ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 03/08/2010

ClinicalTrials.gov ID: NCT00463866

Study Identification

Unique Protocol ID:	D5890L00022
Brief Title:	Local Phase 4 Pan-European SMART Study
Official Title:	
Secondary IDs:	EUROSMART EudraCTNo. 2006-006512-30

Study Status

Record Verification:	March 2010
Overall Status:	Completed
Study Start:	March 2007
Primary Completion:	
Study Completion:	December 2008 [Actual]

Sponsor/Collaborators

Sponsor:	AstraZeneca
Responsible Party:	
Collaborators:	

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? Yes

	Delayed Posting? No
IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: 2007/1 Board Name: Regionala etikprovningsnamnden i Lund, avd 1 Board Affiliation: - Phone: +46 46 22241 80 Email: jacob.branting@med.lu.se
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	Belgium: Federal Agency for Medicinal Products and Health Products Finland: Finnish Medicines Agency France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Germany: Federal Institute for Drugs and Medical Devices Greece: National Organization of Medicines Ireland: Irish Medicines Board Italy: Ethics Committee Netherlands: The Central Committee on Research Involving Human Subjects (CCMO) Norway:National Committee for Medical and Health Research Ethics Russia: Ministry of Health of the Russian Federation Spain: Spanish Agency of Medicines United Kingdom: Medicines and Healthcare Products Regulatory Agency Sweden: Medical Products Agency

Study Description

Brief Summary:	The purpose of this study is to evaluate the effect of two different maintenance doses of Symbicort Maintenance And Reliever Therapy (SMART) in adult asthmatic patients. A 6 month treatment period
Detailed Description:	

Conditions

Conditions:	Asthma
Keywords:	Asthma

Study Design

Study Type:	Interventional

Primary Purpose:	Treatment
Study Phase:	Phase 4
Intervention Model:	Parallel Assignment
Number of Arms:	2
Masking:	Open Label
Allocation:	Randomized
Endpoint Classification:	Efficacy Study
Enrollment:	8424 [Actual]

Arms and Interventions

Intervention Details:
Drug: Budesonide/formoterol

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	
Gender:	Both
Accepts Healthy Volunteers?:	No
Criteria:	Inclusion Criteria:

- Patients at out-patient clinics
- >18 years with a minimum of 6 months documented history of persistent asthma who have used inhaled glucocorticosteroids for at least one month and have a history of use in rapid-acting B2 agonists for symptom relief

Exclusion Criteria:

- Asthma exacerbation within the last 14 days prior to study start
- subject aged >40 years with a smoking history of >10pack-years
- subjects with chronic obstructive lung disease or other significant respiratory disease

Contacts/Locations

Study Officials: Michel Aubier, Prof
Study Principal Investigator
France

Juliette Ostinelli, MD
Study Chair
AstraZeneca, MC France

Locations: Belgium
Research Site
Aalst, Belgium

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Aatrijken, Belgium

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Weston-Super-Mare, United Kingdom

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Whitstable, United Kingdom

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Wishaw, United Kingdom

Research Site
Yaxley, United Kingdom

References

Citations:

Links: URL: http://www.astrazeneca.com/node/emailtriage.aspx
Description Related Info

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	This was a 6-month, randomised, open label, parallel-group, active controlled, multinational study, in participants with uncontrolled/partly controlled asthma, who were symptomatic despite daily use of inhaled glucocorticosteroid (IGCS) with or without Long-Acting β2 agonist (LABA).

Reporting Groups

	Description
Symbicort® SMART®) 1*2	1 inhalation of Symbicort 160µg/4.5µg twice daily plus as-needed.
Symbicort® SMART®) 2*2	2 inhalations of Symbicort 160µg/4.5µg twice daily plus as-needed.

Overall Study

	Symbicort® SMART®) 1*2	Symbicort® SMART®) 2*2
Started	4008 [1]	4045 [2]
Completed	3699	3705
Not Completed	309	340
Adverse Event	70	93
Withdrawal by Subject	81	79
Lost to Follow-up	46	55
Incorrect Enrolment	64	66
Severe Non-Compliance to Protocol	25	21
Safety Reason	1	3
Mis-Randomization of subject	0	1
Unspecified	22	22

[1] 4203 participants randomised. Out of these, 195 had no efficacy data after randomisation.
[2] 4221 participants randomised. Out of these, 176 had no efficacy data after randomisation.

