Product identification of biologicals in ADR reports received from European clinical practice

First published: 20/12/2016

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS16909

Study ID

16910

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

The aim of this study is to assess the level of precise identification of biologicals up to the product level in ADR reports received from European clinical practice.

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

Vermeer Niels

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/05/2016

Actual: 01/05/2016

Study start date
Planned: 01/07/2016

Actual: 01/07/2016

Data analysis start date
Planned: 01/09/2016

Actual: 01/09/2016

Date of final study report
Planned: 01/04/2017

Actual: 01/04/2017

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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

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

Assess quality of ADR reports in EudraVigilance

Data collection methods:

Secondary use of data

Main study objective:

To assess the level of precise identification of biologicals up to the product level in ADR reports received from European clinical practice

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Case-series

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

EPOETIN ALFA

ETANERCEPT

INFLIXIMAB

HUMAN NORMAL IMMUNOGLOBULIN

INTERFERON BETA-1A

INSULIN GLARGINE

FILGRASTIM

OCTOCOG ALFA

SOMATROPIN

FOLLITROPIN ALFA

Population studied

Short description of the study population

The study explored identifiability and traceability of biologicals in spontaneous ADR reports received from the European clinical practice between January 2011 and June 2016.

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

999999

Study design details

Outcomes

The product identification – the extent to which a single reported product is traceable up to the specific manufacturer – will be determined for each reported biological, Batch traceability, differences in ADR reporting patterns between similar and related products

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Data analysis plan

The number and percentage of precise product identification will be calculated for all reported biologicals, and results will be stratified according to the biological category (innovator, biosimilar, related biological product), the product class, the drug role code (suspected/ concomitant), and primary reporting source. In addition, the overall batch traceability may be explored for the reported biologicals, including the temporal trends herein, and factors determining the traceability. Lastly, ADR reporting patterns (e.g. case characteristics, including type of and seriousness of ADRs, temporality of reporting, etc.) may be compared between similar and reference products.

Documents

Study publications

Vermeer NS, Giezen TJ, Zastavnik S, Wolff-Holz E, Hidalgo-Simon A. Identi

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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

No