Registry of Asthma Patients Initiating DUPIXENT® (RAPID)

First published: 18/10/2021

Last updated: 02/07/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS41963

Study ID

46244

DARWIN EU® study

No

Study countries

- [ ] Canada
- [ ] Denmark
- [ ] France
- [ ] Italy
- [ ] Japan
- [ ] Puerto Rico

- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom
- [ ] United States

Study description

The primary objective of the study is to characterize the patients who initiate treatment for asthma with DUPIXENT® in a real-world setting to understand the attributes of treated patients in real life. This includes characterization of: • Patient demographics (eg, gender, age, and race) • Patient baseline characteristics (eg, prior medications and procedures, medical history, asthma history, weight, height) The secondary objectives of the study are: • To characterize real-world use patterns of DUPIXENT® for asthma • To assess the long-term effectiveness of DUPIXENT® in asthma patients in a real-world setting • To assess effectiveness on comorbid type 2 inflammatory conditions in asthma patients treated with DUPIXENT® • To collect long-term safety data on study participants in the real-world setting

Study status

Ongoing

Research institutions and networks

Institutions

Regeneron Pharmaceuticals

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Study Director Regeneron

clinicaltrialdisclosureteam@regeneron.com

Study contact

clinicaltrialdisclosureteam@regeneron.com

Primary lead investigator

Study Director Regeneron

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 26/09/2019

Study start date

Actual: 02/03/2020

Data analysis start date

Planned: 28/01/2026

Date of final study report

Planned: 18/05/2026

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

Regeneron Pharmaceuticals, Inc., Sanofi (Collaborator)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

R668-AS-1885,NCT04287621

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Patient Characterization of population receiving therapy and evaluations of safety and effectiveness

Main study objective:

This is a prospective global product registry, designed to collect data regarding the characteristics of patients who initiate DUPIXENT for asthma according to the country-specific prescribing information, real-world use patterns for DUPIXENT and any co-treatments, and long-term data on DUPIXENT’s safety and effectiveness in the real-world setting.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational prospective product registry

Study drug and medical condition

Medical condition to be studied

Asthma

Population studied

Age groups

Adolescents (12 to < 18 years)

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

1000

Study design details

Outcomes

• Demography • Baseline Characteristics, • Baseline Treatment Characteristics • Incidence of AEs • Physician Assessments: Spirometry & FeNO • Patient Reported Outcomes (PRO): ACQ-6, MiniAQLQ, Global Patient Assessments, PALQ, & WPAI-asthma • PRO (allergic rhinitis): AR-VAS, RQLQS+12 • PRO (chronic (rhino) sinusitis +/- nasal polyps): SNOT-22 • PRO (AD): POEM • Healthcare Utilization: HCRUQ See ClinicalTrials.gov NCT04287621

Data analysis plan

Data collected in this registry will be analyzed descriptively.

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