

# A Non-interventional Observational Longitudinal Post-Authorization Safety Study (PASS) of SIMPONI® in Treatment of Ulcerative Colitis using Nordic National Health Registries (MK-8259-013)

**First published:** 09/11/2015

**Last updated:** 09/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS11484

### Study ID

50508

### DARWIN EU® study

No

### Study countries

☐ Denmark

☐ Sweden

## Study description

Simponi received European marketing authorization for treatment of moderately to severely active ulcerative colitis (UC) on 19-Sep-2013. This registry-based study is being established as a post-marketing commitment to provide additional information on colorectal cancer (CRC), colectomy, and hepatosplenic T-cell lymphoma (HSTCL), as outlined in the Risk Management Plan for SIMPONI® that was approved with authorization of the UC indication.

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## Study status

Finalised

# Research institutions and networks

## Institutions

[Institute of Applied Economics and Health Research \(ApHER\)](#)

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**Institution**

[The Institute for Public Health at University of Southern Denmark 1353 Copenhagen, Denmark](#)  
[Centre for Health Economics at Gothenburg University Vasagatan 1, Gothenburg, Sweden](#)

## Contact details

### Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme LLC

ClinicalTrialsDisclosure@merck.com

Study contact

[ClinicalTrialsDisclosure@merck.com](mailto:ClinicalTrialsDisclosure@merck.com)

### Primary lead investigator

Anders Green

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 16/11/2015

Actual: 09/12/2015

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### Study start date

Planned: 01/12/2015

Actual: 07/02/2017

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### Data analysis start date

Planned: 31/03/2022

Actual: 15/02/2022

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### Date of final study report

Planned: 30/09/2023

Actual: 26/09/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

MSD, Janssen

## Study protocol

[MK-8259-013-00 Protocol Summary.pdf](#)(1.24 MB)

[MK-8259-013-01v2-Prot\\_Final Redaction.pdf](#)(676.17 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)

## Methodological aspects

### Study type

### Study type list

### **Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

**Main study objective:**

To characterize the clinical and demographic profile of first-time users of golimumab (GLM) vs first time users of alternate therapies in the treatment of UC, to describe the risk of incident CRC and the risk of all-cause total colectomy exposed to GLM and alternative therapies.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Name of medicine**

SIMPONI

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

GOLIMUMAB

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## **Anatomical Therapeutic Chemical (ATC) code**

(L04AB06) golimumab

golimumab

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## **Medical condition to be studied**

Colitis ulcerative

Colorectal cancer

Hepatosplenic T-cell lymphoma

Colectomy

## 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**

3000

## Study design details

### **Outcomes**

Incidence of CRC, incidence of all-cause total colectomy

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### **Data analysis plan**

Patients in each cohort will be followed for the outcomes of CRC, HSTCL, and colectomy through 18- Mar-2021. The risk of primary outcomes (incident CRC,

all-cause total colectomy) will be estimated as cumulative incidence within each inception cohort in unadjusted and adjusted analyses. Censoring events will include death, emigration, and first occurrence of study outcomes. The cohort analyses will be conducted based on automated data only using survival analysis techniques (including Kaplan-Meier) to estimate cumulative risks. Sensitivity analyses have been specified that examine the robustness of results to alternate specifications of the study population, risk window, outcome definitions, and additional adjustment using quantitative bias analysis (QBA).

## Documents

### Study report

[MK-8259-013-CSR-Final-Report-may-2024-final-redaction.pdf](#)(3.37 MB)

## 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)

Danish registries (access/analysis)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

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**Data source(s), other**

National Patient Register, Sweden

Danish Civil Registration System, Denmark

Swedish Cause of Death Registry, Sweden

Danish National Prescription Registry, Denmark

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**Data sources (types)**

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

## 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