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

Study contact

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

Name of medicine

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