Survey to Evaluate the Effectiveness of Risk Minimisation Measures for Atezolizumab Use in the European Union

First published: 07/12/2017

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS21920

Study ID

39417

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] Germany
- [ ] Italy
- [ ] Spain

- [ ] Sweden
- [ ] United Kingdom

Study description

This is a multi-country, one-wave, cross-sectional physician survey to evaluate the effectiveness of additional Risk Minimisation Measures (aRMM) for atezolizumab use, covering receipt of, understanding and use, knowledge and behavior among physicians, and in particular aRMM effectiveness in informing physicians to recognize and manage immune-related adverse drug reactions (irADRs). The online survey questionnaire, comprising multiple-choice and true/false questions, will be conducted in several European countries where atezolizumab has been launched.

Study status

Finalised

Research institutions and networks

Institutions

OXON Epidemiology

- [ ] Spain
- [ ] United Kingdom

First published: 06/12/2010

Last updated: 15/03/2024

Institution | Laboratory/Research/Testing facility | Non-Pharmaceutical company | ENCePP partner

Multiple centres: 300 centres are involved in the study

Contact details

Study institution contact

Flavia Di Nucci global.clinical_trial_registry@roche.com

Study contact

global.clinical_trial_registry@roche.com

Primary lead investigator

Flavia Di Nucci

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 12/10/2018

Actual: 12/10/2018

Study start date

Planned: 29/04/2019

Actual: 30/04/2019

Date of final study report

Planned: 06/07/2020

Actual: 26/06/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

F. Hoffmann-La Roche Ltd

Study protocol

WO40486_Protocol_11 Dec 2018_Redacted.pdf (1.58 MB)

Prot WO40486 Tecentriq v1_Redacted.pdf (1.85 MB)

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 main objective of the study is to assess the receipt of the atezolizumab HCP Guide and Patient Alert Card (PAC) for the target physician population and to assess the level of knowledge of key messages related to Immune-related Adverse Drug Reactions (IrADRs) outlined in the atezolizumab HCP Guide and PAC.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

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

ATEZOLIZUMAB

Population studied

Short description of the study population

Physicians who prescribed or managed at least one patient with Tecentriq intheir routine clinical practice.

Eligibility Criteria

Physicians must meet the following criteria for study inclusion:

• Oncologist, pulmonologist or urologist who has prescribed or managed at least one patient with atezolizumab in routine clinical practice.

Physicians who meet any of the following criteria will be excluded from the study:

• Physician used atezolizumab only in clinical trials or in an expanded access programme.

• Physician refuses to participate.

• Physician is a current or former employee of Roche or delegates.

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

Urothelial cancer patients

Estimated number of subjects

Study design details

Outcomes

Primary Outcomes are as follows:- Percentage of respondents that report having received the HCP Guide and PAC.- Percentage of respondents that correctly answered each knowledge sub-question. An individual physician score will be calculated as the proportion of all knowledge sub-questions with correct responses. Secondary Outcomes are as follows:- Percentage of respondents that report having understood the HCP Guide.- Percentage of respondents that report having read or used the HCP Guide and PAC. - Percentage of respondents that correctly answered each behavior sub-question. An individual physician score will be calculated as the proportion of all behavior sub-questions with correct responses.

Data analysis plan

Statistical analyses will be mainly descriptive. Continuous variables will be described by their number (of valid cases, of missing values), mean, standard deviation, median, interquartile range, minimum and maximum. Categorical variables will be described as the total number and relative percentage per category. Confidence intervals of 95% will be evaluated, when relevant. The number of missing data will be indicated. Since missing values are expected to be few and distributed at random, no replacement or imputation will be performed. Missing values will not be considered in the denominators for proportions. For physician questionnaire measures, results will be stratified by country and physician’s specialty. Results may be weighted according to the distribution of physicians in the general population by country and specialty.

Documents

Study results

Final_CSR_Study_WO40486__Published_Output-1_CSR_Synopsis_Redacted.pdf

(1.08 MB)

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

Physicians 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

No