Patients and HCP understanding on additonal monitoring

First published: 29/01/2021

Last updated: 29/01/2021

Study Finalised

Administrative details

EU PAS number

EUPAS39272

Study ID

39273

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] Bulgaria
- [ ] Cyprus
- [ ] Denmark
- [ ] Estonia

- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Iceland
- [ ] Ireland
- [ ] Italy
- [ ] Latvia
- [ ] Liechtenstein
- [ ] Lithuania
- [ ] Luxembourg
- [ ] Netherlands
- [ ] Norway
- [ ] Portugal
- [ ] Romania
- [ ] Slovakia
- [ ] Slovenia
- [ ] Sweden
- [ ] United Kingdom

Study description

The objective of this survey was to assess (a) attitudes towards ADR reporting and reasons for not reporting an ADR and (b) awareness of additional monitoring (AM) among health care professionals (HCPs), patients or their careers in EU countries

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Justina Januskiene ICU@ema.europa.eu

Study contact

ICU@ema.europa.eu

Primary lead investigator

Justina Januskiene

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/01/2017

Actual: 01/01/2017

Study start date

Planned: 01/09/2017

Actual: 01/09/2017

Date of final study report

Planned: 21/04/2020

Actual: 21/04/2020

Sources of funding

- EMA

Regulatory

Was the study required by a regulatory body?

No

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:

To assess attitudes towards adverse drug reactions (ADR) reporting and reasons for not reporting an ADR and awareness of additional monitoring (AM) among HCPs, patients or their careers

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Assessment of awareness of additional monitoring

Data collection methods:

Primary data collection

Main study objective:

To assess (a) attitudes towards ADR reporting and reasons for not reporting an ADR and (b) awareness of AM among HCPs, patients or their careers in EU countries

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Survey questionnaire

Population studied

Short description of the study population

Health care professionals (HCPs), patients or their careers in EU countries.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

2918

Study design details

Outcomes

To assess (a) attitudes towards ADR reporting and reasons for not reporting an ADR and (b) awareness of AM among HCPs, patients or their careers in EU countries

---

Data analysis plan

Survey responses analysis

Documents

Study results

Manuscript - Additional monitoring.pdf (874.51 KB)

Study publications

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 sources (types)

Other

Data sources (types), other

Online Survey

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

Unknown

Data characterisation

Data characterisation conducted

No