Infosheet

Review of real-world data studies

Experience gained in conducting real-world data (RWD) studies and providing real-world evidence (RWE) to support EMA regulatory decision making since September 2021

Sustainable framework to support scientific evaluations in the EU

Overseen by the Network Data Steering Group (NDSG), EMA and the EU network are working to **establish a sustainable framework enabling better integration of RWD/RWE into regulatory decisions**. EMA has reviewed the experience gained so far in conducting studies with RWD and in providing RWE to support regulatory decisions made by its scientific committees and working parties.

The RWE generation aligns with the European Medicines Regulatory Network (EMRN) strategy to 2028.

Ways to deliver RWE for regulatory purposes in the EU

RWE can come from marketing authorisation applicants/holders, academia or national competent authorities. EMA can also generate RWE thanks to:

EMA studies
Conducted by EMA's experts in collaboration with the requester through direct access to European healthcare data sources.

Framework contracts
Studies commissioned to research organisations and consortia with access to specialised data and expertise.

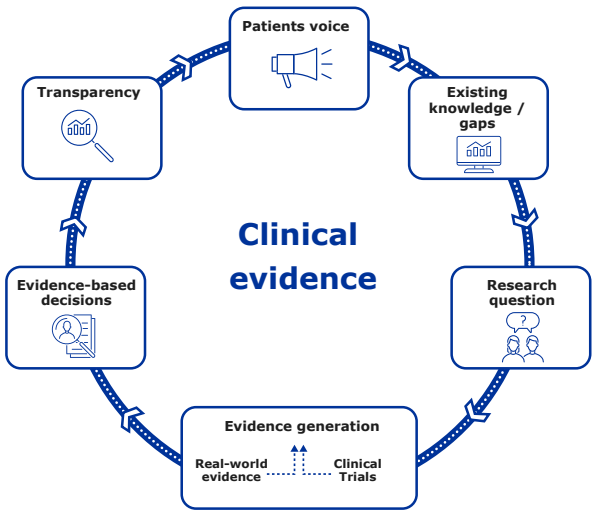
DARWIN EU®
Studies conducted by data partners via a federated network of data, expertise and comprehensive services.

The pathways differ in terms of processes, speed of analysis, capacity and characteristics of data sources.

Clinical Evidence 2030

Building on existing practices, the European medicines regulatory network's vision is that, by 2030, the integration of RWE in clinical evidence generation should follow six guiding principles:

- patients at the centre;
- leverage existing data;
- formulate clear research questions;
- embrace full spectrum of data and methods;
- early, collaborative planning for decision making;
- maintain high levels of transparency.



Source: Clin Pharma and Therapeutics, Volume: 117, Issue: 4, Pages: 884-886, First published: 14 February 2025, DOI: (10.1002/cpt.3596)

The reports

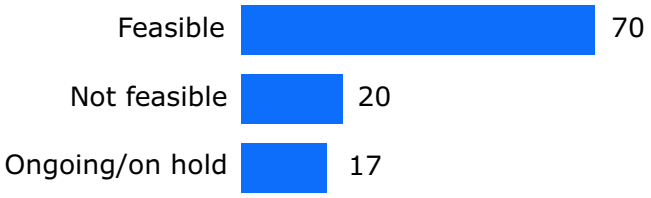
EMA regularly reports on the progress made on RWD studies to support regulatory decision making. The latest report covers the period from 8 February 2024 to 7 February 2025, which corresponds to the third year of DARWIN EU®.

The reports are available on the EMA website.

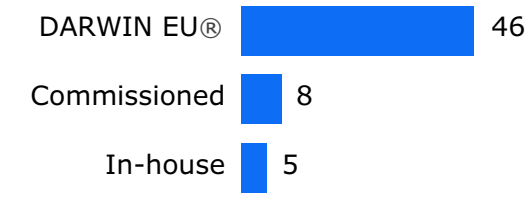
EMA-led RWD studies

From latest reporting period (February 2024 - February 2025):

107 **Research topics addressed**, of which:

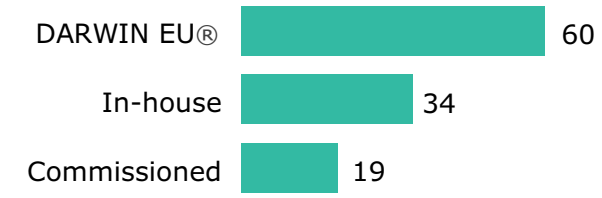


59 **Studies conducted**, of which:



Since start of the reviews (September 2021):

113 **Studies conducted in total**, of which:



Research topics requested by: EMA committees, Working Parties and internal functions, European Centre for Disease Prevention and Control, Health Technology Assessment bodies/payers and European Commission.

Procedures covered: safety signals assessment, periodic safety update report single assessments and applications for paediatric investigation plans.

Other studies: vaccine safety and effectiveness monitoring, shortage prevention and crisis preparedness, EMA geriatric strategy and methodological studies.

Highlights of the latest report

- DARWIN EU® expanded to 30 data partners, with access to data from around 180 million patients from 16 European countries.
- 59 studies were conducted representing a 47.5% increase compared to the previous reporting period.
- The proportion of feasible studies addressing initial requests increased from the previous reporting period (78% vs. 60%).
- The median study duration for DARWIN EU studies is now 4 months from protocol approval to study results.

Recommendations for enabling the use of RWE

A set of recommendations was developed to address identified opportunities and challenges. The third report reflects on the progress made in implementing them, with a list of further actions.

Access to data sources
Wider access to more diverse and complementary data sources.

Accelerate
Strategies to further accelerate RWE generation.

Regulatory context
Anticipate RWE needs of decision makers by identifying research questions earlier.

Capacity and capability
Develop educational and knowledge management sharing tools.

Collaboration and Communication
Close collaboration with decision makers and other stakeholders.

The learnings and recommendations arising from the reviews will further inform the scaling up of DARWIN EU®.