

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

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

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

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS8571

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### Study ID

28166

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### DARWIN EU® study


No

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### Study countries

 Denmark

 Korea, Republic of

 Romania

## Study description

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

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## Study status

Ongoing

## Research institutions and networks

### Institutions

#### Sf.Maria Clinical Hospital

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

**Last updated:** 01/02/2024

Institution

## Contact details

### Study institution contact

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Study contact

[postmarket\\_safetyreport@celltrion.com](mailto:postmarket_safetyreport@celltrion.com)

### Primary lead investigator

SungHwan Park

## Study timelines

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

Actual: 11/12/2014

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### **Study start date**

Planned: 30/09/2015

Actual: 30/09/2015

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### **Data analysis start date**

Planned: 31/01/2016

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### **Date of interim report, if expected**

Planned: 31/05/2016

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### **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

## 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 Remsima™ in Rheumatoid Arthritis (RA) patients.

## Study Design

## Non-interventional study design

Cohort

# Study drug and medical condition

## Medicinal product name

REMSIMA

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## 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)
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## 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

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## 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

### 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**

Prospective patient-based data collection

## 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

## Data characterisation

### **Data characterisation conducted**

No