Baseline Characteristics

Reporting Groups

	Description
Symbicort® SMART®) 1*2	1 inhalation of Symbicort 160µg/4.5µg twice daily plus as-needed.
Symbicort® SMART®) 2*2	2 inhalations of Symbicort 160µg/4.5µg twice daily plus as-needed.

Baseline Measures

	Symbicort® SMART®) 1*2	Symbicort® SMART®) 2*2	Total
Number of Participants	4008	4045	8053
Age, Continuous [units: Years] Mean (Full Range)	47.8 (18 to 96)	47.9 (18 to 90)	47.8 (18 to 96)
Gender, Male/Female [units: Participants]			
Female	2483	2512	4995
Male	1525	1533	3058
Treatment with Long-Acting β2 agonist (LABA) at baseline. [units: Participants]			
Number of participants using LABA at baseline.	3108	3118	6226
Number of participants without LABA at baseline.	900	927	1827
Asthma control questionnaire (ACQ5) score at study entry [1] ACQ5 score at study entry [units: Units on a scale] Mean (Standard Deviation)	1.85 (0.98)	1.86 (1.01)	1.85 (0.99)
Exacerbations past 12 months before study start. [units: Number of exacerbations per participant] Mean (Standard Deviation)	1.47 (2.42)	1.42 (2.42)	1.45 (2.42)

	Symbicort® SMART®) 1*2	Symbicort® SMART®) 2*2	Total
Inhaled glucocorticosteroids (IGCS) dose at study entry. IGCS dose at study entry [units: µg/day] Mean (Standard Deviation)	1046 (595)	1037 (575)	1042 (585)
Participants with a well controlled asthma week at study entry. [units: Percentage of participants] Mean (Full Range)	11.97 (0 to 100)	11.77 (0 to 100)	11.87 (0 to 100)
Pulmonary function test at baseline. [2] Percent Included [units: Percent of predicted normal value of PEF] Mean (Full Range)	90.8 (0 to 100)	90.1 (0 to 100)	90.4 (0 to 100)

[1] ACQ5 was used. The lower value the better with a full range from 0=no impairment, 6= maximum impairment. Awakenings, morning symptoms, limitations, shortness of breath and wheeze.

[2] Peak Expiratory Flow (PEF) was recorded at baseline, the assessment was performed at least 15 minutes after 2 inhalations of Symbicort 160/4.5µg. pn=predicted normal. Symbicort SMART 1*2 arm: n=4001 and Symbicort SMART 2*2 arm: n=4003.

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Number of Severe Asthma Exacerbations Per Participant.
Measure Description	Time to first severe asthma exacerbation, translated to mean number of severe asthma exacerbations per participant. A severe asthma exacerbation is defined as deterioration in asthma requiring oral/systemic glucocorticosteroids for at least 3 days and/or hospitalisation/emergency room visit with oral/systemic glucocorticosteroid treatment.
Time Frame	6 months
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Symbicort® SMART®) 1*2	1 inhalation of Symbicort 160µg/4.5µg twice daily plus as-needed.

	Description
Symbicort® SMART®) 2*2	2 inhalations of Symbicort 160µg/4.5µg twice daily plus as-needed.

Measured Values

	Symbicort® SMART®) 1*2	Symbicort® SMART®) 2*2
Number of Participants Analyzed	4008	4045
Number of Severe Asthma Exacerbations Per Participant. [units: Severe exacerbations per participant] Mean (Full Range)	0.097 (0 to 4)	0.080 (0 to 5)

2. Secondary Outcome Measure:

Measure Title	Fraction of Participants With Severe Asthma Exacerbation
Measure Description	The total number of severe asthma exacerbations was calculated for each participant. A severe asthma exacerbation is defined as deterioration in asthma requiring oral/systemic glucocorticosteroids for at least 3 days and/or hospitalisation/ emergency room visit with oral/systemic glucocorticosteroid treatment.
Time Frame	6 months.
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Symbicort® SMART®) 1*2	1 inhalation of Symbicort 160µg/4.5µg twice daily plus as-needed.
Symbicort® SMART®) 2*2	2 inhalations of Symbicort 160µg/4.5µg twice daily plus as-needed.

