# Implementation of controlled access to and distribution of medicinal products in European Union (CONTROL-EU)

**First published:** 18/09/2024

**Last updated:** 18/06/2025

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS1000000313

**Study ID**

1000000313

**DARWIN EU® study**

No

**Study countries**

- [ ] Austria
- [ ] Greece
- [ ] Latvia
- [ ] Netherlands

- [ ] Portugal
- [ ] Slovenia
- [ ] Spain
- [ ] Sweden

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**Study description**

This project aims to describe national implementation processes of controlled access programmes (CAP) as well as controlled distribution systems (CDS) on a given sample of eight centrally authorised medicinal products in eight different European health care systems (Austria, Greece, Latvia, Netherlands, Portugal, Slovenia, Spain and Sweden). Of special interest is to learn about national barriers and enablers as reported by key stakeholders.

A mixed-method approach is foreseen for this study, including desk research followed by a cross-sectional survey and qualitative semi-structured interviews with key national stakeholders including national competent authorities (NCAs), Marketing Authorisation Holders (MAHs), health care professionals, and patients.

The knowledge generated in this project will provide evidence that may be used for recommendations for regulators to engage with healthcare professional bodies and other responsible parties to investigate whether CAP/CDS are feasible and needed.

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**Study status**

Ongoing

# Research institutions and networks

## Institutions

## Division of Pharmacoepidemiology & Clinical Pharmacology (PECP), Utrecht Institute for Pharmaceutical Sciences (UIPS), Utrecht University

Netherlands

**First published:** 01/03/2010

**Last updated:** 23/05/2024

Institution | Educational Institution | ENCePP partner

## Centre for Health Protection (RIVM-GZB), National Institute for Public Health & Environment

Netherlands

**First published:** 06/11/2022

**Last updated:** 27/03/2024

Institution | EU Institution/Body/Agency | Laboratory/Research/Testing facility | ENCePP partner

## University Medical Center Utrecht (UMCU)

Netherlands

**First published:** 24/11/2021

**Last updated:** 22/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

## Department of Social Pharmacy, Faculty of pharmacy, University of Ljubljana

Slovenia

**First published:** 15/12/2021

**Last updated:** 20/08/2024

Institution | Educational Institution

## Department of Medicine/Laboratory of Hygiene and Environmental Protection, Democritus University of Thrace

Greece

**First published:** 30/11/2022

**Last updated:** 05/12/2022

Institution | Educational Institution | ENCePP partner

## University of Porto

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

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

Institution | Educational Institution

## Uppsala University

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

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

Institution

## Teamit Institute

Spain

**First published:** 12/03/2024

**Last updated:** 12/03/2024

Institution | Other | ENCePP partner

## Gesundheit Österreich Forschungs und Planungs GmbH, a subsidiary of Gesundheit Österreich GmbH (GOEG); Public University of Navarre (Spain); Riga Stradins University (Latvia)

# Networks

# EU Pharmacoepidemiology and Pharmacovigilance (PE&PV) Research Network

Netherlands

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

**Last updated:** 26/11/2024

Network

## Contact details


**Study institution contact**

Marie L De Bruin m.l.debruin@uu.nl

Study contact

m.l.debruin@uu.nl

**Primary lead investigator**

Marie L De Bruin 0000-0001-9197-7068

Primary lead investigator

**ORCID number:**

0000-0001-9197-7068


## Study timelines

**Date when funding contract was signed**

Planned: 23/07/2024

Actual: 23/07/2024

**Study start date**
Planned: 12/09/2024

Actual: 12/09/2024

**Date of final study report**
Planned: 31/03/2026

## Sources of funding

- EMA

## Study protocol

Study protocol_version 2.0_without Appendices.pdf(1.3 MB)

Study protocol_version 2.2_clean without appendices_final.pdf(1.29 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

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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:**

Primary data collection

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**Study design:**

A mixed-methods approach is foreseen including document analysis, a quantitative analysis of cross-sectional survey data as well as a qualitative analysis of stakeholders’ perceptions.

**Main study objective:**

The study aims to describe processes in and national experiences of eight European countries (Austria (AT), Greece (GR), Latvia (LV), Netherlands (NL), Portugal (PT), Slovenia (SI), Spain (ES), and Sweden (SE)) of implementing the EU pharmacovigilance legislation on risk minimisation measures (RMM) with an emphasis on controlled access programmes (CAP) and controlled distribution systems (CDS) using eight centrally authorised medicinal products as examples.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Qualitative study including document analysis, survey and qualitative interviews

## Study drug and medical condition

**Name of medicine**

ASPAVELI 1080 MG - SOLUTION FOR INFUSION

FINTEPLA

REVLIMID

SOLIRIS

SPRAVATO

STRIMVELIS

UPTRAVI

YESCARTA

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

AUTOLOGOUS CD34+ ENRICHED CELL FRACTION THAT CONTAINS CD34+ CELLS TRANSDUCED WITH RETROVIRAL VECTOR THAT ENCODES FOR THE HUMAN ADA CDNA SEQUENCE

AXICABTAGENE CILOLEUCEL

ECULIZUMAB

ESKETAMINE HYDROCHLORIDE

FENFLURAMINE HYDROCHLORIDE

LENALIDOMIDE

PEGCETACOPLAN

SELEXIPAG

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**Anatomical Therapeutic Chemical (ATC) code**

(A08AA02) fenfluramine

fenfluramine

(B01AC27) selexipag

selexipag

(L01XL03) axicabtagene ciloleucel

axicabtagene ciloleucel

(L03) IMMUNOSTIMULANTS

IMMUNOSTIMULANTS

(L04AJ01) eculizumab

eculizumab

(L04AJ03) pegcetacoplan

pegcetacoplan

(L04AX04) lenalidomide

lenalidomide

(N01AX14) esketamine

esketamine

(N03AX26) fenfluramine

fenfluramine

(N06AX27) esketamine

esketamine

(S01XA31) pegcetacoplan

pegcetacoplan

# Population studied

**Short description of the study population**

It is anticipated that the list will include all of the following stakeholders:

- National competent authorities / drug regulatory agency / health inspectorates
- Marketing authorisation holder / distributors of each of the eight medicinal products

- Professional organisations relevant for prescribing/dispensing the eight medicinal products (including physicians and pharmacists)
- Patient / care giver organisations relevant for the eight medicinal products

**Estimated number of subjects**

109000000

## Study design details

**Setting**

Eight European countries (Austria (AT), Greece (GR), Latvia (LV), Netherlands (NL), Portugal (PT), Slovenia (SI), Spain (ES), and Sweden (SE))

**Data analysis plan**

Quantitative analyses will entail descriptive statistics, univariate and bivariate analyses will be conducted according to stratifying variables. The analysis of the semi-structured interviews involves a content analysis based on a close line-by-line reading of the responses and developing a conceptual coding scheme based on the major themes in the interview guide.

# Data management

## Data sources

**Data source(s)**

Other data source

**Data source(s), other**

Three methods are foreseen to collect data from eight European countries including text materials from (online) documents, survey data and interview data.

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**Data sources (types)**

Other

Patient surveys

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**Data sources (types), other**

- Online documents;
- Survey data (including NCAs, MAHs, health care professionals);
- Interview data with NCAs, MAHs, health care professionals, patients.

## 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