

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 [Big Data Steering Group](#) (BDSG), 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 experience is summarised in two reports, covering the periods from September 2021 to February 2023 and from February 2023 to February 2024.

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 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.

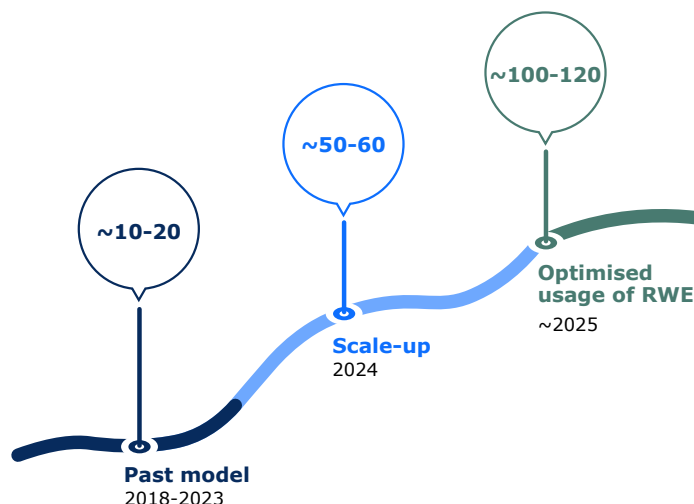
The pathways differ in terms of processes, speed of analysis, capacity and characteristics of data sources.

Transformational journey to fully integrate RWE in EU regulatory decision making

By 2025, the use of real-world evidence will have been enabled and the value will have been established across the full spectrum of regulatory use cases to:

- support the planning and validity of studies performed/submitted by applicants;
- understand the clinical context;
- investigate associations and impact of regulatory decisions.

Number of RWD studies per year:



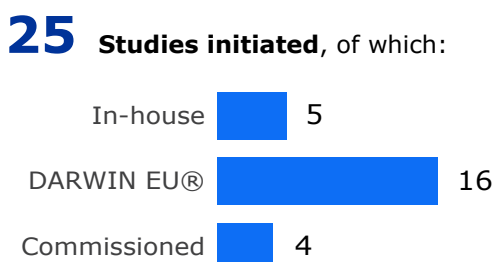
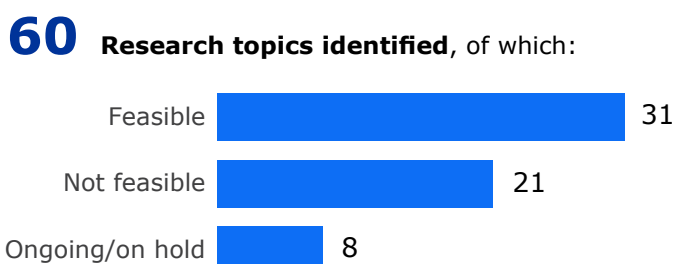
The reports

EMA regularly reports on studies using RWD to support regulatory decision making. The latest report covers the period from 8 February 2023 to 7 February 2024, which corresponds to the second year of DARWIN EU®. It builds on the experience acquired and provides a review of the progress made in delivering on the vision of EU regulators to enable the use of RWE and establish its value for regulatory decision making by 2025.

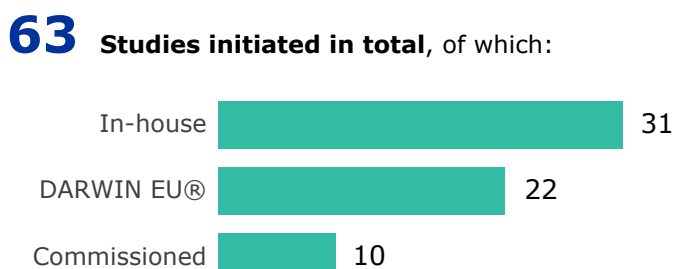
The reports are available on the [EMA website](#).

EMA-led RWD studies

From latest reporting period (Feb 2023 - Feb 2024):



Since start of the reviews (Sep 2021):



The studies mainly addressed research needs of [PRAC](#), [PDCO](#), [CHMP](#), [COMP](#), and [SAWP](#) regarding safety signals, [PSURs](#), applications for paediatric investigation plans and other regulatory procedures. Other studies were conducted outside of regulatory procedures supporting an extended range of stakeholders.

Highlights of the latest report

- DARWIN EU® expanded to 20 data partners, with access to data from around 130 million patients from 13 European countries. It is now the main pathway for the generation of RWE.
- 40 studies ongoing or finalised, including 13 studies to inform vaccine safety and effectiveness related to public health emergencies.
- For the first time, studies were initiated to monitor supply and demand of critical medicines, on herbal substances, for HTA and payer organisations and to support EMA's geriatric medicines strategy.

Recommendations for enabling the use of RWE

A set of recommendations was developed to address identified opportunities and challenges. The second report reflects on the progress made in implementing these recommendations, 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

Close collaboration with decision-makers and other stakeholders.

The learnings and recommendations arising from the reviews will feed into the work of the Big Data Steering Group and further inform the scaling up of [DARWIN EU®](#).