YERVOY Risk Minimisation Tool Evaluation Survey

First published: 07/10/2013

Last updated: 26/02/2021

Study Finalised

Administrative details

EU PAS number

EUPAS4924

Study ID

39673

DARWIN EU® study

No

Study countries

- Austria
- Belgium
- Denmark
- Finland
- France
- Germany

Ireland
Italy
Netherlands
Norway
Spain
Sweden
United Kingdom

Study description

This is a non-interventional observational cross-sectional study using HCP and Patient surveys. In addition the results of the surveys (awareness, knowledge and behaviours) will be co-analysed with the rate of ADRs of interest (irARs) observed from standard pharmacovigilance (spontaneous reports) to explore if irAR reporting rates correlate with knowledge of the risks addressed by the RM tools. The surveys are not intended as a mechanism to collect AEs nor are they intended to result in minimising the numbers of AEs. The surveys are designed to evaluate HCP's and patient's awareness, utilisation, knowledge of irARs and behaviours (via scenarios).

Study status

Finalised

Research institutions and networks

Institutions

Bristol-Myers Squibb (BMS)

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Institution

Multiple centres: 80 centres are involved in the study

Contact details

Study institution contact

Randip Kahlon randip.kahlon@bms.com

Study contact

randip.kahlon@bms.com

Primary lead investigator

Randip Kahlon

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 22/12/2011

Study start date

Planned: 01/05/2014

Actual: 01/05/2014

Data analysis start date
Planned: 30/09/2014

Date of final study report
Planned: 28/11/2014

Actual: 04/12/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bristol-Myers Squibb Company

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

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

Knowledge and behavior survey of educational materials

Data collection methods:

Primary data collection

Main study objective:

1) Determine the proportion of YERVOY HCPs and patients that are aware risk communications tools and how the tools were accessed 2) Determine who uses the RM communication tools, and how, when they are used and how often3) Determine the level of knowledge and comprehension of the key elements of important identified risks associated with YERVOY treat4) Evaluate HCP and Patient behaviours

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Survey, Assessment of risk management educational tools

Study drug and medical condition

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

IPILIMUMAB

Medical condition to be studied

Malignant melanoma

Population studied

Short description of the study population

HCPs prescribing Yevoy/ipilimumab; patients being treated with Yervoy/ipilimumab for advanced melanoma.

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)

Special population of interest

Other

Special population of interest, other

Malignant melanoma patients

Estimated number of subjects

320

Study design details

Data analysis plan

Descriptive statistics for discontinuous data will be used to examine the research questions. The data for the overall population if will be examined by users and non-users, university and community hospital HCPs, oncologists or dermatologists as the principal treating physician and individual countries. Data will be presented in a descriptive fashion with frequency distributions for responses, and 95% confidence intervals. In addition, correlation between the use of RM tools, knowledge of irARs and behaviours obtained from the surveys and the incidence of irARs collected through standard pharmacovigilance (spontaneous reports) will be explored

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

Prospective survey data collection from HCPs and patients

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