

An observational evaluation of prescribing of fixed-dose combination inhaled corticosteroid / long-acting beta2-agonist (ICS/LABA): fluticasone propionate / formoterol (FP/FOR) and adverse events in routine primary care at 18-months and 36-months post launch

**First published:** 08/02/2016

**Last updated:** 23/04/2024

Study

Finalised

## Administrative details

**EU PAS number**

EUPAS12330

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**Study ID**

31771


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**DARWIN EU® study**

No

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## Study countries

 United Kingdom

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## Study description

This study aims to evaluate adverse events, prescribing prevalence and patient characteristics for patients initiating on FP/FOR or other FDC ICS/LABA therapies prescribed in the 18 and 36 months post launch of FP/FOR in the UK. It will be a historical cohort study within which four subgroups will be evaluated (adult patients ( $\geq 12$  years) with asthma, patients with COPD (and no asthma), paediatric asthma patients 4-11 years, patients prescribed ICS/LABA as the “MART” regimen). Patients included have  $\geq 1$  prescriptions for any ICS/LABA fixed-dose combination from 2012. The number and percentage of patients prescribed FP/FOR and other FDC ICS/LABAs and the frequency and percentage of adverse events and patient characteristics including demographic characteristics, comorbidities, medication and disease-severity measures will be evaluated for patients prescribed FP/FOR and other FDC ICS/LABA therapies, and for each of the subgroups.

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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

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**Study contact**

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### Primary lead investigator

David Price

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Actual: 21/08/2014

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### Study start date

Planned: 19/02/2016

Actual: 24/06/2016

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### Date of final study report

Planned: 12/09/2016

Actual: 29/08/2016

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Mundipharma Research Ltd

## Regulatory

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

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

## Methodological aspects

### Study type

### Study type list

### **Study topic:**

Disease /health condition

Human medicinal product

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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

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To quantify the prevalence of on and off-label prescribing of FP/FOR and other FDC ICS/LABA therapies. To evaluate adverse events in patients prescribed FP/FOR versus other FDC ICS/LABA therapies for both licensed and off-label groups.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name, other**

Flutiform, Seretide, Symbicort, Fostair

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**Medical condition to be studied**

Asthma

Chronic obstructive pulmonary disease

## Population studied

### **Short description of the study population**

Patients  $\geq 4$  years old captured in CPRD during the period from 25th September 2015 until 24th September 2015 (i.e. 36-months post UK launch of fluticasone propionate /formoterol (FP/FOR), where FP/FOR launch was on 25th September 2012) who initiated on any FDC ICS/LABA [including FP/FOR, fluticasone/salmeterol (FP/SAL), budesonide/formoterol (BUD/FOR), beclomethasone/formoterol (BDP/FOR)].

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### **Age groups**

- Adolescents (12 to < 18 years)
  - Children (2 to < 12 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**

Other

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

Asthma, Chronic obstructive pulmonary disease patients

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### **Estimated number of subjects**

3500

## Study design details

## Outcomes

Prevalence of on and off-label prescribing of FP/FOR and other FDC ICS/LABA therapies. Adverse events in patients prescribed FP/FOR versus other FDC ICS/LABA therapies for both licensed and off-label groups. Demographic, medication and disease-related characteristics for patients prescribed FP/FOR and other FDC ICS/LABA therapies.

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## Data analysis plan

Number of patients prescribed FP/FOR and each FDC ICS/LABA will be tabulated and detailed as a percentage of (a) all patients captured in CPRD during the time period 18/36-months post UK launch of FP/FOR and (b) each of the licensed/off-label subgroups. First occurrence of an adverse event per patient analysed: Annualised rate of each adverse event per 100 patients and time to each adverse event will be compared across FDC ICS/LABA therapies using Kaplan-Meier survival curves and, if appropriate, hazard ratios. Multiple occurrences of an adverse event per patient: Mean/median (as appropriate) number of each adverse event per patient.

## Documents

### Study results

[160714\\_R02213\\_Flutiform offlabel and AEs\\_Stage 1\\_Final report\\_v2.0 \(1\).pdf](#)  
(6.22 MB)

[160829\\_R02213\\_Flutiform offlabel and AEs\\_Stage 2\\_Final report\\_v1.1 \(1\).pdf](#)  
(5.12 MB)

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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 source(s)

Clinical Practice Research Datalink

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### Data sources (types)

[Electronic healthcare records \(EHR\)](#)

## 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