RRA-19284 Survey of the Effectiveness of the DARZALEX® Educational Materials Regarding the Minimization of Risk of Interference for Blood Typing with Daratumumab

First published: 02/08/2017

Last updated: 11/12/2019

Study Finalised

Administrative details

EU PAS number

EUPAS20119

Study ID

32714

DARWIN EU® study

No

Study countries

Austria

Denmark

Finland
France
Germany
Hungary
Norway
Slovakia
Spain
Sweden
Switzerland

Study status

Finalised

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Edmond Chan

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 22/02/2018

Actual: 22/02/2018

Study start date
Planned: 01/09/2018

Actual: 25/09/2018

Date of final study report
Planned: 30/06/2019

Actual: 26/08/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Janssen

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The objective of this survey is to determine the effectiveness of the educational materials related to daratumumab blood transfusion management.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Survey Questionnaire

Study drug and medical condition

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

DARATUMUMAB

Population studied

Short description of the study population

Health Care Professionals and blood transfusion management department personnel who have received educational materials related to daratumumab blood transfusion management.

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

803

Study design details

Data analysis plan

Data Collecting and Sample:The sampling units are HCPs associated with transfusion departments and non-transfusion HCPs who work closely with daratumumab administration in targeted countries. They will be sampled among lists of haematologists, oncologists, hospital pharmacists and nurses and other specialties. QuintilesIMS will check in its databases to obtain information. HCPs will be randomly selected from the list.Statistical Analysis:The statistical analysis of the data will be carried out using the software SAS® environment Windows™ V9.4 (SAS Institute, North Carolina, USA).Quantitative variables will be described by the usual statistics: staffing (number of knowledgeable data, number of missing values), average, standard deviation, median, minimum, maximum, 1st and 3rd quartiles

Data management

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

A survey of Health Care Professionals and blood transfusion management department personnel

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