# A study assessing the use of GOlimumab in current clinical PRACTICE and its impact on patients with chronic inflammatory arthritis (MK-8259-020) (GO-PRACTICE)

**First published:** 29/10/2014

**Last updated:** 27/02/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS7527

**Study ID**

47243

**DARWIN EU® study**

No

**Study countries**

☐ France

**Study description**

This study has been designed to comply with the February 2012 request from the French Health Authorities, in light of the Simponi® reevaluation scheduled for 2017. The Authorities asked for additional long-term data in patients with chronic inflammatory rheumatic diseases in the form of a post-regulation study. The primary objective of this study is to assess the persistence of golimumab treatment 24 months after the initial prescription in adult patients with chronic inflammatory rheumatic diseases, in routine clinical practice in France.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Merck Sharp & Dohme LLC

United States

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

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Institution | Pharmaceutical company

### Chru De Lille - Hopital B Roger Salengro Rue Emile Laine 59037 Lille CEDEX

# Contact details

**Study institution contact**

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**Primary lead investigator**

Clinical Trials Disclosure Merck Sharp & Dohme LLC

**Primary lead investigator**

# Study timelines

**Date when funding contract was signed**

Planned: 30/09/2014

Actual: 18/12/2014

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**Study start date**

Planned: 30/11/2014

Actual: 12/01/2015

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**Data analysis start date**

Planned: 31/07/2018

Actual: 10/08/2018

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**Date of final study report**

Planned: 31/08/2019

Actual: 12/09/2019

# Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Merck Sharp & Dohme LLC

## Regulatory

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

Yes

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

Not applicable

# 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:**

Drug utilisation

**Data collection methods:**

Primary data collection

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**Main study objective:**

The primary objective of this study is to assess the persistence of golimumab treatment 24 months after the initial prescription in adult patients with chronic inflammatory rheumatic diseases, in routine clinical practice in France.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Multicenter, prospective, national (France) study

## Study drug and medical condition

**Name of medicine**

SIMPONI

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**Medical condition to be studied**

Rheumatoid arthritis

Psoriatic arthropathy

Ankylosing spondylitis

## Population studied

**Short description of the study population**

Adult patients diagnosed with rheumatoid arthritis (RA), psoriatic arthritis (PsA) and ankylosing spondylitis (AS) were recruited successively upon initial golimumab prescription, as per routine clinical practice. The patients were treated as per each center’s standard practice. The decision to treat was at the physician’s discretion, and had to be made prior to the patient’s inclusion in the study.

Inclusion Criteria

1. Patients aged 18 years or older.
2. Patients having given their verbal consent to participate in the study, after having received verbal and written information about the study.
3. Patients diagnosed with a chronic rheumatic inflammatory disease.
4. Patient with an initial hospital prescription for golimumab but who did not yet initiate golimumab treatment.
5. Patients capable of understanding and completing the PRO questionnaires.

Exclusion Criteria

1. Patients who were previously treated with golimumab and/or stopped golimumab before inclusion
2. Patients who had participated in previous studies of golimumab.
3. Patients who had already started golimumab treatment prior to the inclusion visit and/or who were receiving golimumab at the time of the inclusion visit.
4. Conditions or situations that, in the opinion of the investigator, limited the patient’s ability to fully participate in the study or to fulfil study requirements,

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**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**

Immunocompromised

**Estimated number of subjects**

750

## Study design details

**Outcomes**

The primary outcome measure of this study is the overall proportion of patients persisting with golimumab treatment 24 months after the initial prescription. The secondary outcomes include 1) to describe the therapeutic strategy including prior to treatments, prescription pattern of golimumab in routine clinical practice with the dose, regimen, and co-prescriptions, respect of contraindications and reasons for golimumab withdrawal, 2) to describe treated patients, 3) to assess golimumab persistence at 1 year, and 4) to assess the safety profile.

**Data analysis plan**

The primary endpoint is the overall proportion of patients persisting with golimumab treatment at 2 years after the initial prescription, using standard descriptive statistics. Sensitivity analyses will be provided using the following assumptions: 1) All patients lost to follow-up at 2 years have discontinued definitively golimumab (worst hypothesis), 2) All patients lost to follow-up at 2 years are continuing treatment with golimumab at 2 years (best hypothesis).

## Documents

**Study results**

MK-8259-020-CSR_Final Redaction.pdf(4.71 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 sources (types)**

Other

**Data sources (types), other**

Prospective patient-based data collection

## 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