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

Study ID

104769

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany
- [ ] Poland
- [ ] Spain

☐ United Kingdom

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.

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

Primary lead investigator

Daniel Wolin

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 17/11/2021

Study start date

Actual: 24/04/2024

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

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

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

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

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

VENETOCLAX

Anatomical Therapeutic Chemical (ATC) code

(L01XX52) venetoclax

venetoclax

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.

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

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

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No