Leveraging Digital Technology and Artificial Intelligence to Describe the Real World Belgian Chronic Lymphocytic Leukemia Patient Population [BE-CLLEAR]

First published: 03/02/2026

Last updated: 03/02/2026

Study Finalised

Administrative details

EU PAS number

EUPAS1000000394

Study ID

1000000394

DARWIN EU® study

No

Study countries

Belgium

Study description

This multicenter study describes demographics, biomarker testing, and treatment patterns in Belgian patients with chronic lymphocytic leukemia by leveraging natural language processing and the OMOP common data model.

Study status

Finalised

Research institutions and networks

Institutions

AZ Maria Middelares General Hospital

Belgium

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Hospital/Clinic/Other health care facility

AstraZeneca

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Universitair Ziekenhuis Antwerpen (UZA)

Belgium

First published: 11/06/2025

Last updated: 16/06/2025

Institution | Hospital/Clinic/Other health care facility | Laboratory/Research/Testing facility | ENCePP partner

LynxCare Clinical Informartics

Belgium

First published: 20/10/2025

Last updated: 20/10/2025

Institution | Other

Algemeen Ziekenhuis Groeninge; Universitair Ziekenhuis Brussel

Contact details

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Primary lead investigator

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Actual: 16/11/2022

Study start date

Actual: 06/12/2023

Date of final study report

Planned: 01/05/2024

Actual: 28/10/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca BeLux

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

Multicenter study (n = 4) analyzing routinely collected data from pseudonymized electronic health records (EHRs) using natural language

processing (NLP) for unstructured sources. The algorithm mapped variables to a standard terminology, generating OMOP CDM databases, validated per hospital

Main study objective:

- Proof of concept for novel and scalable methodology in CLL
- Characterize clinical and demographic patient profile
- Asses biomarker testing and treatment patterns against evolving guidelines

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Chronic lymphocytic leukaemia

Population studied

Short description of the study population

CLL patients diagnosed between 1 January 2018 and 31 October 2021.

Estimated number of subjects

500

Study design details

Setting

Belgium, diagnosis between 2018 and 2021

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 source(s)

LynxCare

Data sources (types)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

CDM version

5.4

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes

Data characterisation moment

after data extraction

after extract-transform-load to a common data model

after creation of study variables