Measured Values

	Symbicort® SMART®) 1*2	Symbicort® SMART®) 2*2
Number of Participants Analyzed	4008	4045
Fraction of Participants With Severe Asthma Exacerbation [units: Fraction of participants with event] Mean (95% Confidence Interval)	0.09686 (0.08528 to 0.11)	0.07955 (0.06927 to 0.09135)

3. Secondary Outcome Measure:

Measure Title	Total Number of Severe Asthma Exacerbations That Led to Hospitalisation and/or Emergency Room Treatment.
Measure Description	A severe asthma exacerbation is defined as deterioration in asthma requiring oral/systemic glucocorticosteroids for at least 3 days and/or hospitalisation/emergency room visit with oral/systemic glucocorticosteroid treatment. Number of events per participant
Time Frame	6 months.
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Symbicort® SMART®) 1*2	1 inhalation of Symbicort 160µg/4.5µg twice daily plus as-needed.
Symbicort® SMART®) 2*2	2 inhalations of Symbicort 160µg/4.5µg twice daily plus as-needed.

Measured Values

	Symbicort® SMART®) 1*2	Symbicort® SMART®) 2*2
Number of Participants Analyzed	4008	4045
Total Number of Severe Asthma Exacerbations That Led to Hospitalisation and/or Emergency Room Treatment. [units: Number of events per participant] Mean (Full Range)	0.0120 (0 to 3)	0.0091 (0 to 2)

4. Secondary Outcome Measure:

Measure Title	Total Number of Days Per Participant With Oral/Systemic Glucocorticosteroids During Severe Asthma Exacerbation
Measure Description	Total number of days with oral/systemic glucocorticosteroids during severe exacerbation calculated for each participant. A severe asthma exacerbation is defined as deterioration in asthma requiring oral/systemic glucocorticosteroids for at least 3 days and/or hospitalisation/emergency room visit with oral/systemic glucocorticosteroid treatment.
Time Frame	6 months.
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Symbicort® SMART®) 1*2	1 inhalation of Symbicort 160µg/4.5µg twice daily plus as-needed.
Symbicort® SMART®) 2*2	2 inhalations of Symbicort 160µg/4.5µg twice daily plus as-needed.

Measured Values

	Symbicort® SMART®) 1*2	Symbicort® SMART®) 2*2
Number of Participants Analyzed	4008	4045
Total Number of Days Per Participant With Oral/ Systemic Glucocorticosteroids During Severe Asthma Exacerbation [units: Days per participant] Mean (Standard Deviation)	9.6 (8.1)	9.1 (5.5)

5. Secondary Outcome Measure:

Measure Title	Mean Daily Number of Inhalations of As-needed Medication.
Measure Description	The number of as-needed inhalations was measured 2 times during 2 weeks before 13 weeks and 26 weeks of treatment.
Time Frame	4 weeks
Safety Issue?	No

Analysis Population Description
Inhalations of as-needed medication recorded by 3880 participants in the Symbicort SMART 1*2 Reporting Group and recorded by 3881 participants in the Symbicort SMART 2*2 Reporting Group

Reporting Groups

	Description
Symbicort® SMART®) 1*2	1 inhalation of Symbicort 160µg/4.5µg twice daily plus as-needed.
Symbicort® SMART®) 2*2	2 inhalations of Symbicort 160µg/4.5µg twice daily plus as-needed.

