Mabthera Drug Utilisation Study and Patient Alert Card Evaluation in Non-Oncology Patients in Europe: An infusion Centre Based Approach (Mabthera DUS)

First published: 04/01/2016

Last updated: 02/07/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS11957

Study ID

24913

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Germany
- ☐ Italy

Spain

United Kingdom

Study description

follow-up measures (FUMs) following approval of Variation EMEA/H/C/165/II/65 forMabThera use in RA (1) FUM no. 68 (Clinical): Drug Utilisation Study (DUS) to AssessOff-Label Use and (2) FUM No, 71.1 (Pharmacovigilance): Evaluation of Receipt, Use, and Impact of the Patient Alert Card (PAC) on Infections, Including Progressive Multi-focal Leukoencephalopathy (PML).

Study status

Finalised

Research institutions and networks

Institutions

Real World & Late Phase Research (RWLPR), Quintiles

France

First published: 20/03/2015

Last updated: 20/08/2024

Institution **Other**

Contact details

Study institution contact

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Study contact

global.clinical_trial_registry@roche.com

Primary lead investigator

Pierre ENGEL

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/08/2015

Actual: 15/12/2015

Study start date

Planned: 20/12/2015

Actual: 18/12/2015

Data analysis start date

Planned: 31/08/2017

Actual: 29/09/2017

Date of final study report

Planned: 01/02/2018

Actual: 13/04/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Roche Registration Ltd

Study protocol

BA28478 Protocol_v3_Redacted.pdf (1.12 MB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Other study registration identification numbers and links

BA28478

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

1. To quantify and characterise off-label use through an evaluation of the disease andcharacteristics of patients treated with MabThera for non-oncology conditions.2. To evaluate the extent to which patients receive and read the PAC, knowledge of the PAC content among patients receiving MabThera for non-oncology conditions

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective chart review

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L01XC02) rituximab

rituximab

Population studied

Short description of the study population

Nononcology MabThera patients in the UK, Germany, France, Italy, and Spain during a 10-month period concomitantly with the medical record abstraction process.

Age groups

- Adults (18 to < 46 years)

Estimated number of subjects

1000

Study design details

Data analysis plan

Analysis of MabThera off-label use and evaluation of PAC knowledge and utilisation will be descriptive in nature and will entail the tabular display of summary statistics and thefrequency distribution of item responses. A detailed analysis plan describing methods of analysis and presentation, as well as table shells, will be developed prior to starting analysis of data. All analyses will be performed using SAS 9.2 (or higher) statistical software (SASInstitute Inc. Cary, North Carolina, USA).

Documents

Study results

BA28478_Final CSR Synopsis_Redacted_final.pdf (728.23 KB)

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

Retrospective ad-hoc chart review study and cross sectional 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

Unknown