

# An Active Surveillance, Post-Authorization Safety Study to Characterize the Safety of Etrasimod in Patients with Ulcerative Colitis Using Real-World Data in the European Union (C5041046)

**First published:** 09/01/2026

**Last updated:** 27/01/2026

Study

Planned

## Administrative details

### EU PAS number

EUPAS1000000895

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### Study ID

1000000895

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### DARWIN EU® study

No

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### Study countries

 Germany

 Netherlands

## Study description

This multi-country, non-interventional Post-Authorization Safety Study (PASS) aims to characterize the real-world safety of etrasimod (Velsipity®) among patients aged 16 years and older with ulcerative colitis (UC) across Germany, Sweden, and the Netherlands. Using electronic health records, healthcare claims, and registry data, the study follows new users of etrasimod and comparator therapies—including other S1P receptor modulators, biologics, and JAK inhibitors—to estimate incidence rates of key safety outcomes such as macular oedema, serious liver injury, malignancy, serious opportunistic infections, neurologic events including PRES or convulsions, and symptomatic bradycardia. The study describes patient characteristics at treatment initiation, compares incidence rates between etrasimod and comparator cohorts when sample size allows, and evaluates safety in adults aged 65 years and older by assessing rates of eye adverse events, infections, and cardiovascular events.

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## Study status

Planned

## Research institutions and networks

### Institutions

**Pfizer**

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

## Leibniz Institute for Prevention Research and Epidemiology - BIPS

 Germany

**First published:** 29/03/2010

**Last updated:** 30/03/2026

Institution

Not-for-profit

ENCePP partner

## The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

 Netherlands

**First published:** 07/01/2022

**Last updated:** 19/12/2025

Institution

Non-Pharmaceutical company

ENCePP partner

## Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

 Sweden

**First published:** 24/03/2010

**Last updated:** 23/04/2024

**Institution**

**Educational Institution**

**Laboratory/Research/Testing facility**

**Not-for-profit**

**ENCePP partner**

## Networks

### The SIGMA Consortium (SIGMA)

-  Denmark
-  European Union
-  France
-  Germany
-  Italy
-  Netherlands
-  Norway
-  Spain
-  Sweden
-  United Kingdom

**First published:** 10/02/2013

**Last updated:** 19/01/2026

**Network**

**ENCePP partner**

## Contact details

### Study institution contact

Julia Beasley julia.munroe@pfizer.com

Study contact

[julia.munroe@pfizer.com](mailto:julia.munroe@pfizer.com)

**Primary lead investigator**

Shahar Shmuel

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 23/01/2024

Actual: 23/01/2024

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**Study start date**

Planned: 15/11/2026

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**Data analysis start date**

Planned: 01/07/2035

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**Date of interim report, if expected**

Planned: 16/05/2028

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**Date of final study report**

Planned: 31/12/2035

## Study protocol

[C5041046\\_ETRASIMOD PROTOCOL VERSION 3\\_07JULY2025\\_Clean.pdf](#) (1.33 MB)

## 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**

C5041046

**Methodological aspects**

**Study type**

**Study type list**

**Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Study design:**

Non-interventional, multi-country cohort study using real-world data to follow new users of etrasimod or comparator UC therapies, applying a restricted as-treated approach to estimate safety event incidence across Germany, Sweden, and the Netherlands.

**Main study objective:**

The study's main objectives are to describe the characteristics of patients with ulcerative colitis when they initiate etrasimod or comparator therapies, to estimate the incidence rates of key safety events among new users of etrasimod, and to estimate these same rates among patients starting other S1P receptor modulators, biologics, or JAK inhibitors. The study also seeks to compare the incidence of these safety events between etrasimod and each comparator cohort when sample sizes allow. In addition, it aims to evaluate safety in adults aged 65 years and older by estimating the incidence of eye adverse events, infections, and cardiovascular events across all treatment groups.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**VELSIPITY

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

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**Anatomical Therapeutic Chemical (ATC) code**

(L04AE05) etrasimod

etrasimod

## Population studied

**Short description of the study population**

The study population includes patients aged 16 years and older with a confirmed diagnosis of ulcerative colitis (UC) who begin treatment with etrasimod or comparator UC therapies (other S1P receptor modulators, biologics, or JAK inhibitors). Patients must have at least one year of prior healthcare data and no prior use of the same cohort-defining medication. Individuals may enter more than one cohort if they switch therapies, and a subgroup analysis focuses on older adults aged 65 years and above.

## Study design details

**Setting**

The study is conducted across three European countries (Germany, Sweden, and the Netherlands) using large, population-based healthcare databases that capture routine clinical care. These data sources include electronic health records, national health and cancer registries, healthcare claims, inpatient and

outpatient hospital data, and pharmacy dispensing records. Together, they provide broad and complementary coverage of diagnoses, treatments, and outcomes for patients with ulcerative colitis. Each country contributes data through an established research institution: GePaRD in Germany, the Swedish National Health Registers and SWIBREG in Sweden, and the PHARMO Data Network in the Netherlands. The setting reflects real-world clinical practice at national scale, enabling assessment of etrasimod and comparator treatments within diverse healthcare systems.

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### **Comparators**

The study includes three comparator groups representing alternative advanced therapies for ulcerative colitis. These comparators consist of other S1P receptor modulators such as ozanimod, which share a similar mechanism of action to etrasimod; biologic therapies, including TNF inhibitors, integrin receptor antagonists, and interleukin inhibitors, which are commonly used in moderate to severe UC; and JAK inhibitors, another advanced treatment class used when patients have inadequate response to prior therapies.

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### **Outcomes**

The study evaluates several predefined safety outcomes, including macular oedema, serious liver injury, malignancy, serious opportunistic infections, neurologic events such as Posterior Reversible Encephalopathy Syndrome (PRES) or convulsions, and symptomatic bradycardia including conduction disorders. For adults aged 65 and older, it also assesses broader categories of eye adverse events, infections, and cardiovascular events.

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### **Data analysis plan**

The data analysis plan uses a distributed common data model so each country can run identical analytic programs locally while preserving data privacy. Analyses begin with describing cohort selection and patient characteristics,

followed by estimating crude and age-sex-standardized incidence rates for all safety outcomes within each treatment cohort. When sample sizes allow, comparative analyses will be conducted using methods such as propensity score-based inverse probability weighting to adjust for confounding. Additional plans include meta-analysis of country-specific effect estimates in the final study report, predefined subgroup analyses in adults aged 65 and older, and multiple sensitivity analyses to assess the impact of alternative risk windows, outcome definitions, and inclusion criteria.

## 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)**

German Pharmacoepidemiological Research Database

PHARMO Data Network

Other data source

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### **Data source(s), other**

Swedish National Health Registers, Swedish Inflammatory Bowel Disease Registry

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## **Data sources (types)**

Non-interventional study

## Use of a Common Data Model (CDM)

### **CDM mapping**

Yes

## 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**

Not applicable