

# Implementation of EU risk minimisation measures for medicinal products in clinical guidelines

**First published:** 07/06/2022

**Last updated:** 24/09/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS47588

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### Study ID

49902

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### DARWIN EU® study

No

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### Study countries

 Denmark

 Greece

 Latvia

 Netherlands

 Portugal

 Slovenia

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## **Study description**

This project aims to describe and understand the role of healthcare professional associations and public bodies involved in the production of clinical guidelines and the dissemination of emergent safety concerns. The implementation of product specific risk minimization measures (RMMs) in five disease priority areas into clinical guidelines will be assessed in six EU Member States (Denmark, Greece, Latvia, Netherlands, Portugal, Slovenia). A multiple-case study design will be applied, using document content analysis of clinical guidelines combined with qualitative semi-structured interviews with key informants from organizations that produce guidelines as well as representatives from national competent authorities (NCAs).

The methodology involves three components which will be divided over three work packages (WPs): WP1 “Mapping of relevant organisations”, WP2 “Document collection and analysis of clinical guidelines” and WP3 “Key Informant Interviews”.

Findings will be analysed by country, therapeutic area, special population (pregnancy, elderly) and type of health care provider (primary/secondary care). The knowledge generated by the three WPs will provide evidence needed to produce recommendations for regulators to engage with healthcare professional bodies and other responsible parties to strengthen the role to be played by clinical guidelines in RMMs implementation, outlining feasible concrete steps that EMA and NCAs could consider.

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## **Study status**

Finalised

## **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**

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**

## Porto Pharmacovigilance Centre, Faculty of Medicine, University of Porto (UFPorto)



Portugal

**First published:** 17/11/2010

**Last updated:** 12/06/2023

**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:** 30/03/2026

**Institution**

**EU Institution/Body/Agency**

**Laboratory/Research/Testing facility**


**ENCePP partner**

University of Copenhagen Denmark, Riga Stradins University Latvia, Democritus University of Thrace

Greece, Rijksinstituut voor Volksgezondheid en Milieu (RIVM) Netherlands

## Networks

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

 Netherlands

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

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Network

## Contact details

### Study institution contact

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Study contact

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### Primary lead investigator

Helga Gardarsdottir

Primary lead investigator

## Study timelines

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

Planned: 13/04/2022

Actual: 13/04/2022

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### **Study start date**

Planned: 01/10/2022

Actual: 01/09/2022

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### **Data analysis start date**

Planned: 01/02/2023

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

Planned: 21/08/2023

Actual: 11/07/2023

## Sources of funding

- EMA

## Study protocol

[D1\\_SC01\\_L4.02\\_Studyplanning\\_v1.0Final.pdf](#) (834.06 KB)

[D2\\_ROC04\\_Studyprotocol\\_v4.2.pdf](#) (1.38 MB)

## Regulatory

### **Was the study required by a regulatory body?**

No

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

Not applicable

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Other

#### **If 'other', further details on the scope of the study**

The implementation of product specific risk minimization measures (RMMs)

#### **Main study objective:**

The study aims to describe the processes for updating clinical guidelines with regulatory action and the role of clinical guidelines in the implementation of product specific RMMs using five defined cases of disease priority areas and active substances.

The five cases represent medicinal products that are prescribed by a broad selection of health care professionals.

## Study Design

## **Non-interventional study design**

Other

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### **Non-interventional study design, other**

Qualitative study including document analysis and qualitative interviews

## Population studied

### **Age groups**

- Preterm newborn infants (0 - 27 days)
  - Term newborn infants (0 - 27 days)
  - Infants and toddlers (28 days - 23 months)
  - Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
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### **Special population of interest**

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

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### **Estimated number of subjects**

47500000

## Study design details

## Data analysis plan

The extent to which information products cover the RMM will be graded based on the results of the coding of information products.

The analysis of the semi-structured interviews involves an inductive 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.

## Documents

### Study report

[ROC04\\_SC01\\_Lot4\\_IMPACT\\_study\\_report\\_final.pdf](#) (2.46 MB)

### Study publications

[Møllebæk M, Gardarsdottir H, Bikou AG, Kodrič A, Silva AM, Andersen A, Kontogio...](#)

[Grupstra RJ, Siiskonen SJ, Gardarsdottir H. Risicominimalisatiemaatregelen voor...](#)

[Armin Andersen, Mathias Møllebæk, Anna Birna Almarsdóttir, Medicines safety inf...](#)

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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**

For WP1 and WP2, we will study various types of documents and online materials (text) in each of the six countries. For WP3, we will use qualitative interviews to provide a comprehensive overview of processes, facilitators and barriers for integrating information from RMMs in clinical guidelines.

## 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