Effectiveness Evaluation of PALFORZIA Risk Management Plan Educational Materials

First published: 07/04/2021

Last updated: 18/02/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS40247

Study ID

44327

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Germany
- ☐ United Kingdom

Study description

This is a post-authorization cross-sectional descriptive survey study (category 3 PASS Safety Study) required in PALFORZIA RMP approved by EMA. The study is intended to be conducted in the European Union and the UK, with data collected systematically in specific countries when access to PALFORZIA becomes commercially available. After receiving PALFORZIA educational materials distributed according to a defined distribution plan, PALFORZIA prescribing HCPs, parents/caregivers of 4-11 year-old patients who have been prescribed PALFORZIA, and 12 – 17 year old patients who have been prescribed PALFORZIA who provide informed consent will complete an online survey in their local language. Data collection in each country will continue until completed, valid surveys are received from minimum desired sample size of 5 HCPs, 25 parents/caregivers (of 4-11 year-old patients), and 25 patients (age 12-17 years old) in each country.

Study status

Ongoing

Research institutions and networks

Institutions

Aimmune Therapeutics

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Stallergenes

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Last updated: 01/02/2024

Institution

Contact details

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Primary lead investigator

Katia Daghildjian

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/12/2020

Actual: 18/12/2020

Study start date

Planned: 30/03/2022

Actual: 01/01/2022

Date of interim report, if expected

Actual: 14/11/2024

Date of final study report
Planned: 31/12/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Marketing Authorization was transferred from Aimmune Therapeutics to Stallergenes

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

Main objective: Verification of the understandability and retention of core educational material messages by healthcare professionals (HCPs, parent/caregiver and patients)

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medicinal product name

PALFORZIA

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

DEFATTED POWDER OF ARACHIS HYPOGAEA L., SEMEN (PEANUTS)

Anatomical Therapeutic Chemical (ATC) code

(V01AA08) food

food

Medical condition to be studied

Food allergy

Population studied

Age groups

- Children (2 to < 12 years)
- 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

165

Study design details

Outcomes

The educational materials will be considered effective if the minimum score of 80% correct responses on questions designed to assess core messages is

obtained and there is 100% adherence to the educational material distribution plan to healthcare professionals, parents/caregivers, and patients

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Data analysis plan

Prior to analyzing survey data, the data will be cleaned to address missing information and potentially dishonest responses. Completed surveys will be monitored to ensure that the final sample size for analysis includes the appropriate number of valid surveys. For each country, the raw data will be analyzed and reported for each of the three study populations. The following will be reported: the total number of completed participant surveys obtained and included in the analysis (including any known reasons for non-participation), a description of participant demographics, a description of participant responses to each knowledge and process question, the percentage of respondents answering each question correctly, and a description of the overall average percent of participants who answered questions accurately, clearly identifying those domains that met the targeted outcome. Results from each of the countries will also be aggregated and reported.

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

Data sources (types), other

The data will be primary, self-report data collected directly from qualified HCPs, parents/caregivers, and patients using surveys delivered through an online survey platform

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