

# Vedolizumab-4030: Understand the Outcomes of Inflammatory Bowel Disease (IBD) Patients Treated with Biologics in Taiwan – A Decentralized Vedolizumab and Biologic Agents Core Assessments in IBD Collaboration

**First published:** 22/08/2022

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

Study

Finalised

## Administrative details

### EU PAS number

EUPAS48289

---

### Study ID

50648

---

### DARWIN EU® study

No

---

### Study countries

## Study status

Finalised

## Research institutions and networks

### Institutions

#### Takeda

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

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

Institution

Chang Gung Medical Foundation, Linkou Taoyuan City, China Medical University Hospital Taichung City, National Taiwan University Hospital Taipei, Taichung Veterans General Hospital Taichung City

## Contact details

### Study institution contact

Study Lead [trialdisclosures@takeda.com](mailto:trialdisclosures@takeda.com)

**Study contact**

[trialdisclosures@takeda.com](mailto:trialdisclosures@takeda.com)

**Primary lead investigator**

Study Lead

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 03/03/2020

Actual: 03/03/2020

---

**Study start date**

Planned: 27/05/2021

Actual: 27/05/2021

---

**Date of final study report**

Planned: 31/03/2023

Actual: 08/12/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Takeda

# Study protocol

[Vedolizumab-4030\\_Protocol\\_Redacted.pdf](#) (1.75 MB)

## 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:**

Human medicinal product

Disease /health condition

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

---

**Main study objective:**

The main objective of this study is to quantify the relapse rate after biologic discontinuation, and identify predictors of relapse. Additionally, treatment safety and effectiveness of biologics including anti-TNF- $\alpha$  and vedolizumab in IBD patients will be quantified, along with predictors of response to treatment.

## Study Design

**Non-interventional study design**

Cohort

Other

---

**Non-interventional study design, other**

Retrospective study

## Study drug and medical condition

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

VEDOLIZUMAB

---

**Medical condition to be studied**

Inflammatory bowel disease

Crohn's disease

Colitis ulcerative

## Population studied

## **Short description of the study population**

Newly diagnosed inflammatory bowel disease (IBD) patients aged 20 years or older treated with biologics including vedolizumab, adalimumab, infliximab, or golimumab during February 2008 to March 2020.

Inclusion Criteria:

1. Patient aged  $\geq 20$  years old when IBD (CD or UC) was first diagnosed during February 2008 to March 2020 (or per local IRB permitted date).
  - CD (ICD-9-CM: 555.X or ICD-10-CM: K50.XX, K50.XXX)
  - UC (ICD-9-CM: 556.X or ICD-10-CM: K51.XX, K51.XXX)
2. Had received any dose of biologics for IBD treatment, including vedolizumab, adalimumab, infliximab or golimumab, from February 2008 to March 2020 (or per local IRB permitted date)

Exclusion Criteria:

Patients with any suspected diagnosis of CD or UC within one year before the initial date of confirmed IBD diagnosis will be excluded.

---

## **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)
- 

## **Special population of interest**

Other

---

## **Special population of interest, other**

### **Estimated number of subjects**

724

## Study design details

### **Outcomes**

% of relapse and time-to-relapse and correlation b/t clinical variables and the relapse post biologics discontinuation. Incidence rates and potential correlation b/t clinical variables of patients achieving treatment effectiveness and incidence rates of opportunistic, hepatic, GI, respiratory infection/failure or sepsis/septic shock among patients receiving vedolizumab vs those receiving anti-TNF.

---

### **Data analysis plan**

All demographic covariates will be summarized by the types of disease (CD or UC) and by the types of biologics (anti-TNF- $\alpha$  or anti- $\alpha$ 4 $\beta$ 7 integrin) descriptively. Categorical variables will be presented as counts and percentage and will be analyzed by Chi-square test. Continuous variables will be presented as number of observation (n), mean and median, standard deviation, minimum and maximum and will be analyzed by Student's t-test. The predictors will be analyzed using time dependent Cox regression model. All statistical significance will be set at  $p < 0.05$  unless otherwise specified.

## Documents

### **Study results**

[Vedolizumab-4030-Clinical-Study-Report-Redact.pdf](#) (719.28 KB)

---

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

Chang Gung Research Database (CGRD) Taiwan, China Medical University Hospital (CMUH)-Clinical Research Database Taiwan, National Taiwan University Hospital-integrated Medical database (NTUH-iMD) Taiwan, Taichung Veterans General Hospital (TVGH)-Research Database Taiwan

---

### Data sources (types)

[Electronic healthcare records \(EHR\)](#)

## 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