

# A Cross-Sectional Post-Authorization Safety Study to Assess Healthcare Provider Awareness of Risks Associated with Zydelig® in the European Union

**First published:** 27/07/2017

**Last updated:** 16/02/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS16606

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### Study ID

28467

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### DARWIN EU® study

No

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### Study countries

 France

 Germany

 Italy

 Spain

 United Kingdom

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### Study description

GS-EU-313-4226: Non interventional, cross sectional survey of medical oncologists and hematologists in the European Union. The primary objective of this study was to determine the HCPs' level of knowledge about the newly identified infection risks associated with Zydelig treatment and the corresponding recommendations to minimize these risks.

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### 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:** 142 centres are involved in the study

### 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: 09/01/2017

Actual: 09/01/2017

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**Study start date**

Planned: 27/11/2017

Actual: 29/11/2017

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**Data analysis start date**

Planned: 17/07/2018

Actual: 22/10/2018

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**Date of final study report**

Planned: 20/12/2018

Actual: 12/12/2018

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Gilead Sciences Europe, Ltd.

## Study protocol

[protocol+GS-EU-313-4226-19apr2017.pdf](#) (789.38 KB)

## Regulatory

### **Was the study required by a regulatory body?**

No

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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:**

Assessment of risk minimisation measure implementation or effectiveness

Other

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

To Assess Healthcare Provider Awareness of Risks Associated with Zydelig® in the European Union

**Data collection methods:**

Primary data collection

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**Main study objective:**

To determine the HCPs' level of knowledge about the newly identified infection risks associated with Zydelig treatment and the corresponding recommendations to minimize these risks.

## Study Design

**Non-interventional study design**

Cross-sectional

Other

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**Non-interventional study design, other**

Survey of medical oncologists and hematologists in the European Union

## Population studied

## **Short description of the study population**

Practicing oncologists and hematologists in the United Kingdom, Italy, Spain, France and Germany who treat patients with Chronic lymphocytic leukemia (CLL) or Follicular lymphoma (FL) representing specialties considered likely to prescribe Zydelig.

Patients with following criteria were included:

1. Registered oncologists and hematologists
  2. Registered medical doctors who are currently enrolled in an advanced training program leading to specialization in oncology and/or hematology
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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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## **Estimated number of subjects**

150

# Study design details

## **Data analysis plan**

Responses to questions for all completed surveys were analyzed using descriptive statistics. Continuous variables were described by the mean, standard deviation, median and range. Categorical variables were described by the number and proportion in each category. The amount of missing data for each variable were reported. Data were presented by summary tables and/or graphs. No formal hypothesis testing was conducted. An 80% threshold for

prescriber awareness was generally considered acceptable. The numbers of invitees and respondents were recorded, and the response rates were reported overall and by country.

## Documents

### Study results

[CSR-Final-PASS-GS-EU-313-4226.pdf](#) (349.57 KB)

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## 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](#)

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### Data sources (types), other

Survey study

## Use of a Common Data Model (CDM)

## **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No