Qualitative Study – Barriers and Facilitators Assessment of adherence to the Risk Minimisation Measures (RMMs), specifically Pregnancy Prevention Programme (PPP) for Women of Childbearing Potential Using Oral Retinoids (acitretin, alitretinoin, and isotretinoin)

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Study Planned

Administrative details

EU PAS number

EUPAS1000000721

Study ID

1000000721

DARWIN EU® study

No

Study countries

France

Germany

Poland

Spain

Study description

Retinoic acid analogues, known as retinoids, are prescribed for various skin disorders, but their use poses teratogenic risks, leading to strict Pregnancy Prevention Programme (PPP) since 2003.

Based on results from the drug utilisation study (DUS)/survey study, the PRAC has requested marketing authorisation holders' (MAHs) to conduct a qualitative study to investigate adherence to PPP issues despite high awareness of the measures. The PRAC's request for a qualitative study stem from a recognition of the persistent issue of poor adherence to the PPP, despite high levels of awareness among healthcare professionals and WCBP as shown in the DUS/survey study. The committee seeks a deeper understanding of the underlying factors contributing to this low compliance to inform more effective interventions. By imposing a qualitative study, the PRAC aims to explore the nuanced barriers and drivers of adherence behaviour beyond mere awareness. This qualitative study allows for a comprehensive assessment of the sociocultural, psychological, and systemic factors influencing adherence to PPPs.

This study, categorized as a Category 3 PASS, aims to utilize an implementation science framework, specifically aligning with the PRECEDE-PROCEED Model. By adopting the PRECEDE-PROCEED framework, the study seeks to support targeted interventions and improve PPP implementation in real-world clinical settings, addressing the

persistent gaps in adherence to PPP measures while WCBP using oral retinoid therapies.

Study status

Planned

Research institutions and networks

Institutions

IQVIA

United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

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Primary lead investigator

Ana Maria Rodriguez

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/01/2024

Actual: 03/04/2024

Study start date
Planned: 01/10/2025

Data analysis start date
Planned: 03/11/2025

Date of interim report, if expected
Planned: 13/07/2026

Date of final study report
Planned: 12/07/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

The joint initiative involves several companies via a consortium: 2CARE4GENERICS, ALFASIGMA ESPAÑA, ALMIRALL, AUROBINDO, AXXON, BAILLEUL, BAUSCH HEALTH COMPANIES, CHEPLAPHARM, DERMAPHARM, ENNOGEN, ESPECIALIDADES FARMACÉUTICAS CENTRUM, S.A. EXPANSCIENCE, FIDIA, GALENPHARMA, GAP, GSK, HEXAL AG, IASIS PHARMA, INDUSTRIAL FARMACÉUTICA CANTABRIA, S.A., ISDIN, MEDINFAR, MYLAN PHARMACEUTICALS LIMITED, ORIFARM, PELPHARMA, PHARMATHEN, PIERRE FABRE, ROCHE, SMB,

STADA, SUN PHARMA, TARGET, and TEVA

Study protocol

Oral Retinoids PASS Qualitative Protocol FV_20250109_final_v1.0_redacted.pdf
(1.12 MB)

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:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Study design:

This is a non-interventional qualitative cross-sectional study that will be conducted in multiple European countries (i.e., France, Germany, Poland, and Spain). The data will be collected using qualitative interviews.

Main study objective:

In Europe, what are the barriers and reasons for low adherence to the oral retinoid therapy PPP measures from the perspectives of (i) healthcare professionals (HCPs) who prescribe or dispense oral retinoid therapy to women of childbearing potential (WCBP), (ii) WCBP who recently used or are currently using oral retinoid therapy, (iii) parents, guardians, or caregivers of adolescent WCBP who recently used or are currently using an oral retinoid therapy?

The overarching global objectives for all three populations of this study are the following:

P1. To describe the understanding of oral retinoid therapy PPP measures

P2. To describe the perception of oral retinoid therapy PPP measures

P3. To identify barriers and potential facilitators influencing adherence to oral retinoid therapy PPP measures

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medicinal product name

TOCTINO

NEOTIGASON

ROACCUTANE

Medicinal product name, other

Oral retinoids:

• Acitretin: D05BB02

• Alitretinoin: D11AH04

• Isotretinoin: D10BA01

Population studied

Short description of the study population

The study target population includes HCPs who prescribe or educate on oral retinoids PPP measures, WCBP taking or having taken oral retinoid therapies, or parents of adolescents WCBP taking or having taken oral retinoid therapies.

Age groups

- Adults (18 to < 46 years)

Special population of interest

Women of childbearing potential not using contraception

Women of childbearing potential using contraception

Estimated number of subjects

100

Study design details

Setting

The inclusion criteria for HCPs include being a medical specialist (dermatologists, paediatricians, and/or general practitioners) or an allied HCP (pharmacists and/or nurses, if applicable per country) who dispensed and/or educated WCBP on oral retinoid therapy PPP measures) at least once in the last 6 months in France, Germany, Spain or Poland.

The inclusion criteria for WCBP include being aged 18-49 and currently or recently (in the past 6 months) using any oral retinoid therapies in France, Germany, Spain, or Poland.

The inclusion criteria for parents, guardians, or caregivers, the primary inclusion criterion is being a parent, caregiver, or guardian of an adolescent WCBP aged 13-17 currently or recently (in the last 6 months) using oral retinoids (except alitretinoin) in France, Germany, Spain, or Poland.

Recruitment channels include clinician referral, patient advocacy groups, social media outreach, and IQVIA's in-house physician and patient panels.

The study population will include a sample, per country, of:
• 30 HCPs including 20 oral retinoid therapy prescribers (dermatologists, paediatricians, or general practitioners) and 10 dispensers and/or educators (pharmacists and/or nurses, if applicable in the targeted country about oral retinoid therapy PPP measures);

• 25 to 28 WCBP aged 18-49 per country, who currently or recently (in the past 6 months) used oral retinoid therapy, aiming with a distribution to represent:
o 15 WCBP aged 18-49 using isotretinoin (n=60 across all countries),
o 5 WCBP* aged 18-49 using acitretin (n=20 across all countries), and
o 5-8 WCBP* aged 18-49 using alitretinoin in France, Germany, and Spain (n=20 across all countries);
• 10 parents, guardians, or caregivers of adolescent WCBP aged 13-17 currently or recently (in the past 6 months) used oral retinoid therapies, excluding alitretinoin

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Data analysis plan

Data obtained during the study interviews will be summarized in table and/or narrative format with supportive
quotes. A combination of descriptive and qualitative analysis approaches will be used to present participants'
experiences, opinions and responses to interview questions.
Illustrative table shells are presented for each of the study populations included in the study and for each
specific objective described in the semi-structured discussion guide topics.
Preferences for ordering of results
as presented in future deliverables (e.g., qualitative study report) will be confirmed at the time of report outlining.

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.

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

Unknown