Early stakeholder interaction and advice on RWD and RWE: a scoping review

First published: 11/07/2025

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000669

Study ID

1000000669

DARWIN EU® study

No

Study countries

☐ Netherlands

Study description

Real-World Data (RWD) and Real-World Evidence (RWE) are increasingly being considered in the scientific evaluation of human medicines both globally and within the European regulatory framework.

The European Medicines Agency (EMA) plays a key role in providing scientific advice and support to pharmaceutical companies throughout the drug development process. This support can begin even before marketing authorisation, during the early stages of scientific dialogue related to drug research and regulatory approval.
The Agency engages with a wide range of stakeholders - including small and medium-sized enterprises (SMEs), large pharmaceutical companies, and academic institutions - through various mechanisms. These include specialised working groups and divisions that actively incorporate RWE into their advice.
The outcomes of these engagements vary: some documents remain internal and confidential within the Agency, while others are incorporated into official EMA documents, such as assessment reports, and made publicly available.
This study aims to analyse the content and focus of stakeholder requests, along with the corresponding advice or outcomes provided by EMA during early interactions related to RWD and RWE, by reviewing EMA documents over the past five years (2020–2025).
Through this analysis, the study also aims to identify gaps in how RWD/RWE-related requests are currently addressed during early stakeholder engagement to enhance the quality and consistency of scientific advice. It will also assess how aligned the support provided is across different EMA mechanisms, with the goal of informing strategies for more effective and coherent regulatory collaboration in the future.

Study status

Ongoing

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Networks

Pharmacoepidemiology and Pharmacovigilance Network

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Network

Contact details

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Study timelines

Date when funding contract was signed

Planned: 18/11/2024

Actual: 09/07/2025

Study start date

Planned: 18/11/2024

Actual: 09/07/2025

Date of final study report

Planned: 11/01/2026

Sources of funding

- EMA

Study protocol

DRAFT_Protocol_Early Stakeholder interaction on RWE.pdf(157.85 KB)

Regulatory

Was the study required by a regulatory body?

Unknown

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Other

Study type:

Not applicable

Scope of the study:

Scoping review (including literature review)

Data collection methods:

Secondary use of data

Study design:

Scoping reviews are a fast-growing evidence synthesis approach for providing an overview across a variety of fields, so their main purpose is usually to describe and map a body of literature in terms of general characteristics.

Main study objective:

This study aims to analyse the content and focus of stakeholder requests, along with the corresponding advice or outcomes provided by EMA during early

interactions related to RWD and RWE, by reviewing EMA documents over the past five years (2020–2025).

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s), other

“Grey literature” is defined as what “is produced on all levels of government, academics, business and industry in print and electronic formats, but which is not controlled by commercial publishers”. So, many of EMA unofficial and confidential documents can be described as types of “grey literature”.

Data sources (types)

Other

Data sources (types), other

We will include documents stored in official repositories of EMA produced between 1 January, 2020 and 01 March, 2025.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

No

Check completeness

No

Check stability

No

Check logical consistency

No

Data characterisation

Data characterisation conducted

Not applicable