# Dissemination of additional risk minimisation measures for patients and healthcare professionals in EU/EEA countries

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**Last updated:** 29/08/2025





# Administrative details

EU PAS number	
EUPAS100000524	
Charder ID	
Study ID	
100000524	
DARWIN EU® study	
No	
Study countries	
Finland	
Hungary	
Italy	

<ul><li>☐ Lithuania</li><li>☐ Netherlands</li><li>☐ Romania</li></ul>
Study status Ongoing
Research institutions and networks
Institutions
University of Naples Federico II  First published: 01/02/2024  Last updated: 01/02/2024  Institution
Real-World Evidence Team, University of Eastern Finland (RWE team)  Finland  First published: 20/12/2017  Last updated: 27/08/2024  Institution  Educational Institution  ENCePP partner

Pharmacy and Pharmacology center, Faculty of Medicine, Vilnius University (PharmCenter VU)
Lithuania
First published: 08/01/2024
<b>Last updated:</b> 08/01/2024
Institution



Syreon Research Institute, Universitatea Babes-Bolyai, DESAN Research Solutions

Contact details

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## **Primary lead investigator**

Liset Van Dijk

**Primary lead investigator** 

# Study timelines

## Date when funding contract was signed

Actual: 28/02/2025

#### Study start date

Actual: 28/02/2025

## Date of interim report, if expected

Planned: 28/04/2026

## **Date of final study report**

Planned: 29/06/2026

# Sources of funding

EMA

# Study protocol

ROC30\_Annex V\_Response template\_Nivel\_16012025\_DEF.pdf (868.54 KB)

D2. Protocol DEF 29082025.pdf (3.06 MB)

# Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

# 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:** 

#### Study design:

Focus groups, interviews, and surveys among the different populations, desk research

#### Main study objective:

- 1. To describe and analyse aRMM dissemination: Process & frequency; key stakeholders involved; roles & responsibilities by type of aRMM, by dissemination method, by medicinal product and by country
- 2. To describe and analyse how access is ensured by type of aRMM, by medicinal product, by key stakeholder involved, and by country
- 3. To identify key challenges of disseminating healthcare professional- and patient-targeted aRMMs by type of aRMM, by dissemination method, by key stakeholder involved and by country
- 4. To identify and describe preferences for aRMM tools by type of aRMM, by dissemination method, by key stakeholder involved and by country
- 5. To provide recommendations by identifying feasible and concrete steps at each step of implementation pathway

# Study Design

## Non-interventional study design

Cross-sectional

# Study drug and medical condition

### Name of medicine

**XELJANZ** 

**AUBAGIO** 

LEMTRADA

**EYLEA** 

#### Name of medicine, other

Valproate containing medicinal products

Retinoids containing medicinal products

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

**TOFACITINIB CITRATE** 

**TERIFLUNOMIDE** 

**ALEMTUZUMAB** 

**AFLIBERCEPT** 

**EDOXABAN** 

**ACITRETIN** 

**ADAPALENE** 

**ALITRETINOIN** 

**BEXAROTENE** 

**ISOTRETINOIN** 

**TRETINOIN** 

**TAZAROTENE** 

# Population studied

#### Short description of the study population

Patients using these drugs, HCPs prescribing these drugs, Competent Authorities, pharmacists, Marketing AuthorizationHolders (MAH)

# 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)**

Non-interventional study

Other

Patient surveys

Published literature

### Data sources (types), other

Focus groups and surveys among healthcare professionals

Focus group and interviews with National Competent Authorities and Market

Authorisation Holders

# 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