DARWIN EU® update: focus on studies

ENCePP Plenary
22 Nov 2024

Presented by Andrej Segec
European Medicines Agency, Data Analytics and Methods Taskforce – Real World Evidence

Disclaimer

The presenter does not have any conflict of interests.

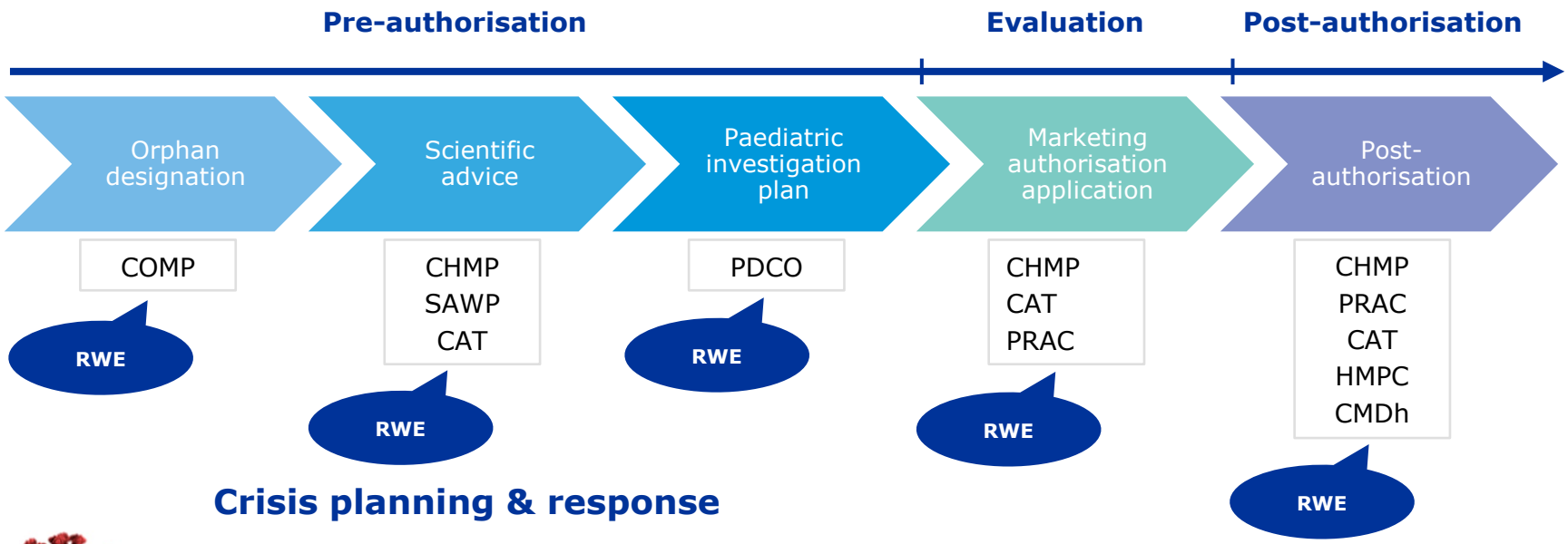
DARWIN EU

EUROPEAN MEDICINES AGENCY

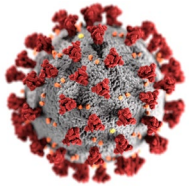
By 2025 the use of Real-World Evidence will have been enabled and the value will have been established across the spectrum of regulatory use cases

- 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

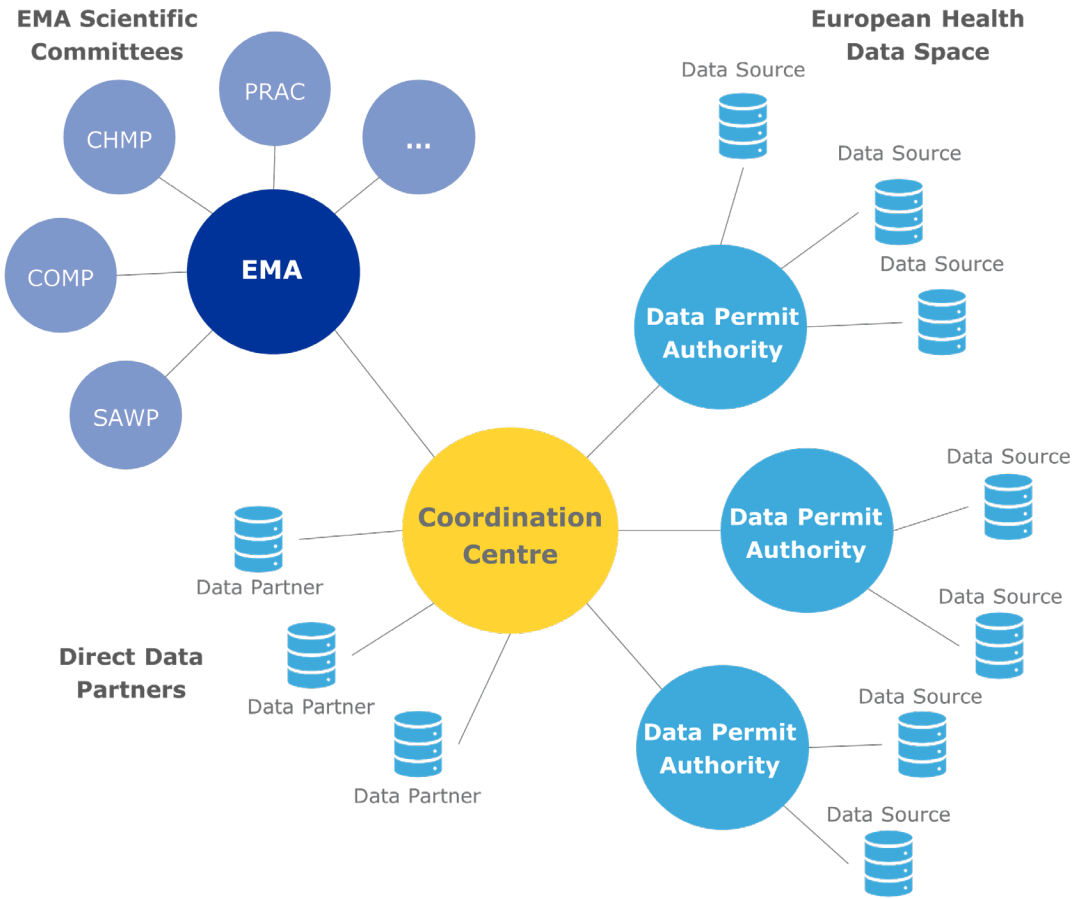
2 Support the planning and validity of studies

