An Active Surveillance, Post Authorization Safety Study (PASS) to Estimate Incidence Rates of Serious Infection, Malignancy, Cardiovascular (CV) and Other Safety Events of Interest among all Patients Treated with Ruxience for Rheumatoid Arthritis (RA) within the German Registry Rheumatoide Arthritis: Beobachtung der Biologika Therapie (RABBIT)

First published: 21/10/2020 Last updated: 16/10/2024





### Administrative details

**EU PAS number** 

EUPAS37691

Study ID

41900

DARWIN EU® study
No
Study countries  Germany
Study description
To estimate incidence rates of infections, including serious infections,
malignancies, cardiovascular events, and events associated with use during pregnancy among patients with rheumatoid arthritis in the RABBIT register who initiate Ruxience.
Study status Finalised
Research institutions and networks
Institutions
Pfizer
First published: 01/02/2024
<b>Last updated:</b> 01/02/2024
Institution
Epidemiology Unit, Deutsches Rheuma-
Forschungszentrum Berlin (DRFZ)

Germany

First published: 02/05/2010

**Last updated:** 20/08/2024



**Educational Institution** 

### Contact details

#### **Study institution contact**

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Study contact

cynthia.deluise@pfizer.com

#### **Primary lead investigator**

Cynthia de Luise

Primary lead investigator

## Study timelines

Date when funding contract was signed

Actual: 01/07/2020

### **Study start date**

Planned: 02/06/2021

Actual: 02/06/2021

### Data analysis start date

Planned: 31/12/2023

Actual: 31/12/2023

#### **Date of final study report**

Planned: 30/11/2024 Actual: 23/08/2024

## Sources of funding

• Pharmaceutical company and other private sector

## More details on funding

Pfizer, Inc

## Study protocol

B3281012\_PROTOCOL AND APPROVAL\_RABBIT PASS Ruxience\_V1.0\_ 140CT2020.pdf (3.98 MB)

## 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 Disease epidemiology

Drug utilisation

#### Main study objective:

To estimate incidence rates of infections, including serious infections, malignancies, cardiovascular events, and events associated with use during pregnancy among patients with rheumatoid arthritis in the RABBIT register who initiate Ruxience.

## Study Design

#### Non-interventional study design

Cohort

## Study drug and medical condition

#### Name of medicine

RUXIENCE

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

#### **Anatomical Therapeutic Chemical (ATC) code**

#### Medical condition to be studied

Rheumatoid arthritis

## Population studied

#### Age groups

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

#### Special population of interest

Pregnant women

#### **Estimated number of subjects**

50

## Study design details

#### **Data analysis plan**

Descriptive summaries of Ruxience exposed patients and crude incidence rates and 95% confidence intervals of safety event of interest.

### **Documents**

#### **Study report**

B3281012 RABBIT NI Study Report Abstract\_23AUG2024.pdf (103.13 KB)
B3281012 RABBIT Final Study Report 23AUG2024.pdf (455.73 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 source(s)

Rheumatoid Arthritis - Observation of Biologic Therapies

### Data sources (types)

Disease registry

## Use of a Common Data Model (CDM)

### **CDM** mapping

No

## Data quality specifications

### **Check stability**

**Check conformance** 

Unknown

### **Check logical consistency**

Unknown

# Data characterisation

#### **Data characterisation conducted**

No