

# 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

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/27566>

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### EU PAS number

EUPAS5171

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### Study ID

27566

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### DARWIN EU® study

No

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### Study countries

Australia

- France
  - Italy
  - Netherlands
  - Norway
  - Spain
  - Sweden
  - United Kingdom
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### **Study description**

Retrospective, cross-sectional, observational, database analysis using the international 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 their asthma.

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### **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

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

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### Study start date

Planned: 03/01/2011

Actual: 03/01/2011

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### Data analysis start date

Planned: 07/10/2013

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## **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

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

Not applicable

## Methodological aspects

### Study type

### Study type list

### **Study topic:**

Disease /health condition

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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

Disease epidemiology

**Data collection methods:**

Secondary use of data

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**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.

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## **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)

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## **Special population of interest**

Other

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## **Special population of interest, other**

Asthma patients

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## **Estimated number of subjects**

500

# Study design details

## **Outcomes**

Characteristics, Risk assessment

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## **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...

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## Data management

### 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

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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**

Unknown