Real-life effectiveness (and cost impact) evaluation of fixed-dose combination fluticasone propionate/formoterol (Flutiform®) for the management of asthma in a routine UK primary care population - Phase 1 (Real-life effectiveness of Flutiform® Phase 1)

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### Administrative details

**EU PAS number** 

EUPAS4872

Study ID

8878

**DARWIN EU® study** 

No

#### **Study countries**

United Kingdom

#### **Study status**

**Finalised** 

### Research institutions and networks

### **Institutions**

### Research in Real Life

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Institution

### Contact details

### **Study institution contact**

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Study contact

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### Primary lead investigator

Daina Lim

**Primary lead investigator** 

# Study timelines

#### Date when funding contract was signed

Planned: 25/07/2012 Actual: 25/07/2012

#### Study start date

Planned: 01/09/2012 Actual: 01/08/2013

#### Data analysis start date

Planned: 01/11/2013 Actual: 01/11/2013

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

Planned: 31/01/2014 Actual: 31/01/2014

## Sources of funding

- Pharmaceutical company and other private sector
- Other

### More details on funding

Napp Pharmaceuticals, Resesarch in Real Life

# Study protocol

2014\_01\_28 RiRL Napp Study Protocol - Realworld Evaluation of Flutiform version2 Phase1.pdf(316.27 KB)

# Regulatory

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

No

# Methodological aspects

# Study type

# Study type list

#### **Study topic:**

Human medicinal product

Disease /health condition

#### Study type:

Non-interventional study

#### Scope of the study:

Drug utilisation

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

Secondary use of data

#### Main study objective:

To evaluate the success of changing real-life asthma patients from fluticasone propionate / salmeterol (Seretide®, FP/SAL) to fluticasone propionate / formoterol (Flutiform®, FP/FOR)

# Study Design

#### Non-interventional study design

Other

#### Non-interventional study design, other

Retrospective study

# Study drug and medical condition

#### Name of medicine, other

Flutiform, Seretide

#### Medical condition to be studied

**Asthma** 

### Population studied

#### Short description of the study population

Asthma patients who had changed from fluticasone propionate / salmeterol (Seretide®; FP/SAL) to fluticasone propionate / formoterol (Flutiform®; FP/FOR)

#### Age groups

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

Other

#### Special population of interest, other

Asthma patients

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

100

### Study design details

#### **Outcomes**

In this Phase 1 study, change success will be evaluated. Change success is defined as Percentage of FP/FOR patients who received  $\geq 2$  prescriptions of FP/FOR (i.e.  $\geq 1$  prescription in addition to that issued at IPD). If failed, the potential reasons for discontinuation will be evaluated including: (i) Occurrence of severe exacerbations within the 6-month period defined as:(ii) Loss of asthma control (in the subset of patients controlled at baseline) (iii) Adverse events

#### Data analysis plan

GeneralStatistically significant results will be defined as p<0.05 and trends as 0.05≤p<0.10.All analyses will be carried out using SPSS version 19 89, SAS version 9.3 910 and Microsoft Office EXCEL 2007. Summary statisticsSummary statistics will be produced for all baseline and outcome variables, as a complete dataset and by treatment groups. For variables measured on the interval or ratio scale, these will include: Sample size (n) Percentage non-missing Mean Variance / Standard Deviation Range (Minimum / Maximum) Median Interquartile Range (25th and 75th percentiles) For categorical variables, the summary statistics will include: Sample size (n) Range (if applicable) Count

### **Documents**

#### **Study results**

IPCRG14LB-1326-v2 Final submitted edited.pdf(115.71 KB)

#### Study, other information

R03212a\_PCRS abstract\_Real world effectiveness Seretide\_Napp\_2014-06-06\_FINAL submitted.pdf(35.8 KB)

R03212a\_REG poster abstract\_Real world effectiveness Flutiform\_Napp\_2014-06-06\_FINAL.pdf(36.75 KB)

#### **Study publications**

Global Initiative for Asthma

Politiek MJ, Boorsma M, Aalbers R. Comparison of formoterol, salbutamol and sal...

Masoli M, Fabian D, Holt S, Beasley R, Global Initiative for Asthma (GINA) Prog...

Demoly P, Gueron B, Annunziata K, Adamek L, Walters RD. Update on asthma contro...

Bahadori K, Doyle-Waters MM, Marra C, Lynd L, Alasaly K, Swiston J, FitzGerald ....

## Data management

### Data sources

# Data sources (types) Electronic healthcare records (EHR) Other Data sources (types), other Routine patient questionaires 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