Measured Values

	Symbicort® SMART®) 1*2	Symbicort® SMART®) 2*2
Number of Participants Analyzed	3880	3881
Mean Daily Number of Inhalations of As-needed Medication. [units: Inhalations per day per participant] Mean (Full Range)	0.897 (0 to 9.14)	0.625 (0 to 9.07)

6. Secondary Outcome Measure:

Measure Title	Percent of Participants With a Well Controlled Asthma Week.
Measure Description	The mean percent of participants fulfilling the criteria for a well controlled asthma week in each treatment. A well controlled asthma week is defined as a week with no exacerbations and no night-time awakenings due to asthma and a maximum of 2 days with symptoms and as-needed inhalation use.
Time Frame	6 months.
Safety Issue?	No

Analysis Population Description

Data for this measure recorded by 3714 participants in the Symbicort SMART 1*2 Reporting Group and recorded by 3718 participants in the Symbicort SMART 2*2 Reporting Group.

Reporting Groups

	Description
Symbicort® SMART®) 1*2	1 inhalation of Symbicort 160µg/4.5µg twice daily plus as-needed.
Symbicort® SMART®) 2*2	2 inhalations of Symbicort 160µg/4.5µg twice daily plus as-needed.

Measured Values

	Symbicort® SMART®) 1*2	Symbicort® SMART®) 2*2
Number of Participants Analyzed	3714	3718
Percent of Participants With a Well Controlled Asthma Week. [units: Percentage of participants] Mean (Full Range)	43.69 (0 to 100)	54.26 (0 to 100)

7. Secondary Outcome Measure:

Measure Title	Mean Overall Asthma Control Questionnaire (ACQ) Score
Measure Description	The ACQ5 was used. The lower value the better with a full range from 0=no impairment, 6= maximum impairment. Awakenings, morning symptoms, limitations, shortness of breath and wheeze.
Time Frame	6 months.
Safety Issue?	No

Analysis Population Description

Data for this measure recorded by 3709 participants in the Symbicort SMART 1*2 Reporting Group and recorded by 3735 participants in the Symbicort SMART 2*2 Reporting Group.

Reporting Groups

	Description
Symbicort® SMART®) 1*2	1 inhalation of Symbicort 160µg/4.5µg twice daily plus as-needed.
Symbicort® SMART®) 2*2	2 inhalations of Symbicort 160µg/4.5µg twice daily plus as-needed.

Measured Values

	Symbicort® SMART®) 1*2	Symbicort® SMART®) 2*2
Number of Participants Analyzed	3709	3735
Mean Overall Asthma Control Questionnaire (ACQ) Score [units: Scores in a scale] Mean (Full Range)	1.18 (0 to 5.7)	1.089 (0 to 5.0)

8. Secondary Outcome Measure:

Measure Title	The Mean Total Daily Dose of Steroids From Symbicort.
Measure Description	The mean total daily dose of steroids from Symbicort was calculated as the sum of the maintenance dose and the as-needed dose.
Time Frame	4 weeks
Safety Issue?	No

Analysis Population Description

: Data for this measure recorded by 3874 participants in the Symbicort SMART 1*2 Reporting Group and recorded by 3873 participants in the Symbicort SMART 2*2 Reporting Group.

Reporting Groups

	Description
Symbicort® SMART®) 1*2	1 inhalation of Symbicort 160µg/4.5µg twice daily plus as-needed.
Symbicort® SMART®) 2*2	2 inhalations of Symbicort 160µg/4.5µg twice daily plus as-needed.

Measured Values

	Symbicort® SMART®) 1*2	Symbicort® SMART®) 2*2
Number of Participants Analyzed	3874	3873
The Mean Total Daily Dose of Steroids From Symbicort. [units: µg budesonide per day] Mean (Standard Deviation)	462.96 (179.10)	736.58 (152.70)

9. Secondary Outcome Measure:

Measure Title	Mean Cost Per Participant Per Country
Measure Description	Mean cost is calculated for each country using participants from the whole study and country specific costs. Mean value for the whole study can not be calculated.
Time Frame	6 months
Safety Issue?	No

Outcome Measure Data Not Reported

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	[Not specified]

Reporting Groups

	Description
Symbicort® SMART®) 1*2	1 inhalation of Symbicort 160µg/4.5µg twice daily plus as-needed.
Symbicort® SMART®) 2*2	2 inhalations of Symbicort 160µg/4.5µg twice daily plus as-needed.

