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

First published: 14/07/2023

**Last updated:** 16/08/2024





# Administrative details

EU PAS number	
EUPAS104768	
Study ID	
104769	
DARWIN EU® study	
No	
Study countries	
☐ France ☐ Germany	
Poland	
Spain	

United Ki	ngdom
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#### **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
<b>Last updated:</b> 13/03/2025

# 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: 31/12/2025

# 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 type:

Non-interventional study

#### Scope of the study:

Effectiveness study (incl. comparative)

#### 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

#### Name of medicine

**VENCLYXTO** 

#### Medical condition to be studied

Chronic lymphocytic leukaemia

# Population studied

#### 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

Other	(types)				
Data sources	(types), othe	r			
Prospective pa	ient-based dat	a collectio	n		
Use of a (	Common	Data N	Model (	CDM)	
CDM mapping					
No					
Data qua	ity spacit	fication	2.5		
Data qua	ity specii	icatioi	15		
Check confor		icatioi	15		
•		icatioi	15		
Check confor	nance	icatioi	15		
Check confor	nance	icatioi	15		
Check conford Unknown Check comple	nance teness	icatioi	15		

# Data characterisation

#### **Data characterisation conducted**

No