

# Patient and Prescriber Survey: Effectiveness measures to investigate awareness, knowledge and adherence to the Risk Minimisation Measures (RMMs) of the Pregnancy Prevention Program (PPP) for Oral Retinoids (Acitretin, Alitretinoin, and Isotretinoin)

**First published:** 16/11/2020

**Last updated:** 28/02/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS38096

### Study ID

50298

### DARWIN EU® study

No

## **Study countries**

- France
- Germany
- Greece
- Norway
- Poland
- Spain
- United Kingdom

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## **Study description**

This survey aims to assess the effectiveness of the updated risk minimisation measures (RMMs) among female oral retinoid patients who are of childbearing potential and their prescribers and to assess patients' and prescribers' (HCPs') awareness and knowledge of and adherence to the pregnancy prevention programme (PPP). Primary objective: to assess the effectiveness of the PPP based on pre-defined success thresholds for PPP awareness, knowledge, and adherence in HCPs and patients. Secondary objectives: (1) to assess HCPs' and patients' awareness of the updated PPP (2) to assess HCPs' and patients' knowledge of the risks and RMMs associated with the use of oral retinoids (3) to assess whether HCPs and patients adhere to the RMMs of the updated PPP

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## **Study status**

Finalised

## **Research institutions and networks**

### **Institutions**

**Real World Solutions, IQVIA**

- Netherlands
- United Kingdom (Northern Ireland)

**First published:** 28/04/2011

**Last updated:** 22/03/2024

**Institution**

**Other**

**ENCePP partner**

## Contact details

### **Study institution contact**

Birgit Ehlken [PAS\\_registrations@iqvia.com](mailto:PAS_registrations@iqvia.com)

**Study contact**

[PAS\\_registrations@iqvia.com](mailto:PAS_registrations@iqvia.com)

### **Primary lead investigator**

Birgit Ehlken

**Primary lead investigator**

## Study timelines

### **Date when funding contract was signed**

Planned: 30/06/2018

Actual: 30/11/2018

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### **Study start date**

Planned: 31/03/2021

Actual: 24/03/2021

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## **Data analysis start date**

Planned: 01/10/2021

Actual: 07/10/2021

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## **Date of final study report**

Planned: 31/03/2022

Actual: 15/02/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

A Consortium of Marketing Authorization Holders for oral retinoids

## Study protocol

[20200727\\_Oral Retinoids\\_PASS\\_Survey\\_Protocol\\_v5.0\\_Redacted\\_NO ANNEX.pdf](#)  
(2.71 MB)

## 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 topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

Primary objective: to assess the effectiveness of the PPP based on pre-defined success thresholds for PPP awareness, knowledge, and adherence in HCPs and patients

## Study Design

**Non-interventional study design**

Cross-sectional

Other

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**Non-interventional study design, other**

Multinational, multi-channel survey

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(D05BB02) acitretin

acitretin

(D10BA01) isotretinoin

isotretinoin

(D11AH04) alitretinoin

alitretinoin

## Population studied

### **Short description of the study population**

A survey of healthcare professionals prescribed or administered oral retinoids (acitretin, alitretinoin and isotretinoin) to female patients of childbearing potential according to the local label in seven European countries.

Inclusion criteria:

HCPs

- HCPs who prescribed or administered oral retinoids (acitretin, alitretinoin and isotretinoin) to female patients of childbearing potential in the past 6 months

Patients

- Female gender
- Childbearing age (i.e., 13 to 49 years of age)
- Receiving prescriptions for oral retinoids (acitretin, isotretinoin or alitretinoin) at the time of the survey, or who have received prescriptions within the last 6 months
- Willing, understanding and consenting to participate in this self-administered survey. For patients between 13 to 17 years of age, the survey shall be filled out by their parent, guardian or caregiver.

Exclusion criteria

HCPs

- Inactive and retired HCPs (when documented information is available to identify them) will be deleted from the contact lists before randomization.
- HCPs who are not involved in patient treatment (e.g. researchers)
- HCPs who may have conflicts of interest with the survey (i.e., HCPs employed by regulatory bodies, pharmaceutical companies)
- HCPs who belong to a practice from which there are already at least two other HCPs participating in the survey
- HCPs who have participated in testing the questionnaire for comprehensibility, consistency and the appropriateness of medical terms

#### Patients

- Patients who may have conflicts of interest with the survey (i.e. patients employed by regulatory bodies, pharmaceutical companies)
- Patients who have a condition that prevents them from becoming pregnant and having children

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#### Age groups

- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

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#### Special population of interest

Pregnant women

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#### Estimated number of subjects

600

## Study design details

#### Data analysis plan

Results will be presented, overall and at country level stratified by HCP speciality and per molecule. Continuous variables will be described by the number of valid cases and missing data, mean, standard deviation, median, first quantile (Q1), third quantile (Q3), minimum, and maximum. Categorical variables will be described as the total number and relative percentage per category. Confidence intervals (CIs) of 95% will be calculated when relevant. Individual awareness, knowledge and adherence scores will be calculated as the percentage of correctly answered survey questions. Overall domain level scores will be calculated as the mean of individual scores. Calculations will first be performed on raw data, which will be stratified by speciality for the HCP survey, and weighted according to the real proportion of targeted responders for both the HCP and patient surveys per country to accurately reflect the population the survey seeks to measure.

## Documents

### **Study results**

[38096\\_20220215 Oral Retinoids\\_PASS\\_Survey\\_Final Report\\_v1.0\\_Abstract.pdf](#)  
(228.94 KB)

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## 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**

The recruitment of HCPs will be conducted using the OneKey database, which provides the lists and contact details of healthcare providers. Patients will be recruited by HCPs from OneKey.

## 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

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## Data characterisation

**Data characterisation conducted**

No