

Patient Experience Data in Non-Interventional Studies Supporting EMA Marketing Authorisation Applications between 2018 and 2023

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Study

Ongoing

Administrative details

EU PAS number

EUPAS1000001011

Study ID

1000001011

DARWIN EU® study

No

Study countries



Netherlands

Study description

This was a retrospective analysis of European Medicines Agency (EMA) regulatory documents to characterise the use of Patient Experience Data (PED) in Non-Interventional Studies (NIS) included in initial marketing authorisation applications (MAAs) and extensions of indication (Eols) submitted between 2018 and 2023

Study status

Ongoing

Research institutions and networks

Institutions

Pharmacoepidemiology and Pharmacovigilance Unit,
Department of Pharmacy, Pharmacology and Health
Technologies, Faculty of Pharmacy University of
Lisbon (FFUL)

 Portugal

First published: 01/06/2010

Last updated: 07/11/2025

Institution

Educational Institution

ENCePP partner

European Medicines Agency (EMA)

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Contact details

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Planned: 01/02/2025

Actual: 15/03/2025

Study start date

Planned: 15/03/2025

Actual: 15/03/2025

Data analysis start date

Planned: 01/06/2025

Actual: 01/06/2025

Date of final study report

Planned: 01/05/2026

Study protocol

[PED AR Protocol_V5.1.pdf](#) (415.86 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Other

Study topic, other:

Patient Experience Data

Study type:

Not applicable

Study design:

Retrospective descriptive analysis

Main study objective:

The primary objective of this study is to characterise the use of PED in non-interventional NIS submitted to support regulatory decision-making within initial marketing authorisation applications (MAAs) and extensions of indication (Eols) incorporating real-world data (RWD) and assessed by the European Medicines Agency (EMA) between 2018 and 2023. This includes describing the regulatory lifecycle stage (pre- or post-authorisation), study design, objectives, data sources, and the types of PED collected, as well as the instruments and methodologies used

Study design details

Setting

Not applicable

Interventions

Not applicable

Comparators

Not applicable

Outcomes

Not applicable

Data analysis plan

Regulatory documents of eligible submissions were screened to identify NIS including PED, as well as patient engagement (PE) activities. Data were extracted on study and PED characteristics. Descriptive statistics will be used to summarise the characteristics of PED use across the identified NIS. Quantitative variables will be analysed descriptively, including counts, percentages, means and medians. Statistical analyses will be performed using Excel

Summary results

250 applications were screened. 42 (17%) submissions included PED in NIS or PE activities. Most of these submissions concerned antineoplastic and immunomodulating agents and frequently involved orphan medicinal products. Across all these submissions, a total of 47 NIS using PED and 6 PE activities were identified, with most NIS conducted in the post authorisation setting, often as additional pharmacovigilance activities. PROs were the most common form of PED, primarily assessing quality of life, while patient preference studies were less frequently used.

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

Regulatory documents including assessment reports from the Committee for Medicinal Products for Human Use (CHMP), Risk Management Plans (RMPs), and, where applicable, protocols and assessment reports of post-authorisation studies.

Data sources (types)

[Vaccination registry](#)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Not applicable