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

Study Finalised

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

Last updated: 01/02/2024

Institution

Epidemiology Unit, Deutsches Rheuma-Forschungszentrum Berlin (DRFZ)

Germany

First published: 02/05/2010

Last updated: 20/08/2024

Institution | Educational Institution

Contact details

Study institution contact

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Study contact

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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_14OCT2020.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

Medicinal product name

RUXIENCE

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

RITUXIMAB

Anatomical Therapeutic Chemical (ATC) code

(L01XC02) rituximab

rituximab

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 conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No