09/2024

Study **Ongoing**

DARWIN EU® - Characterising interstitial lung disease in Europe

France Germany Spain United Kingdom

EU PAS number: EUPAS1000000172

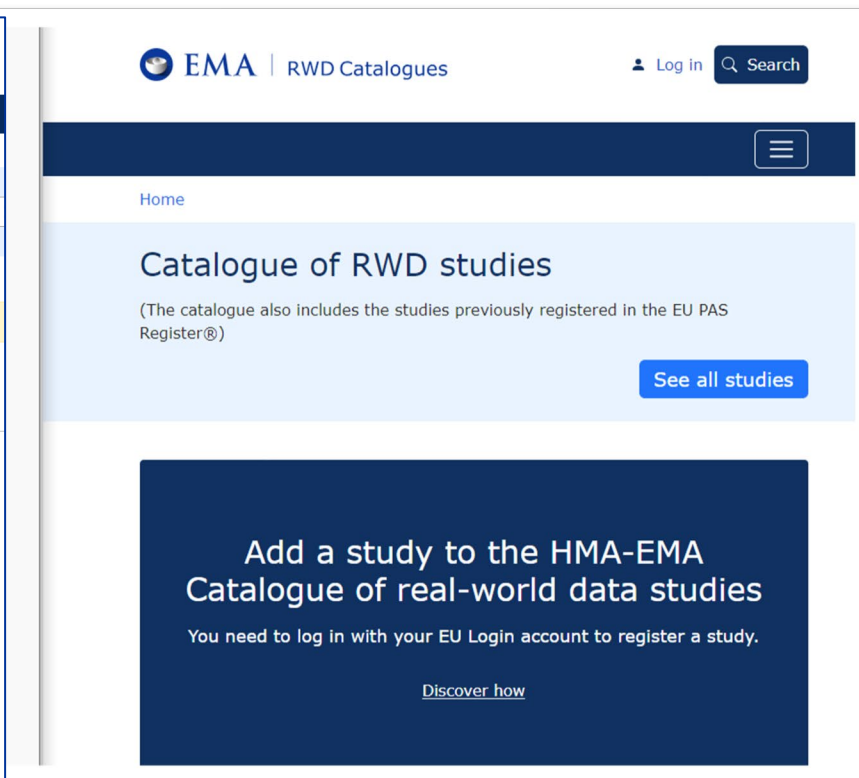
First published: 24/05/2024 **Last updated:** 16/09/2024

Study **Ongoing**

DARWIN EU® Prevalence of rare blood cancers in Europe

Belgium Germany Netherlands Spain United Kingdom

EU PAS number: EUPAS50800



EMA | RWD Catalogues

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Catalogue of RWD studies

(The catalogue also includes the studies previously registered in the EU PAS Register@)

[See all studies](#)

Add a study to the HMA-EMA Catalogue of real-world data studies

You need to log in with your EU Login account to register a study.

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Examples of the breadth of DARWIN EU® studies

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

PRAC
OTS

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

PDCO
OTS

e. CGRP antagonists - Treatment patterns and users characteristics
[EUPAS1000000240](#)

PRAC
OTS

f. Background incidence rates of selected vaccine adverse events of special interest (AESIs) in Europe
[EUPAS1000000254](#)

PRAC
complex

c. Overall survival in patients with advanced or metastatic non-small cell lung (NSCLC**) cancer treated with selected **immunotherapies as first line** of treatment.**
[EUPAS1000000112](#)

HTA Payer
Complex

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

HTA / Payers
OTS

g. Suicidality following exposure to doxycycline
[EUPAS1000000280](#)

PRAC
Complex

h. Azathioprine - user characteristics
[EUPAS1000000322](#)

PRAC
OTS

OTS = off-the-shelf study

completed

Closing remarks

- RWE use is being enabled and established across regulatory use cases → informing regulatory decision making on medicines across their lifecycle
- DARWIN EU completed establishment and scale-up enable this: focus on Data Partners, studies, pilot use cases and developing standard analytical pipelines
- As of 2024: bigger network and higher study volume and shorter timelines for studies



[Data Analysis and Real World Interrogation Network \(DARWIN EU\) | European Medicines Agency \(europa.eu\)](#)



Coordination Centre website: www.darwin-eu.org

For questions to the Coordination Centre, please contact: enquiries@darwin-eu.org



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Related, [Reflection paper on the use of Artificial Intelligence \(AI\) in the medicinal product lifecycle](#)



Thank you for your attention

Further information

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