

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

**First published:** 09/06/2025

**Last updated:** 11/12/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000000524

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### Study ID

1000000524

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### DARWIN EU® study

No

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### Study countries

- Finland
- Hungary
- Italy

- Lithuania
- Netherlands
- Romania

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### Study status

Ongoing

## Research institutions and networks

### Institutions

#### [University of Naples Federico II](#)

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

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

[Institution](#)

#### [Pharmacy and Pharmacology center, Faculty of Medicine, Vilnius University \(PharmCenter VU\)](#)

Lithuania

**First published:** 08/01/2024

**Last updated:** 08/01/2024

[Institution](#)

[Educational Institution](#)

[ENCePP partner](#)

# Netherlands Institute for Health Services Research (Nivel)

Netherlands

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

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

**Institution**

**Not-for-profit**

# Pharmaceutical Policy - research group, University of Eastern Finland

Finland

**First published:** 30/10/2025

**Last updated:** 30/10/2025

**Institution**

**Educational Institution**

**ENCePP partner**

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

## Contact details

### **Study institution contact**

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[Study contact](#)

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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

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#### **Study start date**

Actual: 28/02/2025

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#### **Date of interim report, if expected**

Planned: 28/04/2026

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#### **Date of final study report**

Planned: 29/06/2026

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## 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

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

Not applicable

## 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:**

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

**Medicinal product name**

XELJANZ

AUBAGIO

LEMTRADA

EYLEA

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### **Medicinal product name, other**

Valproate containing medicinal products

Retinoids containing medicinal products

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### **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](#)

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### **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

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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