# Characteristics of asthma patients at risk of failed Diskus use in primary care: a retrospective cohort study

First published: 18/11/2013

**Last updated:** 01/04/2024





# Administrative details

EU PAS number	
EUPAS5171	
Study ID	
27566	
DARWIN EU® study	
No	
Study countries	
Australia	
France	
Italy	
Netherlands	

☐ Norv	vay		
Spai	n		
Swee	den		
Unite	ed Kingdom		

#### **Study description**

Retrospective, cross-sectional, observational, database analysis using theinternational dataset: implementing Helping Asthma in Real Patients (iHARP) for describing characteristics of patients at risk of making critical errors in usage of DPI Diskus for there asthma.

#### **Study status**

**Finalised** 

## Research institutions and networks

## Institutions

Observational & Pragmatic Research Institute Pte (OPRI)
United Kingdom
First published: 06/10/2015
Last updated: 19/08/2024
Institution Educational Institution Laboratory/Research/Testing facility
ENCePP partner

## Contact details

#### **Study institution contact**

## Victoria Carter victoria@opri.sg

Study contact

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#### **Primary lead investigator**

**David Price** 

**Primary lead investigator** 

# Study timelines

#### Date when funding contract was signed

Planned: 01/11/2013

Actual: 01/11/2013

#### Study start date

Planned: 03/01/2011

Actual: 03/01/2011

#### Data analysis start date

Planned: 07/10/2013

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

Planned: 07/01/2014

Actual: 15/03/2016

# Sources of funding

• Pharmaceutical company and other private sector

# More details on funding

**TEVA** 

# Regulatory

Was the study required by a regulatory body?

Unknown

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

Not applicable

# Methodological aspects

Study type

Study type list

**Study topic:** 

Disease /health condition

**Study type:** 

Non-interventional study

#### Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

#### **Data collection methods:**

Secondary use of data

#### Main study objective:

Describe characteristics of patients at risk of failed diskus use

# Study Design

#### Non-interventional study design

Cross-sectional

# Population studied

#### Short description of the study population

Patients 16 years and older, who have a current diagnosis of asthma and have received two or more prescriptions for fixed-dose combination ICS/long-acting beta-agonist(LABA) therapy in the year before the review.

#### **Age groups**

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**

#### Special population of interest, other

Asthma patients

#### **Estimated number of subjects**

500

# Study design details

#### **Outcomes**

Characteristics, Risk assessment

#### **Data analysis plan**

We evaluated patient subjective and objective usage of inhaler, patient demographic characteristics, smoking state and comorbidity and asthma outcome were obtain from the iHARP database.

### **Documents**

#### **Study publications**

Westerik JA, Carter V, Chrystyn H, Burden A, Thompson SL, Ryan D, Gruffydd-Jone...

## 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)

Spontaneous reports of suspected adverse drug reactions

## 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**

Unknown