Serious Adverse Events

	Symbicort® SMART®) 1*2	Symbicort® SMART®) 2*2
	Affected/At Risk (%)	Affected/At Risk (%)
Total	77/4008 (1.92%)	88/4045 (2.18%)
Blood and lymphatic system disorders		
Anaemia [A] †	1/4008 (0.02%)	1/4045 (0.02%)
Cardiac disorders		
Angina Pectoris [A] †	1/4008 (0.02%)	1/4045 (0.02%)
Atrial Fibrillation [A] †	2/4008 (0.05%)	1/4045 (0.02%)
Atrioventricular Block [A] †	1/4008 (0.02%)	0/4045 (0%)
Coronary Artery Disease [A] †	1/4008 (0.02%)	0/4045 (0%)
Myocardial Infarction [A] †	1/4008 (0.02%)	1/4045 (0.02%)
Tachyarrhythmia [A] †	1/4008 (0.02%)	0/4045 (0%)
Tachycardia [A] †	0/4008 (0%)	1/4045 (0.02%)
Congenital, familial and genetic disorders		
Exomphalos [A] †	1/4008 (0.02%)	0/4045 (0%)
Ear and labyrinth disorders		
Vertigo [A] †	1/4008 (0.02%)	0/4045 (0%)
Eye disorders		
Cataract [A] †	0/4008 (0%)	2/4045 (0.05%)
Gastrointestinal disorders		
Abdominal Pain [A] †	1/4008 (0.02%)	0/4045 (0%)
Abdominal Pain Lower [A] †	1/4008 (0.02%)	0/4045 (0%)
Colitis [A] †	2/4008 (0.05%)	0/4045 (0%)
Constipation [A] †	1/4008 (0.02%)	0/4045 (0%)

	Symbicort® SMART®) 1*2	Symbicort® SMART®) 2*2
	Affected/At Risk (%)	Affected/At Risk (%)
Crohn's Disease [A] †	1/4008 (0.02%)	0/4045 (0%)
Diarrhoea [A] †	2/4008 (0.05%)	0/4045 (0%)
Diverticulum Intestinal [A] †	0/4008 (0%)	1/4045 (0.02%)
Gastrointestinal Disorder [A] †	1/4008 (0.02%)	0/4045 (0%)
Inguinal Hernia [A] †	1/4008 (0.02%)	1/4045 (0.02%)
Pancreatitis [A] †	1/4008 (0.02%)	0/4045 (0%)
Pancreatitis Acute [A] †	1/4008 (0.02%)	0/4045 (0%)
Peritonitis [A] †	1/4008 (0.02%)	0/4045 (0%)
Reflux Oesophagitis [A] †	1/4008 (0.02%)	0/4045 (0%)
Salivary Gland Enlargement [A] †	0/4008 (0%)	1/4045 (0.02%)
Umbilical Hernia [A] †	1/4008 (0.02%)	1/4045 (0.02%)
Vomiting [A] †	1/4008 (0.02%)	0/4045 (0%)
General disorders		
Chest Pain [A] †	2/4008 (0.05%)	1/4045 (0.02%)
Cyst [A] †	0/4008 (0%)	1/4045 (0.02%)
Death [A] †	1/4008 (0.02%)	1/4045 (0.02%)
Non-Cardiac Chest Pain [A] †	1/4008 (0.02%)	0/4045 (0%)
Pain [A] †	1/4008 (0.02%)	0/4045 (0%)
Hepatobiliary disorders		
Cholecystitis [A] †	0/4008 (0%)	1/4045 (0.02%)
Cholecystitis Acute [A] †	0/4008 (0%)	1/4045 (0.02%)
Cholelithiasis [A] †	0/4008 (0%)	4/4045 (0.1%)

