

# Rates for Anaphylaxis for Patients with Rheumatoid Arthritis Treated with Tocilizumab or Other Biologics: An Analysis Based on Health Claims Data

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Study

Finalised

## Administrative details

### EU PAS number

EUPAS18844

### Study ID

18901

### DARWIN EU® study

No

### Study countries

United States

### Study status

Finalised

## Research institutions and networks

# Institutions

## F. Hoffmann-La Roche

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

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**Institution**

# Contact details

## **Study institution contact**

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**Study contact**

[global.clinical\\_trial\\_registry@roche.com](mailto:global.clinical_trial_registry@roche.com)

## **Primary lead investigator**

Khaled Sarsour

**Primary lead investigator**

# Study timelines

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

Actual: 15/11/2014

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## **Study start date**

Actual: 01/12/2014

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**Data analysis start date**

Actual: 01/12/2014

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**Date of final study report**

Actual: 03/12/2014

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

F. Hoffmann-La Roche Ltd

## Regulatory

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

No

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

EU RMP category 3 (required)

## Other study registration identification numbers and links

GA29837

## 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:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

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**Main study objective:**

Incidence rate of anaphylaxis and fatal anaphylaxis

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Retrospective database study

## Study drug and medical condition

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

**Medical condition to be studied**

Rheumatoid arthritis

**Population studied**

**Short description of the study population**

Patients with rheumatoid arthritis treated with Tocilizumab or other biologics.

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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)

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**Special population of interest**

Other

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**Special population of interest, other**

Rheumatoid arthritis patients

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**Estimated number of subjects**

0

**Study design details**

## Outcomes

- Incidence rate of anaphylaxis and fatal anaphylaxis- Incidence rate of fatal anaphylaxis

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## Data analysis plan

For IV drugs, anaphylaxis rates will be calculated for events occurring within 7 days, 14 days and 30 days following anaphylaxis. The primary analysis is that of events occurring within 7 days of drug infusion. The rest are sensitivity analyses. Fatal Anaphylaxis rates will be calculated for events occurring within 7 days, 14 days and 30 days following anaphylaxis. The primary analysis will be for fatal events occurring within 7 days of anaphylaxis. Fatal events occurring with 14 and 30 days will be conducted as sensitivity analyses. Descriptive statistics including patient numbers and proportions will be calculated for all study cohorts by patient age, gender, insurance plan, and region. Duration of enrollment (i.e. database history) will be calculated from enrollment date to index date and from index date to disenrollment or database cutoff date. Means with standard deviation (SD) and medians with interquartile range (IQR) will be presented where appropriate.

## 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)

Disease registry

Drug registry

## 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

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## Data characterisation

### **Data characterisation conducted**

Unknown