- ✓ 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.

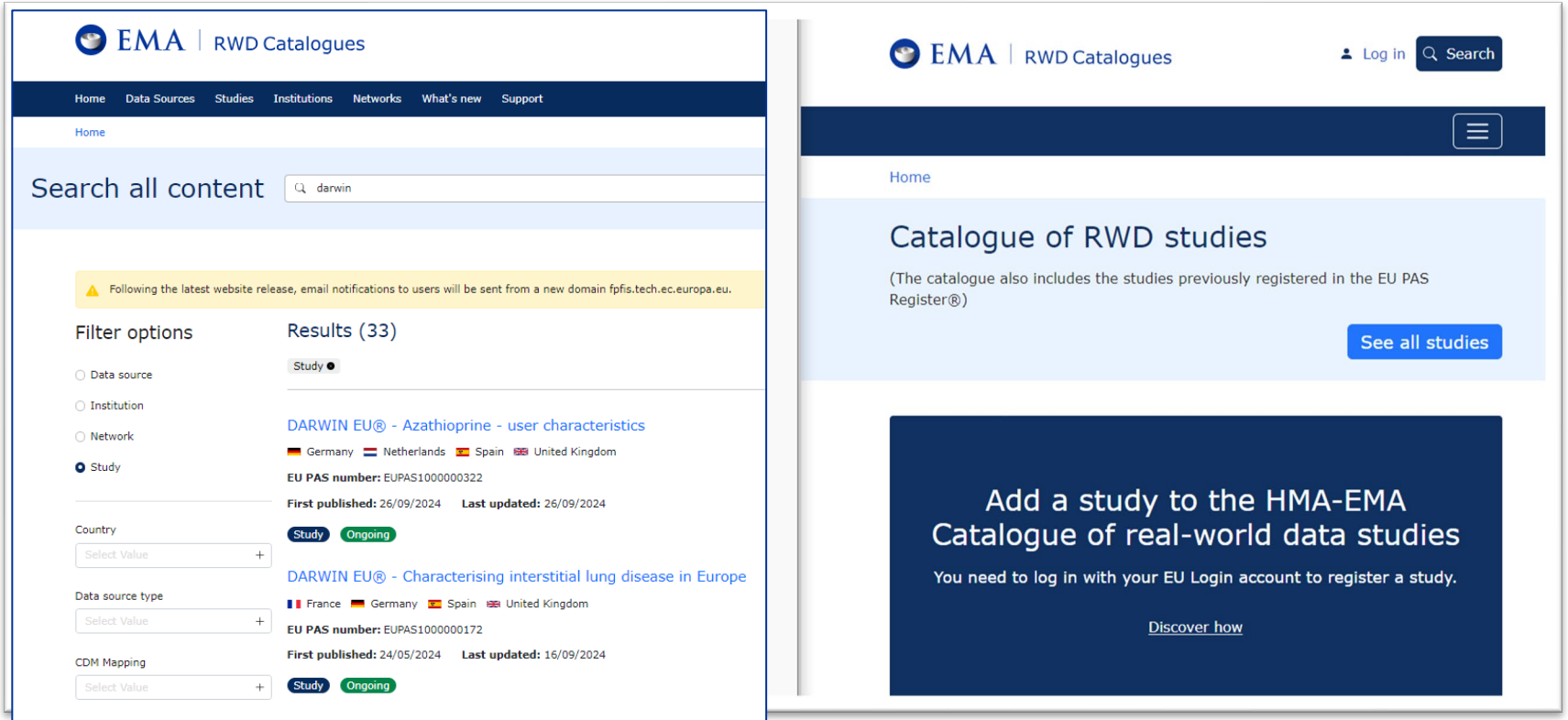
- Patient-level characterisation
- Patient-level DUS analyses

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



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

Subscribe here to receive future issues of the Big Data Highlights

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

Thank you for your attention

Further information

Contact me at Andrej.Segec@ema.europa.eu

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

Follow us on **@EMA_News**