	Symbicort® SMART®) 1*2	Symbicort® SMART®) 2*2
	Affected/At Risk (%)	Affected/At Risk (%)
Immune system disorders		
Food Allergy [A] †	0/4008 (0%)	1/4045 (0.02%)
Hypersensitivity [A] †	0/4008 (0%)	1/4045 (0.02%)
Sarcoidosis [A] †	0/4008 (0%)	1/4045 (0.02%)
Infections and infestations		
Appendicitis [A] †	1/4008 (0.02%)	1/4045 (0.02%)
Bronchiectasis [A] †	1/4008 (0.02%)	0/4045 (0%)
Bronchitis [A] †	0/4008 (0%)	2/4045 (0.05%)
Campylobacter Gastroenteritis [A] †	1/4008 (0.02%)	0/4045 (0%)
Chronic Sinusitis [A] †	0/4008 (0%)	1/4045 (0.02%)
Epstein-Barr Virus Infection [A] †	0/4008 (0%)	1/4045 (0.02%)
Erysipelas [A] †	1/4008 (0.02%)	1/4045 (0.02%)
Gastroenteritis [A] †	1/4008 (0.02%)	1/4045 (0.02%)
Influenza [A] †	1/4008 (0.02%)	0/4045 (0%)
Lower Respiratory Tract Infection [A] †	1/4008 (0.02%)	1/4045 (0.02%)
Lung Infection [A] †	0/4008 (0%)	1/4045 (0.02%)
Meningitis Viral [A] †	0/4008 (0%)	1/4045 (0.02%)
Pilonidal Cyst [A] †	0/4008 (0%)	1/4045 (0.02%)
Pneumonia [A] †	3/4008 (0.07%)	3/4045 (0.07%)
Respiratory Tract Infection [A] †	1/4008 (0.02%)	0/4045 (0%)
Sinusitis [A] †	0/4008 (0%)	1/4045 (0.02%)
Tonsillitis [A] †	0/4008 (0%)	1/4045 (0.02%)

	Symbicort® SMART®) 1*2	Symbicort® SMART®) 2*2
	Affected/At Risk (%)	Affected/At Risk (%)
Tracheobronchitis [A] †	1/4008 (0.02%)	0/4045 (0%)
Injury, poisoning and procedural complications		
Animal Bite [A] †	0/4008 (0%)	1/4045 (0.02%)
Ankle Fracture [A] †	1/4008 (0.02%)	0/4045 (0%)
Fall [A] †	1/4008 (0.02%)	1/4045 (0.02%)
Femur Fracture [A] †	1/4008 (0.02%)	0/4045 (0%)
Fibula Fracture [A] †	1/4008 (0.02%)	0/4045 (0%)
Joint Dislocation [A] †	1/4008 (0.02%)	1/4045 (0.02%)
Joint Injury [A] †	0/4008 (0%)	1/4045 (0.02%)
Ligament Rupture [A] †	1/4008 (0.02%)	0/4045 (0%)
Lower Limb Fracture [A] †	0/4008 (0%)	2/4045 (0.05%)
Meniscus Lesion [A] †	1/4008 (0.02%)	0/4045 (0%)
Multiple Drug Overdose [A] †	0/4008 (0%)	1/4045 (0.02%)
Overdose [A] †	0/4008 (0%)	1/4045 (0.02%)
Rib Fracture [A] †	0/4008 (0%)	1/4045 (0.02%)
Tibia Fracture [A] †	1/4008 (0.02%)	0/4045 (0%)
Traumatic Fracture [A] †	0/4008 (0%)	1/4045 (0.02%)
Upper Limb Fracture [A] †	1/4008 (0.02%)	1/4045 (0.02%)
Metabolism and nutrition disorders		
Dehydration [A] †	0/4008 (0%)	1/4045 (0.02%)
Hypokalaemia [A] †	0/4008 (0%)	1/4045 (0.02%)
Type 2 Diabetes Mellitus [A] †	0/4008 (0%)	1/4045 (0.02%)

