

# Quantitative Testing of Healthcare Provider Knowledge about YESCARTA® (axicabtagene ciloleucel) Risk Minimisation Measures

**First published:** 25/03/2019

**Last updated:** 22/02/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS28523

---

### Study ID

43134

---

### DARWIN EU® study

No

---

### Study countries

- Austria
- Czechia
- France

- Germany
  - Italy
  - Netherlands
  - Poland
  - Spain
  - Sweden
  - United Kingdom
- 

### **Study description**

KT-EU-471-0116: The study was a non-interventional, cross-sectional survey of Health Care Providers (HCPs) based in Europe. It was conducted using an online platform. The primary study objective was to assess HCPs' awareness and knowledge of the routine and additional Risk Minimisation Measures (RMMs) addressing the key important identified risks associated with the use of Yescarta and their understanding of the handling and administration of Yescarta.

---

### **Study status**

Finalised

## Research institutions and networks

### Institutions

#### **Gilead Sciences**

**First published:** 12/02/2024

**Last updated:** 12/02/2024

Institution

Pharmaceutical company

Multiple centres

## Contact details

### Study institution contact

Gilead Study Director [ClinicalTrialDisclosure@gilead.com](mailto:ClinicalTrialDisclosure@gilead.com)

Study contact

[ClinicalTrialDisclosure@gilead.com](mailto:ClinicalTrialDisclosure@gilead.com)

### Primary lead investigator

Gilead Study Director

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 22/02/2019

Actual: 22/02/2019

---

### Study start date

Planned: 01/07/2020

Actual: 23/07/2020

---

### Date of final study report

Planned: 30/06/2021

Actual: 01/06/2021

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Gilead Sciences

## Study protocol

[KT-EU-471-0116-appendix-16.1.1-protocol\\_f-redact.pdf](#) (1.24 MB)

[KT-EU-471-0116-appendix-16.1.1-protocol amendment 2\\_f-redact.pdf](#) (917.82 KB)

## 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:**

Other

**If 'other', further details on the scope of the study**

Assess HCPs' awareness and knowledge of the routine and additional RMMs addressing the key important identified risks associated with the use of Yescarta and their understanding of the handling and administration of Yescarta

**Data collection methods:**

Primary data collection

---

**Main study objective:**

The primary study objective was to assess awareness and knowledge of the routine and additional RMMs addressing the key important identified risks associated with the use of Yescarta, and their understanding of the handling and administration of Yescarta.

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

## Medicinal product name

YESCARTA

## Population studied

### Short description of the study population

The survey questionnaire will collect data from HCPs from qualified sites in Europe who prescribe, dispense, handle or administer Yescarta or manage patients experiencing Yescarta related ADRs

#### Inclusion Criteria

- The study population will be comprised of HCPs in selected countries who have received training on the educational materials and prescribe, dispense, handle or administer Yescarta or manage patients experiencing Yescarta related ADRs.

#### Exclusion Criteria

- HCPs who participated in qualitative pre-testing of the Yescarta survey.  
- HCPs who confirm whether they and/or any of their immediate family members ever worked for Kite Pharma, Inc., Gilead Sciences, Inc., ICON, or the EMA.

---

### 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

1617

## Study design details

## Outcomes

Measured HCPs' knowledge of known important identified risks associated with Yescarta, Assessed whether HCPs understood 1) how to identify/treat cytokine release syndrome (CRS) or serious neurologic adverse reactions, 2) understood the correct way of handling/method of administration of Yescarta, 3) were aware of patient alert card (PAC), distributed PAC, informed patients about the PACs' content.

---

## Data analysis plan

Responses to questions for all completed surveys were analysed using descriptive statistics. HCPs' knowledge was evaluated and expressed as proportions or scores. The results were presented overall, as well as by country and HCP specialty. Categorical variables were described by the number and proportion in each category. Frequency point-estimates with two-sided 95% CIs using the binomial distribution were constructed to describe the proportion of HCPs aware of specified risks. On key questions identified as being essential to measure HCP knowledge of the additional RMMs an acceptable level of knowledge was set at 80%. Missing data for each variable were reported. Data were presented by means of summary tables. The numbers of invitees, respondents and non-responders were recorded, and the response rates were reported overall, by country, HCP's responsibility and HCP's speciality. Analyses was performed according to pre-specified statistical analysis plan.

## Documents

### Study results

[KT-EU-471-0116-csr-body final\\_f-redact.pdf](#) (1.09 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

Cross-sectional survey of EU-based HCPs

## 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