# An Observational, Prospective Cohort Study to Evaluate Safety and Efficacy of RemsimaTM in Patients with Rheumatoid Arthritis

**First published:** 11/02/2015

**Last updated:** 15/02/2019

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS8571

**Study ID**

28166

**DARWIN EU® study**

No

**Study countries**

- ☐ Denmark
- ☐ Korea, Republic of
- ☐ Romania

Spain

**Study description**

The objective of this study is to assess the long-term safety and efficacy of RemsimaTM in Rheumatoid Arthritis (RA) patients.

**Study status**

Ongoing

## Research institutions and networks

## Institutions

### Sf.Maria Clinical Hospital

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**Institution**

## Contact details

**Study institution contact**

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**Study contact**

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**Primary lead investigator**

SungHwan Park

Primary lead investigator

# Study timelines

**Date when funding contract was signed**
Actual: 11/12/2014

**Study start date**
Planned: 30/09/2015

Actual: 30/09/2015

**Data analysis start date**
Planned: 31/01/2016

**Date of interim report, if expected**
Planned: 31/05/2016

**Date of final study report**
Planned: 30/10/2026

# Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Celltrion

# Study protocol

CT-P13 4 2_RA registry protocol_EU-specific_Ver 2.1 03Jun15_Synopsis for PASS_clean.pdf(31.86 KB)

## Regulatory

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

Yes

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**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

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness
Effectiveness study (incl. comparative)

**Main study objective:**

The primary objective of this study is to assess the long-term safety and efficacy of RemsimaTM in Rheumatoid Arthritis (RA) patients.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Name of medicine**

REMSIMA

**Medical condition to be studied**

Disseminated tuberculosis

Cardiac failure congestive

Opportunistic infection

Serum sickness

## Population studied

**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)

**Estimated number of subjects**

450

## Study design details

**Outcomes**

to assess the long term safety of Remsima in RA patients, to evaluate efficacy in patients with RA

**Data analysis plan**

the statistical analysis will be performed using SAS software version.9.1.3 or later. Interim report of study results will be generated every May from 2016 and the final report will be generated in 2026.

## Documents

**Study, other information**

01 EULAR 2017_CT-P13 4.2 2Y_Abstract (publication only).pdf(185.04 KB)

# Data management

## Data sources

**Data sources (types)**

Other

**Data sources (types), other**

Prospective patient-based data collection

## 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