# A Long-Term Non-Interventional Registry to Assess Safety and Effectiveness of HUMIRA® (Adalimumab) in Patients with Moderately to Severely Active Ulcerative Colitis (UC)

**First published:** 11/10/2017

**Last updated:** 14/03/2024

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS21010

**Study ID**

48639

**DARWIN EU® study**

No

**Study countries**

- ☐ Australia
- ☐ Austria

- [ ] Belgium
- [ ] Canada
- [ ] Croatia
- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Ireland
- [ ] Israel
- [ ] Italy
- [ ] Mexico
- [ ] Netherlands
- [ ] New Zealand
- [ ] Norway
- [ ] Puerto Rico
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom
- [ ] United States

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**Study description**

This is a registry study to evaluate the long-term safety and effectiveness of adalimumab in adult patients with moderately to severely active UC who are treated as recommended in the product label.

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**Study status**

Ongoing

## Contact details

**Study institution contact**

Clinical Trial Disclosure AbbVie CT.Disclosures@abbvie.com

Study contact

CT.Disclosures@abbvie.com

**Primary lead investigator**

Clinical Trial Disclosure AbbVie

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 01/01/2011

Actual: 01/01/2011

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**Study start date**

Planned: 29/04/2013

Actual: 29/04/2013

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**Date of final study report**

Planned: 25/05/2031

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

AbbVie

# Study protocol

p11282 synopsis.pdf(96.74 KB)

p11282-protocol-amendment4-synopsis.pdf(102.35 KB)

# 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

P11-282

# Methodological aspects

## Study type

## Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Main study objective:**

The primary objective of this study is to evaluate the long-term safety of HUMIRA® in moderately to severely active UC adult patients (18 years of age or older) who are treated per routine clinical practice.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

ADALIMUMAB

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**Medical condition to be studied**

Colitis ulcerative

## 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)

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**Estimated number of subjects**

5450

## Study design details

**Outcomes**

Number and percent of patients experiencing serious adverse events (SAEs) and adverse events of interest (AEIs), - Safety reporting forms will be used to estimate health care resource utilization - Partial Mayo Score - CRP, hemoglobin and fecal calprotectin values - Short Quality of Life in Inflammatory Bowel Disease Questionnaire (SIBDQ) - Work Productivity and Activity Impairment (WPAI) - Treatment Satisfaction Questionnaire for Medication (TSQM) - EQ-5D-5L

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**Data analysis plan**

For demographics/baseline, medical history, previous/concomitant medication and effectiveness data, categorical variables will be summarized using frequencies and percentages. Continuous variables will be summarized using descriptive statistics by the number of non-missing observations, mean, standard deviation, 1st quartile, median, 3rd quartile, minimum and maximum. In addition for effectiveness data, 95% CI for the mean will be provided. For safety data, treatment-emergent (TE) and observational adverse events (AEs) will be coded using the most current version of the Medical Dictionary for

Regulatory Activities (MedDRA). The number and percent of patients experiencing TE and observational AEs will be summarized as well as tabulated by system organ class (SOC) and MedDRA preferred term (PT). The number of AEs per 100 patient-years will be summarized. In addition, by-patient listings will be provided for TE and observational AEs.

# 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 sources (types)**

Disease registry

## 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