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 be generated by marketing authorisation applicants/holders, academia or national competent authorities and it is an increasingly important component of regulatory decisions.

EMA can generate RWE with the aim to support active regulatory procedures, to improve clinical or methodological understanding and to increase preparedness for shortages or public health emergencies.

This is achieved via two main pathways:

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

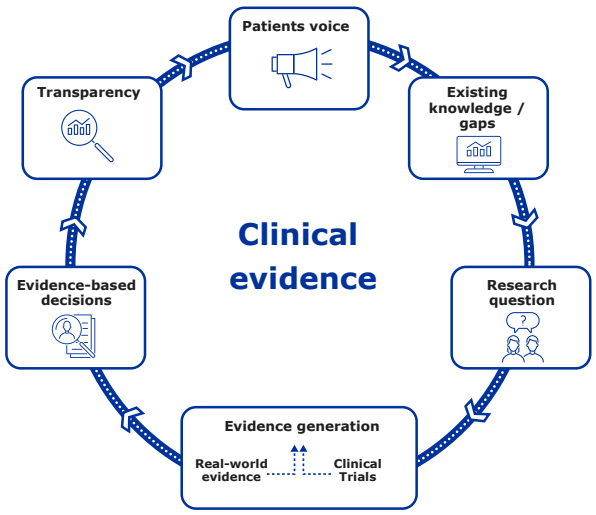
DARWIN EU®
Studies conducted by data partners via a federated network of data, expertise and comprehensive services.

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

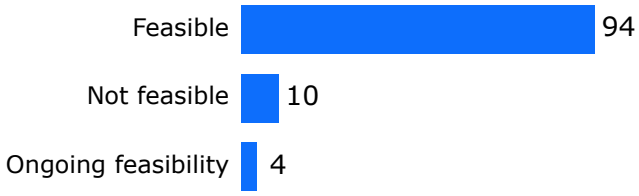
EMA regularly reports on the progress made on RWD studies to support regulatory decision making. The latest report covers the period from 8 February 2025 to 7 February 2026, which corresponds to the third year of DARWIN EU®.

The reports are available on the EMA website.

EMA-led RWD studies

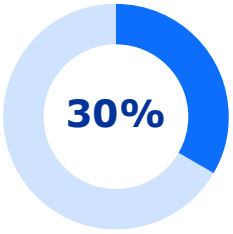
From latest reporting period (February 2025 - February 2026):

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

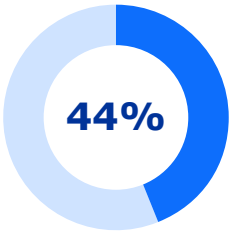


88 **Studies conducted**, of which:

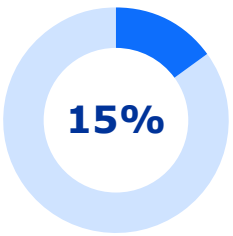
Value of generated RWE



of studies directly supported a formal regulatory decision in an active procedure



improved clinical or methodological understanding



supported preparedness

Highlights of the latest report

- DARWIN EU® expanded to 40 data partners across 18 European countries, covering over 250 million patients, with inclusion of US data.
- Number of completed or ongoing studies increased by 49%.
- Number of complex studies doubled and the first very complex studies were launched.
- Median number of data partners per study doubled (from 3 to 6).

Recommendations for enabling the use of RWE

A set of recommendations was developed to address identified opportunities and challenges. The fourth 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®.