Medication Errors – a characterisation of spontaneously reported cases in EudraVigilance

First published: 09/01/2018

Last updated: 31/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS22214

Study ID

22246

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Medication Errors – a characterisation of spontaneously reported cases in EudraVigilance

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

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Primary lead investigator

Victoria Newbould

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 09/02/2006

Actual: 09/02/2006

Study start date
Planned: 01/01/2002

Actual: 01/02/2002

Date of final study report
Planned: 01/06/2017

Actual: 01/06/2017

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:

Medication errors

Study type:

Not applicable

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

Characterisation of cases in database

Main study objective:

This study aims to characterise spontaneously reported cases of medication errors in EudraVigilance over the period 2002-2015 before the release of European Union good practice guidance.

Population studied

Short description of the study population

Spontaneous case reports in the EudraVigilance Post-Authorisation Module were used. Valid case reports include, at a minimum, an identifiable reporter, an identifiable patient, and at least one drug and one adverse drug reaction.

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)

- Adolescents (12 to < 18 years)
- 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

0

Study design details

Data analysis plan

Cases reports were identified through the adverse reaction section where a MedDRA® term is reported and included in the Standardised MedDRA® Query (SMQ) for medication errors. These case reports were further categorised by MedDRA® terms, geographical region, patient age group and Anatomical Therapeutic Chemical classification system of suspect medicinal product(s).

Documents

Study publications

Newbould V, Le Meur S, Goedecke T, Kurz X. Medication errors: a characterisatio...

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

EudraVigilance

Data sources (types)

Spontaneous reports of suspected adverse drug reactions

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

Unknown