

# An Analysis of Real-World Data on the Safety of Etanercept in Elderly Patients with Rheumatoid Arthritis

**First published:** 21/09/2018

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS25655

---

### Study ID

25656

---

### DARWIN EU® study

No

---

### Study countries

 United States

---

### Study description

Both rheumatoid arthritis (RA) and older age are associated with a higher risk of comorbidities, and the appropriate treatment approach for older patients is unclear. We evaluated real-world data (RWD) to determine whether there is an association between etanercept (ETN) and select adverse events (AEs) in patients with RA, stratified by age. We hypothesized that there is no difference in risk of AEs between younger (aged  $\leq 65$  yr) and older (aged  $> 65$  yr) patients.

---

### **Study status**

Finalised

## Research institutions and networks

### Institutions

Truven MarketScan

## Contact details

### **Study institution contact**

Heather Jones [heather.e.jones@pfizer.com](mailto:heather.e.jones@pfizer.com)

**Study contact**

[heather.e.jones@pfizer.com](mailto:heather.e.jones@pfizer.com)

### **Primary lead investigator**

Heather Jones

**Primary lead investigator**

# Study timelines

## **Date when funding contract was signed**

Actual: 01/09/2012

---

## **Study start date**

Actual: 26/03/2018

---

## **Date of final study report**

Actual: 05/06/2018

# Sources of funding

- Pharmaceutical company and other private sector

# More details on funding

Pfizer

# Study protocol

[EUPAS25655\\_protocol.pdf](#) (221.42 KB)

# 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 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:**

Both RA and older age are associated with a higher risk of comorbidities, and the appropriate treatment approach for older patients is unclear. We evaluated RWD to determine whether there is an association between ETN and select AEs in patients with RA, stratified by age. We hypothesized that there is no difference in risk of AEs between younger (aged  $\leq 65$  yr) and older (aged  $> 65$  yr) patients.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

ENBREL

---

**Medical condition to be studied**

Rheumatoid arthritis

## Population studied

**Short description of the study population**

Elderly Patients with Rheumatoid Arthritis.

---

**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**

450000

## Study design details

## Outcomes

The primary outcome is that we determine that our hypothesis is correct that there is no difference in risk of certain AEs between younger (aged  $\leq 65$  yr) and older (aged  $> 65$  yr) patients using Enbrel. Determine the risk of CHF, SI, NMSC, and ILD in patients using Enbrel

---

## Data analysis plan

Data from 2013 to 2018 were analyzed from the IBM Watson Health MarketScan Database which contains information on 104.5 million distinct patients, including 531,996 with RA. Patients were required to be enrolled  $\geq 1$  yr prior to RA diagnosis, the first exposure to ETN was after RA diagnosis and before the AE of interest: congestive heart failure (CHF), serious infection (SI), non-melanoma skin cancer (NMSC), or interstitial lung disease (ILD). Proportion of patients experiencing each AE was determined for patients  $\leq 65$  yr and  $> 65$  yr receiving and not receiving ETN. Differences were evaluated using Fisher's Exact test. Logistic regression models assessed the interaction between ETN and age group. Propensity matching was performed, and logistic regression was applied using the propensity-score-matched cohort. Patients receiving and not receiving ETN were matched by age, age  $> 65$  yr, gender, and geographical region.

## Documents

### Study results

[results.pdf](#) (360.66 KB)

---

## 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**

Unknown