# 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:** 03/06/2026

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

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**Study start date**

Planned: 29/04/2019

Actual: 30/04/2019

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**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

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Primary data collection

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**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.

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**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)

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**Special population of interest**

Other

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**Special population of interest, other**

Urothelial cancer patients

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**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.

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**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