

# Cold Agglutinin Disease Real World Evidence Registry (Cadence)

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Study

Planned

## Administrative details

### EU PAS number

EUPAS47940

### Study ID

47941

### DARWIN EU® study

No

### Study countries

- ☐ Austria
- ☐ France
- ☐ Germany
- ☐ Italy
- ☐ Japan
- ☐ Spain

☐ United Kingdom

☐ United States

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### **Study description**

The aim of the Cadence registry is to develop a large, international database of patients with cold agglutinin disease (CAD) or cold agglutinin syndrome (CAS, previously known as secondary CAD) to prospectively collect longitudinal data and better understand patient and clinical characteristics, complications, long-term clinical and patient-reported outcomes associated with the different CAD and CAS treatments and health-resource utilization. This registry will also improve the understanding of the natural history of CAD and CAS and will help raise awareness of CAD and CAS and their management. In addition, the registry will include a cohort study to assess the safety and the effectiveness of sutimlimab in patients with CAD in a real-world setting.

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### **Study status**

Planned

## Research institutions and networks

### Institutions

[Prof Alexander Röth](#)

## Contact details

### **Study institution contact**

Ronnie Yoo Ronnie.Yoo@sanofi.com

Study contact

Ronnie.Yoo@sanofi.com

**Primary lead investigator**

Alexander Röth

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 01/01/2019

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**Study start date**

Planned: 30/06/2022

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**Data analysis start date**

Planned: 01/09/2023

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**Date of interim report, if expected**

Planned: 29/12/2023

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**Date of final study report**

Planned: 31/12/2031

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Sanofi US Services Inc.

## 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

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

#### Main study objective:

To develop an international database of patients with CAD or CAS (previously known as secondary CAD) to prospectively collect longitudinal data and better understand patient and clinical characteristics, disease progression, complications, treatment impact, and patient-reported outcomes. To assess the safety and the effectiveness of sutimlimab in patients with CAD in a real-world setting.

## Study Design

### **Non-interventional study design**

Cohort

## Study drug and medical condition

### **Name of medicine**

ENJAYMO

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

Cold type haemolytic anaemia

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### **Additional medical condition(s)**

Cold agglutinin syndrome

## 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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### **Special population of interest**

Renal impaired  
Hepatic impaired  
Immunocompromised  
Pregnant women

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### **Estimated number of subjects**

400

## Study design details

### **Data analysis plan**

Continuous variables will be characterized with non-missing observations, mean and standard deviation, median, 1st and 3rd quartiles, minimum and maximum, and number of missing data. Categorical variables will be characterized by the frequency and percent distribution in each category and the number of missing data. 95% confidence intervals of means and percentages will be provided, if relevant. Time-to-event outcomes will be assessed using Kaplan-Meier analysis. Repeated measures analyses may be used for outcomes collected at more than one time point, such as HRQoL or laboratory values.

## 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)

[Disease registry](#)

[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