

# Drug utilisation study of new users of fluticasone furoate / vilanterol (FF/VI) in the primary care setting: UK Clinical Practice Research Datalink (CPRD) study (205052)

**First published:** 07/02/2017

**Last updated:** 18/04/2024

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/48241>

### EU PAS number

EUPAS17720

### Study ID

48241

### DARWIN EU® study

No

## Study countries

☐ United Kingdom

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## Study description

In the 24-months following the availability of fluticasone furoate / vilanterol (FF/VI) in the United Kingdom, this study will identify new users of FF/VI or other inhaled-corticosteroid/long-acting beta-2-agonist (ICS/LABA) fixed dose combination (FDC) medications from primary care Electronic Medical Records database. Objectives: 1. Separately among new users of FF/VI and other ICS/LABA FDC, describe patient characteristics (incl. demographics, disease burden, selected comorbidities and respiratory medication use) and diagnosis group (asthma, COPD-including an asthma history stratification, other). 2. Among new users of FF/VI, describe off-label prescribing including: • FF/VI 200/25 (pre-dispensed doses, all doses in mcg) formulation in patients with evidence of a COPD diagnosis (only FF/VI 100/25 is licensed for use in patients with COPD) • FF/VI (any dose) in children <12 years of age (neither FF/VI 200/25 nor FF/VI 100/25 is licensed for use in children <12 years of age) 3. Among new users of FF/VI, describe the treatment patterns and adherence to therapy by diagnosis group.

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## Study status

Finalised

# Research institutions and networks

## Institutions

**GlaxoSmithKline (GSK)**

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

## Clinical Practice Research Datalink (CPRD)

☐ United Kingdom

**First published:** 15/03/2010

**Last updated:** 17/01/2025

**Institution**

**Laboratory/Research/Testing facility**

**ENCePP partner**

## Contact details

### Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

**Study contact**

[Pharma.CDR@gsk.com](mailto:Pharma.CDR@gsk.com)

### Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 29/07/2016

Actual: 29/07/2016

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**Study start date**

Planned: 01/03/2017

Actual: 04/04/2017

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**Date of final study report**

Planned: 31/07/2017

Actual: 15/09/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GlaxoSmithKline

## Study protocol

[gsk-205052-protocol-redact.pdf](#)(350.66 KB)

## Regulatory

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

No

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

EU RMP category 3 (required)

## 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:**

Drug utilisation

Other

**If 'other', further details on the scope of the study**

Off-label use

**Data collection methods:**

Secondary use of data

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**Main study objective:**

Off-label use and treatment patterns of FF/VI as well as patient characteristics will be evaluated in study with the use of UK primary care Electronic Medical

Records (EMR) database

## Study Design

### **Non-interventional study design**

Cohort

Other

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### **Non-interventional study design, other**

Retrospective, longitudinal, non-interventional, observational study

## Study drug and medical condition

### **Name of medicine**

RELVAR

REVINTY

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### **Study drug International non-proprietary name (INN) or common name**

FLUTICASONE FUROATE

VILANTEROL TRIFENATATE

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### **Anatomical Therapeutic Chemical (ATC) code**

(R03AK10) vilanterol and fluticasone furoate

vilanterol and fluticasone furoate

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### **Medical condition to be studied**

Chronic obstructive pulmonary disease

Asthma

## Population studied

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

The main study population consisted of new users of FF/VI or other ICS/LABA FDC medications with 'acceptable' data quality in CPRD-GOLD. Patients are labelled as 'acceptable' if they have continuous follow up and do not meet criteria for poor data recording.

Inclusion criteria:

- Record of a new prescription of FF/VI or other ICS/LABA FDC during the inclusion period (January 1, 2014 through December 31, 2015).
- $\geq 12$  months of registration at a practice with 'up to standard data' recording prior to index prescription date to allow for characterization of patient's status, demographics and clinical characteristics. Data are considered 'up to standard' when the GP practice has continuous high quality data fit for use in research.

Exclusion criteria:

- Patients were excluded if they had ever had a prescription for the same specific inclusion medication prior to the index prescription. Prior use of another ICS/LABA FDC product was permitted. All available data prior to the index date was used to ascertain new use of FF/VI and other ICS/LABA FDC. Concomitant use of respiratory medications was allowed.

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## **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)

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### **Estimated number of subjects**

4220

## Study design details

### **Outcomes**

Patient characteristics (including demographics and clinical characteristics), off-label prescribing, treatment patterns and adherence to therapy.

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### **Data analysis plan**

Objective 1 Among the new users of FF/VI or other ICS/LABA FDC patient demographics, comorbidities and disease history characteristics at date of index prescription will be summarised by diagnosis group. Objective 2 Among the new users of FF/VI calculate the proportion with off label use according to pre-specified definitions. Objective 3 Among the new users of FF/VI describe treatment patterns (discontinuation, switching and augmentation) and adherence to treatment using medication possession ratio proportion of days covered during follow-up.

## Documents

### **Study results**

[gsk-205052-clinical-study-report-redact.pdf](#) (3.94 MB)

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## Data management

## 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