

# Effectiveness Evaluation of PALFORZIA Risk Management Plan Educational Materials

**First published:** 07/04/2021

**Last updated:** 06/05/2025

Study

Planned

## Administrative details

### EU PAS number

EUPAS40247

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### Study ID

44327

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### DARWIN EU® study

No

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### Study countries

- ☐ France
  - ☐ Germany
  - ☐ United Kingdom
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## 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.

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## Study status

Planned

## Research institutions and networks

### Institutions

**Aimmune Therapeutics**

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

**Last updated:** 01/02/2024

**Institution**

### Contact details

### Study institution contact

Robert Ryan rryan@aimmune.com

Study contact

[rryan@aimmune.com](mailto:rryan@aimmune.com)

### Primary lead investigator

Robert Ryan

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 18/12/2020

Actual: 18/12/2020

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### Study start date

Planned: 30/03/2022

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### Date of final study report

Planned: 31/12/2025

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Aimmune Therapeutics Ireland Limited

## 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:

Effectiveness study (incl. comparative)

#### 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

**Anatomical Therapeutic Chemical (ATC) code**

(V01AA08) food

food

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**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)

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**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**

### **Data sources**

#### **Data sources (types)**

[Other](#)

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#### **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

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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