

# Early Experience with Etrasimod in Ulcerative Colitis Patients: an Observational Study in the United States

**First published:** 17/09/2025

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Study

Planned

## Administrative details

### EU PAS number

EUPAS1000000587

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### Study ID

1000000587

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### DARWIN EU® study

No

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### Study countries

 United States

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### Study description

This is a population-based retrospective cohort study of adults (ages  $\geq 18$  years of age) with ulcerative colitis (UC) initiating treatment with etrasimod since its marketing authorization, using claims data from a large United States (US) database.

Primary endpoint is baseline characteristics of patients. Secondary endpoints are adherence, measured by proportion of days covered method, persistence (delay until etrasimod discontinuation), the use of corticosteroids and change in level of fecal calprotectin, within 12 months of etrasimod initiation.

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## Study status

Planned

## Research institutions and networks

### Institutions

**Pfizer**

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

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Institution

## Contact details

### Study institution contact

jeremie rudant jeremie.rudant@pfizer.com

Study contact

[jeremie.rudant@pfizer.com](mailto:jeremie.rudant@pfizer.com)

**Primary lead investigator**

Jeremie Rudant 0009-0007-7805-9589

Primary lead investigator

**ORCID number:**

0009-0007-7805-9589

## Study timelines

**Date when funding contract was signed**

Planned: 27/05/2025

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**Study start date**

Planned: 08/09/2025

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**Data analysis start date**

Planned: 08/09/2025

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**Date of final study report**

Planned: 30/10/2026

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

# Study protocol

[C5041059\\_NIS Protocol\\_Etrasimod tt patterns\\_V1.0\\_22AUG2025.pdf](#) (1.84 MB)

## Regulatory

**Was the study required by a regulatory body?**

No

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

Not applicable

## Other study registration identification numbers and links

C5041059

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

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**Study type:**

**Scope of the study:**

Drug utilisation

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Study design:**

The study cohort will be defined as UC patients initiating etrasimod from its marketing authorization. For the secondary objectives, patients with closed claims will be followed for up to 12 months after the index date or to the end of their continuous enrollment, whichever comes first.

**Main study objective:**

Primary Objective

1. To describe the baseline demographic characteristics, comorbidities, disease and treatment characteristics of patients with UC who initiated treatment with etrasimod.

Secondary Objectives

1. To describe the treatment patterns of etrasimod (adherence and persistence) among patients with UC within 12 months of etrasimod initiation.

2. To describe corticosteroid use among patients with UC within 12 months of etrasimod initiation.

3. To describe the change in level of fecal calprotectin in patients with UC, from baseline through 12 months of etrasimod initiation.

## 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

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## Medical condition to be studied

Colitis ulcerative

# Population studied

## Short description of the study population

The population under study will be US patients diagnosed with UC and initiating etrasimod from its marketing authorization on October, 13, 2023, to the end of study period.

Inclusion criteria:

Patients must meet all of the following inclusion criteria to be eligible for inclusion in the study:

1. Patients who have initiated etrasimod, defined by a filled pharmacy claim

2. Patients with at least  $\geq 1$  inpatient or outpatient claim with evidence of UC diagnosis in medical claims using ICD-10-CM codes: K51.x on or prior to index date
3. Patients aged  $\geq 18$  years at index date
4. Data availability  $\geq 12$  months prior to index date

#### Exclusion Criteria

Patients meeting any of the following criteria will not be included in the study:

1. Patients with medical claims with diagnosis code(s) corresponding to Crohn's disease (CD) during pre-index period or index date
  2. Patients with medical claims with procedure code(s) corresponding to colectomy during pre-index period or index date
  3. Any co-prescription with select immunomodulators (methotrexate, tacrolimus, cyclosporin, thiopurine) or advanced therapies for UC (biologics, anti-TNFs, interleukin 12 and 23, anti-integrin, small molecules such as Janus kinase inhibitors [JAKi], or with any other S1P receptor modulator) on index date
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#### Age groups

- **Adult and elderly population ( $\geq 18$  years)**
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#### Estimated number of subjects

800

## Study design details

#### Setting

The population under study will be US patients diagnosed with UC and initiating etrasimod from its marketing authorization on October, 13, 2023 to the end of study period.

This study will use existing data from large US claims database, which captures claims data from 300 million US people sufficiently representative of the US population with insurance coverage. Data from the eligible patients available in the datasource, i.e from 2015 to latest date of data availability will be used in the study, to document baseline characteristics and assess endpoints of interest.

The US UC population will be identified from the database, by considering all patients with an ICD-10 diagnosis code equal to K51.x (UC) between 2015 to the end of study period.

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### **Comparators**

No comparison

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### **Outcomes**

Primary endpoint is baseline characteristics of patients.

Secondary endpoints are adherence, measured by proportion of days covered method, persistence (delay until etrasimod discontinuation), the use of corticosteroids and change in level of fecal calprotectin, within 12 months of etrasimod initiation.

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### **Data analysis plan**

All analyses defined in detail in the statistical analytical plan (SAP), which will be the reference document.

Primary objective (baseline characteristics) will be analyzed among patients who have met the selection criteria (eligible population). For the analysis of secondary objectives, analyses will be performed on patients with closed index etrasimod claim and continuous enrollment after the index date. Specific windows of minimal continuous enrollment will be defined in the SAP for each analysis.

**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), other

Panalgo-MMIT (NorstellaLinQ)

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### Data sources (types)

[Administrative healthcare records \(e.g., claims\)](#)

[Laboratory tests and analyses](#)

## 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