

# Cross-sectional Study Evaluating the Effectiveness of the Venetoclax Patient Card Among Adult Patients in Europe

**First published:** 14/07/2023

**Last updated:** 12/12/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS104768

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### Study ID

104769

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### DARWIN EU® study

No

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### Study countries

 France

 Germany

 Poland

 Spain

## Study description

This study will be a cross-sectional survey of knowledge of the risks and safe use of venetoclax as outlined in the patient card among adult patients who have recently received venetoclax for treatment of CLL per standard of care. Patients will be identified through a diverse selection of medical practices representing haematologists who prescribe venetoclax across at least 5 European countries. Patients will be invited to participate by their physician and will be asked to complete a one-time self-administered structured questionnaire.

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## Study status

Ongoing


# Research institutions and networks


## Institutions


### RTI Health Solutions (RTI-HS)

 France

 Spain

 Sweden

 United Kingdom

 United Kingdom (Northern Ireland)

 United States

**First published:** 21/04/2010

**Last updated:** 13/03/2025

Institution

Not-for-profit

ENCePP partner

## Contact details

### Study institution contact

Clinical Trial Disclosure AbbVie CT.Disclosures@abbvie.com

Study contact

[CT.Disclosures@abbvie.com](mailto:CT.Disclosures@abbvie.com)

### Primary lead investigator

Daniel Wolin

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 17/11/2021

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### Study start date

Actual: 24/04/2024

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### Date of final study report

Planned: 31/12/2026

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

AbbVie

## Study protocol

[P22-905-protocol-abstract\\_redacted.pdf](#) (123.39 KB)

## 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)

## Other study registration identification numbers and links

P22-905

## 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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**Study design:**

This study will be a cross-sectional survey of knowledge of the risks and safe use of venetoclax as outlined in the PC among adult patients who have recently received venetoclax for treatment of CLL per standard of care.

**Main study objective:**

To assess patients' knowledge of the following:

- TLS as a risk of venetoclax treatment for CLL
- Symptoms of TLS
- Steps to take to reduce the risk of TLS
- Actions to take if symptoms of TLS appear

To assess patients' use of the PC, including the following:

- Whether the patient keeps the PC on their person
- Whether the PC is shared with all medical providers when seeking care

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

### Medicinal product name

VENCLYXTO

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

VENETOCLAX

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### Anatomical Therapeutic Chemical (ATC) code

(L01XX52) venetoclax

venetoclax

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### Medical condition to be studied

Tumour lysis syndrome

## Population studied

### Short description of the study population

Patients initiating venetoclax for the treatment of CLL in the past 8 weeks will be targeted

for participation in the study. Patients will be identified and recruited through clinical sites. Countries

are anticipated to include France, Germany, Spain, Poland, and the UK.

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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**

200

## Study design details

### **Data analysis plan**

The analyses will be descriptive in nature and will include distributions of the responses to all of the individual questions and, if appropriate, summary measures across logical groupings of questions. Descriptive tables will be generated for the patients overall and stratified by country and other identified variables of interest. Analysis tables will include the frequency and percentage of patients who select each response to each individual question.

## 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**

Prospective patient-based data collection

## **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