# Patients and HCP understanding on additonal monitoring

**First published:** 29/01/2021

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Study Finalised

## Administrative details

**PURI**

https://redirect.ema.europa.eu/resource/39273

**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

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**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

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**Study status**

Finalised

# Research institutions and networks

## Institutions

### European Medicines Agency (EMA)

**First published:** 01/02/2024

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**Institution**

# Contact details

**Study institution contact**

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**Study contact**

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**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

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**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

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**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

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**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

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**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.

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**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)

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**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

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**Data analysis plan**

Survey responses analysis

## Documents

**Study results**

Manuscript - Additional monitoring.pdf(874.51 KB)

**Study publications**

Januskiene J, Segec A, Slattery J, Genov G, Plueschke K, Kurz X, Arlett P. What...

# Data management

## 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