ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: January 19, 2017

ClinicalTrials.gov ID: NCT00461500

Study Identification

Unique Protocol ID:	SAM108037
Brief Title:	SERETIDE 100/50 bd (Twice Daily) Versus FLIXOTIDE 100 bd As Initial Maintenance Therapy In Moderate Asthma In Adults
Official Title:	Seretide 100 DK vs Flixotide 100 DK in IMT in Moderate Asthma in Adults on Static Lung Volumes (Mechanistic Study)
Secondary IDs:	

Study Status

Record Verification:	January 2017
Overall Status:	Completed
Study Start:	March 2007 []
Primary Completion:	December 2007 [Actual]
Study Completion:	December 2007 [Actual]

Sponsor/Collaborators

Sponsor:	GlaxoSmithKline
Responsible Party:	
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	

U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: 06/437 Board Name: Comite Consultatif de Protection des Personnes Est II Board Affiliation: France Phone: +33 3 81 21 93 12 Email: Address:
Data Monitoring:	

Study Description

Brief Summary:	This study will compare during 12 weeks, two treatment strategies for Initial Maintenance Therapy : fluticasone propionate alone or the salmeterol/fluticasone propionate combination in adults with moderate persistent asthma
Detailed Description:	A multicentre randomised, double-blind, parallel-group study to compare the salmeterol/fluticasone propionate combination (SERETIDETM DISKUSTM 50/100) 50/100µg one inhalation twice daily with fluticasone propionate (FLIXOTIDETM DISKUSTM 100) 100µg one inhalation twice daily as initial maintenance therapy for 12 weeks in adults with persistent moderate asthma

Conditions

Conditions:	Asthma
Keywords:	persistent moderate asthma adults Initial Maintenance Therapy

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 4
Interventional Study Model:	Parallel Assignment

Number of Arms:	
Masking:	Double (masked roles unspecified)
Allocation:	Randomized
Enrollment:	81 [Actual]

Arms and Interventions

Intervention Details:

Drug: Salmeterol xinafoate/fluticasone propionate combination
SFC 100

Other Names:

- SERETIDE FLIXOTIDE

Drug: Fluticasone propionate
FP 100

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	40 Years
Sex:	All
Gender Based:	
Accepts Healthy Volunteers:	No

Criteria: Inclusion criteria:

- male or female ≥ 18
- documented history of asthma
- reversibility FEV1 or PEF ≥ 12% (post 400µg salbu)
- moderate asthma (daily symptoms, daily rescue use, PEF = 60-80% predicted value)
- naive or ≥ 4weeks-free ICS (inhaled corticosteroids)

Exclusion criteria:

- respiratory disorder
- FEV1<60% predicted
- exacerbation/respiratory infection ≤ 4 weeks

- oral/parenteral/depot corticosteroids ≤ 6 months
- LABA/oral β2 agonist/ ALT/ theophylline ≤ 4 weeks
- smoker or former smoker ≥ 5 packs year

Contacts/Locations

Central Contact Person: US GSK Clinical Trials Call Center
Telephone: 877-379-3718

Central Contact Backup:

Study Officials: GSK Clinical Trials, MD
Study Director
GlaxoSmithKline

Locations:

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Study Results

Participant Flow

Reporting Groups

	Description
SFC (Salmeterol Xinafoate/ Fluticasone Propionate Combination)	Analysis population are all randomized subjects in this arm. 50/100ug - one inhalation twice daily
FP (Fluticasone Propionate)100	Analysis population are all randomized subjects in this arm. 100ug - one inhalation twice daily

Overall Study

	SFC (Salmeterol Xinafoate/Fluticasone Propionate Combination)	FP (Fluticasone Propionate)100
Started	37	44
Completed	30	38
Not Completed	7	6
Adverse Event	1	0
Lack of Efficacy	0	1
Expired Drug Treatment	1	1
Study Stopped	1	2
Drug Treatment Misuse	1	0
No Longer Willing to Take Part in Study	1	0
Lost to Follow-up	2	2

Baseline Characteristics

Reporting Groups

	Description
SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	Analysis population used in this arm is ITT (intent-to-treat) population (Randomised subjects who received at least one dose of study drug and with evaluation for at least one efficacy criteria).
FP 100: Fluticasone Propionate.	Analysis population used in this arm is ITT population(Randomised subjects who received at least one dose of study drug and with evaluation for at least one efficacy criteria).

