

# A MULTICENTER, OBSERVATIONAL POST-MARKET CLINICAL FOLLOW-UP STUDY IN PATIENTS WITH RA, PsA, OR axSpA ASSESSING THE PATIENT EXPERIENCE WITH THE CIMZIA AVA DEVICE OR OTHER TNF-BLOCKER AUTO-INJECTOR DEVICES

**First published:** 03/12/2019

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS32246

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### Study ID

32247

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### DARWIN EU® study

No

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### Study countries

 Belgium

 Germany

 Italy

 Spain

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### **Study description**

This observational post-market clinical follow-up (PMCF) device study is designed to assess utility and use of auto-injection devices available on the market for administration of tumor necrosis factor (TNF)-blocking agents in patients with rheumatoid arthritis (RA), psoriatic arthritis (PsA) or axial spondyloarthritis (axSpA), specifically of the certolizumab pegol (CZP) ava device (ava) and other auto-injectors.

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### **Study status**

Finalised

## Contact details

### **Study institution contact**

Clinical Trial Registries and Results Personal identifiable data of lead investigator are not published here, as consent according to Section 4a of the German Federal Act on Data Protection is not available. [clinicaltrials@ucb.com](mailto:clinicaltrials@ucb.com)

**Study contact**

[clinicaltrials@ucb.com](mailto:clinicaltrials@ucb.com)

### **Primary lead investigator**

Clinical Trial Registries and Results Personal identifiable data of lead investigator are not published here, as consent

according to Section 4a of the German Federal Act on Data Protection is not available.

Primary lead investigator

## Study timelines

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

Actual: 26/03/2019

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### **Study start date**

Actual: 15/11/2019

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

Actual: 19/05/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

UCB Biopharma S.R.L.

## Regulatory

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

No

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

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Other

**If 'other', further details on the scope of the study**

Assess utility and use of auto-injection devices available on the market for administration of tumor necrosis factor (TNF)-blocking agents in patients with rheumatoid arthritis (RA), psoriatic arthritis (PsA) or axial spondyloarthritis (axSpA)

**Main study objective:**

Assess the patients' satisfaction with self-injection by either ava or other auto-injector devices for administration of a tumor necrosis factor (TNF)-blocking agent at observational point 1 (OP1, about 3 months after device prescription), using 6 questions of the post-self-injection assessment questionnaire (SIAQ) V2.1 satisfaction domain

## Study Design

## **Non-interventional study design**

Other

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## **Non-interventional study design, other**

Post-approval study on Device utilisation

## Study drug and medical condition

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

CERTOLIZUMAB PEGOL

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### **Medical condition to be studied**

Rheumatoid arthritis

Psoriatic arthropathy

Axial spondyloarthritis

## 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**

200

## Study design details

## **Outcomes**

The summary score describing patient's satisfaction with self-injection as calculated from 6 questions (Q15, and Q17 to Q21) of the post-self-injection assessment questionnaire (SIAQ) V2.1 satisfaction domain documented about 3 months (OP1) after device prescription, The time in days from initial prescription to discontinuation of device use at about 12 months (360 days) after device prescription (persistence of use)

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## **Data analysis plan**

This is an exploratory study design without any formal statistical hypothesis testing. The study will estimate the true population proportion or mean of self-injection related endpoints for each device group separately (ava and all other devices). Data will be appropriately summarized and analyzed using tabulation and graphs with respect to demographic/baseline characteristics, disposition, utility/safety observations and other measurements. Summary statistics for continuous variables will include: number of available observations, mean with 95% confidence interval (CI), standard deviation (SD), minimum, median, and maximum. For categorical variables, the number and proportion of patients will be presented. Time-to-event variables will be summarized by Kaplan- Meier analyses.

## **Documents**

### **Study results**

[DV0005-synopsis-public-PDFA.pdf](#) (669.44 KB)

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## **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