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

Study ID

49902

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] Greece
- [ ] Latvia
- [ ] Netherlands

☐ Portugal

☐ Slovenia

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.

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: 27/03/2024

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

Last updated: 24/09/2025

Network

Contact details

Study institution contact

Helga Gardarsdottir h.gardarsdottir@uu.nl

Study contact

h.gardarsdottir@uu.nl

Primary lead investigator

Helga Gardarsdottir

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 13/04/2022

Actual: 13/04/2022

Study start date
Planned: 01/10/2022

Actual: 01/09/2022

Data analysis start date
Planned: 01/02/2023

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

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

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

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)

Special population of interest

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

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…

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

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No