

# Post-marketing Study Assessing the Long-term Safety of Abatacept

**First published:** 24/02/2015

**Last updated:** 30/03/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS8718

---

### Study ID

18489

---

### DARWIN EU® study

No

---

### Study countries

 United States

---

### Study description

This is a retrospective cohort study that will be conducted using administrative health care databases in the United States to estimate and compare the risk of malignancies and infections among patients exposed to abatacept and patients

exposed to other treatments for rheumatoid arthritis (RA).

---

## Study status

Finalised

## Research institutions and networks

### Institutions

#### Bristol-Myers Squibb (BMS)

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

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

Institution

## Contact details

### Study institution contact

Nicole Baker [nicole.baker@bms.com](mailto:nicole.baker@bms.com)

Study contact

[nicole.baker@bms.com](mailto:nicole.baker@bms.com)

### Primary lead investigator

Nicole Baker

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Actual: 08/10/2013

---

**Study start date**

Planned: 01/06/2014

Actual: 01/06/2014

---

**Date of final study report**

Planned: 31/12/2016

Actual: 27/01/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Bristol-Myers Squibb

## 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:**

Disease /health condition  
Human medicinal product

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

---

**Main study objective:**

To estimate and compare the risk of malignancies and infections among a cohort of RA patients who are prescribed abatacept and a cohort of patients who are prescribed other RA treatments.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

ABATACEPT

---

**Medical condition to be studied**

Rheumatoid arthritis

## Population studied

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

Patients with risk of malignancies and infections among a cohort of rheumatoid arthritis (RA) patients who are prescribed abatacept and a cohort of patients who were prescribed other RA treatments.

---

### **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**

Rheumatoid arthritis patients

---

### **Estimated number of subjects**

140000

## Study design details

### **Outcomes**

Primary outcomes of interest include lung cancer, lymphoma, breast cancer, non-melanoma skin cancer, all malignancies, hospitalized infections, pneumonia, opportunistic infections and tuberculosis. lupus, multiple sclerosis and psoriasis

---

### **Data analysis plan**

Descriptive analyses of the data will be conducted. Overall incidence rates and rates stratified by age group and sex will be calculated. Unadjusted and adjusted Cox proportional hazards regression analyses will be performed.

## 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**

Ingenix (OptumInsight) United States, Truven MarketScan Commercial United States, Truven marketScan Supplemental Medicare United States, IMS LifeLink: PharMetrics Plus - US

---

### **Data sources (types)**

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

## 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**

Unknown