# Comparative safety of abatacept in rheumatoid arthritis with COPD: A real-world population-based observational study

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Study Ongoing

## Administrative details

**EU PAS number**

EUPAS25405

**Study ID**

25561

**DARWIN EU® study**

No

**Study countries**

United States

**Study status**

Ongoing

## Research institutions and networks

## Institutions

### Centre d'Épidémiologie Clinique de Montreal

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Institution

## Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Teresa Simon

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Actual: 19/10/2016

**Study start date**

Actual: 01/01/2007

**Date of final study report**
Planned: 31/10/2018

## 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 type:**

Non-interventional study

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Main study objective:**

To assess whether treatment with abatacept for RA among patients with COPD is associated with an increased risk of COPD exacerbation, bronchitis and pneumonia/influenza compared with other BDMs.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medical condition to be studied**

Chronic obstructive pulmonary disease

Infective exacerbation of chronic obstructive airways disease

Pneumococcal infection

Influenza

Bronchitis

## Population studied

**Age groups**

- 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**

12650

## Study design details

**Outcomes**

Primary outcomes of interest include COPD exacerbations, bronchitis and pneumonia/influenza, Secondary outcome will be combining COPD exacerbation, bronchitis and pneumonia/influenza

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**Data analysis plan**

Descriptive statistics will be calculated within each database to compare baseline characteristics between patients who are prescribed abatacept and other BDMs. The primary analysis will be based on the cox proportional hazards regression model to estimate the hazard ratio and 95% CI of each outcome event comparing patients using abatacept with users of other BDMs, further adjusted for confounders found to be unbalanced despite matching on propensity scores.

# 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)**

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

No