

# Assessing Long-Term Outcomes of DUPIXENT® Treatment in Patients with Chronic Rhinosinusitis with Nasal Polyposis (AROMA)

**First published:** 11/08/2021

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

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS41565

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### Study ID

42822

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### DARWIN EU® study

No

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### Study countries

 Canada

 Germany

 Italy

 Japan

 Netherlands

 United States

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## Study description

The primary objectives of the study are: • To longitudinally characterize the long-term effectiveness of DUPIXENT® through assessment of patient-reported symptoms, Health-Related Quality of Life (HRQoL) related to chronic rhinosinusitis with nasal polyposis (CRSwNP) and other type 2 comorbidities, and their change over-time. • To characterize patients who receive DUPIXENT® for CRSwNP in a real-world setting with respect to their medical history, demographic and disease characteristics, and type 2 comorbidities The secondary objectives of the study are: • To characterize real-world utilization of DUPIXENT® for patients with CRSwNP • To collect patient and physician global assessment of disease severity and treatment satisfaction for patients receiving DUPIXENT® for CRSwNP • To collect long-term safety data for patients receiving DUPIXENT® for CRSwNP

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## Study status

Ongoing

# Research institutions and networks

## Institutions

**Regeneron Pharmaceuticals**

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

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## Contact details

### Study institution contact

Study Director Regeneron

[clinicaltrialdisclosureteam@regeneron.com](mailto:clinicaltrialdisclosureteam@regeneron.com)

Study contact

[clinicaltrialdisclosureteam@regeneron.com](mailto:clinicaltrialdisclosureteam@regeneron.com)

### Primary lead investigator

Study Director Regeneron

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 09/06/2021

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### Study start date

Planned: 13/08/2021

Actual: 12/08/2021

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### Data analysis start date

Planned: 26/04/2027

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### Date of final study report

Planned: 07/06/2027

## Sources of funding

- Other
- Pharmaceutical company and other private sector

## More details on funding

Regeneron Pharmaceuticals, Inc., Sanofi

## 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

## Other study registration identification numbers and links

R668-cSNP-2072,NCT04959448

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Herbal medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Evaluation of patient-reported outcomes

Other

Safety study (incl. comparative)

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

Characterization of population receiving therapy

**Main study objective:**

- To longitudinally characterize the long-term effectiveness of DUPIXENT® through assessment of patient-reported symptoms, HRQoL related to CRSwNP and other type 2 comorbidities and their change over-time.
- To characterize patients who receive DUPIXENT® for CRSwNP in a real-world setting with respect to their medical history, demographic and disease characteristics, and type 2 comorbidities

## Study Design

**Non-interventional study design**

Other

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## Non-interventional study design, other

Observational prospective product registry

# Study drug and medical condition

## Medicinal product name

DUPIXENT

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

DUPILUMAB

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## Anatomical Therapeutic Chemical (ATC) code

(D11AH05) dupilumab

dupilumab

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## Medical condition to be studied

Chronic rhinosinusitis with nasal polyps

# 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

709

# Study design details

## Outcomes

- Baseline Patient Characteristics
  - Baseline Disease Characteristics,
  - Descriptive summaries of DUPIXENT and other CRSwNP treatments used during the study as defined in the protocol
  - Reasons for initiation of new CRSwNP treatments, concomitant therapies, treatment durations, and reasons for discontinuation and/or switching
  - Global assessment of disease severity and treatment satisfaction
  - Descriptive summary of adverse events See add'l info NCT04959448
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## Data analysis plan

Data collected in this registry will be analyzed descriptively.

## 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