	Symbicort® SMART®) 1*2	Symbicort® SMART®) 2*2
	Affected/At Risk (%)	Affected/At Risk (%)
Musculoskeletal and connective tissue disorders		
Arthralgia [A] †	0/4008 (0%)	2/4045 (0.05%)
Fibromyalgia [A] †	0/4008 (0%)	1/4045 (0.02%)
Intervertebral Disc Protrusion [A] †	1/4008 (0.02%)	2/4045 (0.05%)
Muscle Mass [A] †	1/4008 (0.02%)	0/4045 (0%)
Muscle Spasms [A] †	0/4008 (0%)	1/4045 (0.02%)
Muscular Weakness [A] †	1/4008 (0.02%)	0/4045 (0%)
Osteoarthritis [A] †	3/4008 (0.07%)	3/4045 (0.07%)
Spinal Disorder [A] †	0/4008 (0%)	1/4045 (0.02%)
Tendonitis [A] †	1/4008 (0.02%)	0/4045 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Basal Cell Carcinoma [A] †	0/4008 (0%)	1/4045 (0.02%)
Bladder Neoplasm [A] †	1/4008 (0.02%)	0/4045 (0%)
Breast Cancer [A] †	0/4008 (0%)	4/4045 (0.1%)
Metastases To Liver [A] †	0/4008 (0%)	1/4045 (0.02%)
Parathyroid Tumour Benign [A] †	0/4008 (0%)	1/4045 (0.02%)
Prostate Cancer [A] †	0/4008 (0%)	1/4045 (0.02%)
Uterine Leiomyoma [A] †	1/4008 (0.02%)	1/4045 (0.02%)
Vocal Cord Neoplasm [A] †	0/4008 (0%)	1/4045 (0.02%)
Nervous system disorders		
Carotid Sinus Syndrome [A] †	1/4008 (0.02%)	0/4045 (0%)
Cerebrovascular Accident [A] †	1/4008 (0.02%)	2/4045 (0.05%)

	Symbicort® SMART®) 1*2	Symbicort® SMART®) 2*2
	Affected/At Risk (%)	Affected/At Risk (%)
Haemorrhage Intracranial [A] †	1/4008 (0.02%)	0/4045 (0%)
Haemorrhagic Stroke [A] †	1/4008 (0.02%)	0/4045 (0%)
Ischaemic Cerebral Infarction [A] †	1/4008 (0.02%)	0/4045 (0%)
Loss Of Consciousness [A] †	1/4008 (0.02%)	0/4045 (0%)
Migraine [A] †	1/4008 (0.02%)	0/4045 (0%)
Syncope [A] †	0/4008 (0%)	1/4045 (0.02%)
Pregnancy, puerperium and perinatal conditions		
Abortion Spontaneous [A] †	1/4008 (0.02%)	0/4045 (0%)
Reproductive system and breast disorders		
Endometriosis [A] †	0/4008 (0%)	1/4045 (0.02%)
Menorrhagia [A] †	1/4008 (0.02%)	0/4045 (0%)
Vaginal Haemorrhage [A] †	1/4008 (0.02%)	0/4045 (0%)
Respiratory, thoracic and mediastinal disorders		
Asthma [A] †	13/4008 (0.32%)	9/4045 (0.22%)
Asthmatic Crisis [A] †	0/4008 (0%)	1/4045 (0.02%)
Chronic Obstructive Pulmonary Disease [A] †	0/4008 (0%)	1/4045 (0.02%)
Cough [A] †	0/4008 (0%)	1/4045 (0.02%)
Dyspnoea [A] †	1/4008 (0.02%)	2/4045 (0.05%)
Epistaxis [A] †	0/4008 (0%)	1/4045 (0.02%)
Pharyngeal Disorder [A] †	0/4008 (0%)	1/4045 (0.02%)
Pneumothorax [A] †	1/4008 (0.02%)	0/4045 (0%)
Pulmonary Embolism [A] †	0/4008 (0%)	2/4045 (0.05%)

	Symbicort® SMART®) 1*2	Symbicort® SMART®) 2*2
	Affected/At Risk (%)	Affected/At Risk (%)
Sleep Apnoea Syndrome [A] †	1/4008 (0.02%)	1/4045 (0.02%)
Vascular disorders		
Deep Vein Thrombosis [A] †	1/4008 (0.02%)	0/4045 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 11.1

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 1%

	Symbicort® SMART®) 1*2	Symbicort® SMART®) 2*2
	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/4008 (0%)	0/4045 (0%)

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

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