# A Prospective Observational Study to Evaluate Long-term Safety of AMGEVITA in Patients With Rheumatoid Arthritis (20160264)

**First published:** 07/11/2019

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Study Ongoing

## Administrative details

**EU PAS number**

EUPAS31796

**Study ID**

32417

**DARWIN EU® study**

No

**Study countries**

United Kingdom

**Study description**

The current study is designed to fulfill a post-authorization commitment to evaluate long-term safety of AMGEVITA and utilizes an existing registry, the BSRBR-RA. This method supports the collection of long-term safety data for new, similar biological product treatments in the postmarketing setting and is an efficient approach for conducting post-authorization safety studies (PASS).

**Study status**

Ongoing

## Research institutions and networks

## Institutions

### Amgen

United States

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

**Last updated:** 27/03/2026

**Institution**

## Contact details

**Study institution contact**

Global Development Leader Amgen Inc.
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**Study contact**

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**Primary lead investigator**

Global Development Leader Amgen Inc.

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 08/03/2019

Actual: 08/03/2019

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**Study start date**

Planned: 15/11/2019

Actual: 15/11/2019

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**Data analysis start date**

Planned: 02/06/2027

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**Date of final study report**

Planned: 27/10/2027

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

20160264_01.02.06 Public Redacted Protocol Ver 1.0 2019-06-13 English.pdf (5.06 MB)

## Regulatory

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

Yes

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

EU RMP category 3 (required)

# 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:**

The primary objective of this study is to estimate the incidence rates of the following safety concerns (identified risks of adalimumab) in patients with RA exposed to AMGEVITA: serious infections (ie, infectious events which require IV antibiotics, hospitalization, or meet other criteria for a serious adverse event)

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Prospective observational cohort study

## Study drug and medical condition

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

ADALIMUMAB

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**Medical condition to be studied**

Rheumatoid arthritis

## Population studied

**Age groups**

- Adolescents (12 to < 18 years)
- 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**

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

**Estimated number of subjects**

300

## Study design details

**Outcomes**

The primary outcome measures are: Incidence of serious infections (ie, infectious events which require IV antibiotics, hospitalization, or meet other criteria for a serious adverse event) in patients with RA exposed to AMGEVITA, The secondary outcome measures are: • Incidence of serious hypersensitivity reactions in patients with RA exposed to AMGEVITA • incidence of other serious adverse events (safety concerns) in patients with RA exposed to AMGEVITA• incidence rates safety concerns from both the BSRBR-RA anti-TNFand nbDMARD comparison cohorts.

**Data analysis plan**

All analyses will be descriptive. For categorical variables, the frequency and percentage, with 95% CI where appropriate, will be provided. Summary statistics for continuous variables will include the number of patients, mean, median, SD or standard error, minimum and maximum. Follow-up among the AMGEVITA-treated patients will start from initiation of the drug and end with the occurrence of death, discontinuation of AMGEVITA or the end of the 5-year follow-up period, whichever comes first. For the purposes of context, current incidence rates will also be calculated from both of the following BSRBR-RA comparison cohorts: anti-TNF comparison cohort, which is a cohort of patients receiving an established anti-TNF drug (adalimumab, etanercept or infliximab) who were recruited within 6 months of first exposure. nbDMARD comparison

cohort, which is a cohort of patients with similar disease activity receiving conventional systemic DMARDs who have never been exposed to biologic therapy

# 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)**

Other

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**Data sources (types), other**

Exposure 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