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

First published: 07/06/2022
Last updated: 02/07/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/49902

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 institution 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
22/12/2021

Institution
Educational Institution
ENCePP partner

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
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Network

Contact details

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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 results
D3_ROC04_SC01_Lot4_IMPACT_study_report_final_v2_abstract.pdf(247.6 KB)

Data management

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