Baseline Measures

	SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	FP 100: Fluticasone Propionate.	Total
Overall Number of Participants	34	43	77

		SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	FP 100: Fluticasone Propionate.	Total
Age, Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	34 participants	43 participants	77 participants
		47.3 (17.9)	49.3 (19.3)	48.4 (18.6)
Sex: Female, Male Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	34 participants	43 participants	77 participants
	Female	21 61.76%	25 58.14%	46 59.74%
	Male	13 38.24%	18 41.86%	31 40.26%
Smoking Status Measure Type: Number Unit of measure: participants	Number Analyzed	34 participants	43 participants	77 participants
Current Smoker		5	4	9
Ex-Smoker		5	5	10
Never Smoked		24	34	58

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Change From Baseline in Mean Morning Peak Expiratory Flow (PEF) Over Weeks 5-12
Measure Description	Mini Wright Peak Flow Meter used to allow patients to monitor their asthma - Peak Flow (or PEF - peak expiratory flow) is a measurement of how fast you can blow out. When someone is well, their PEF is higher - when the airways are narrow (as in asthma), PEF is lower. Readings based on age, height and gender.
Time Frame	Baseline, Weeks 5-12

Analysis Population Description

Intent-to-Treat population are all randomized patients having received one study drug dose and had at least one complete efficacy assessment.

Reporting Groups

	Description
SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	50/100ug - one inhalation twice daily
FP 100: Fluticasone Propionate	100ug - one inhalation twice daily

Measured Values

	SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	FP 100: Fluticasone Propionate
Overall Number of Participants Analyzed	29	37
Change From Baseline in Mean Morning Peak Expiratory Flow (PEF) Over Weeks 5-12 Mean (Standard Deviation) Unit of measure: Liters per minute (L/min)	59.21 (70.42)	50.98 (71.05)

Statistical Analysis 1 for Change From Baseline in Mean Morning Peak Expiratory Flow (PEF) Over Weeks 5-12

Statistical Analysis Overview	Comparison Group Selection	SFC 100: Salmeterol Xinafoate/Fluticasone Propionate Combined, FP 100: Fluticasone Propionate
	Comments	[Not specified]
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.683
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Mean Difference (Net)
	Estimated Value	7.23
	Confidence Interval	(2-Sided) 95% -27.96 to 42.43
	Parameter Dispersion	Type: Standard Error of the Mean Value: 17.60

	Estimation Comments	mean difference = drug SFC 100 minus FP 100

2. Secondary Outcome Measure:

Measure Title	Change From Baseline in Pre-dose FEV1 (Forced Expiratory Volume in One Second) Through Week 12 (Using Last Observation Carried Forward [LOCF] Approach)
Measure Description	FEV1 is the amount of air (in liters) you can blow out within one second. A spirometer is the device used to measure FEV1. With normal lungs and airways you can normally blow out most of the air from your lungs within one second. Age, height and gender is used to determine what is normal. Change from baseline could have been measured at any time during the study (up to Week 12), using the LOCF. In the LOCF approach, for each individual, missing values are replaced by the last observed value of that variable.
Time Frame	Baseline through Week 12

Analysis Population Description
Intent-to-Treat population.

Reporting Groups

	Description
SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	50/100ug - one inhalation twice daily
FP 100: Fluticasone Propionate	100ug - one inhalation twice daily

Measured Values

	SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	FP 100: Fluticasone Propionate
Overall Number of Participants Analyzed	33	42
Change From Baseline in Pre-dose FEV1 (Forced Expiratory Volume in One Second) Through Week 12 (Using Last Observation Carried Forward [LOCF] Approach) Mean (Standard Deviation) Unit of measure: Liters	0.25 (0.37)	0.11 (0.35)

3. Secondary Outcome Measure:

Measure Title	Change From Baseline in Pre-dose (Percent Predicted) FEV1 Through Week 12 (Using Last Observation Carried Forward [LOCF] Approach)

Measure Description	Percent predicted is based on tables of normal values that use variables such as age, gender, and weight as a method of standardization. Spirometry results are expressed as a percentage, and are generally considered abnormal if less than 80 percent of the normal predicted value. Change from baseline could have been measured at any time during the study (up to Week 12), using the LOCF. In the LOCF approach, for each individual, missing values are replaced by the last observed value of that variable.
Time Frame	Baseline through Week 12

Analysis Population Description
Intent-to-Treat population.

Reporting Groups

	Description
SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	50/100ug - one inhalation twice daily
FP 100: Fluticasone Propionate	100ug - one inhalation twice daily

Measured Values

	SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	FP 100: Fluticasone Propionate
Overall Number of Participants Analyzed	33	42
Change From Baseline in Pre-dose (Percent Predicted) FEV1 Through Week 12 (Using Last Observation Carried Forward [LOCF] Approach) Mean (Standard Deviation) Unit of measure: Percentage predicted of FEV1	7.46 (12.34)	4.97 (13.07)

4. Secondary Outcome Measure:

Measure Title	Change From Baseline in FEV1 Reversibility Through Week 12 (Using Last Observation Carried Forward [LOCF] Approach)
Measure Description	Reversibility is calculated as the percentage improvement of FEV1 from baseline. Change from baseline could have been measured at any time during the study (up to Week 12), using the LOCF. In the LOCF approach, for each individual, missing values are replaced by the last observed value of that variable. Percent reversibility of FEV1 was calculated as follows: (Post-bronchodilator FEV1 – pre-bronchodilator FEV1)/pre-bronchodilator FEV1 x 100. A negative difference indicates less reversibility.
Time Frame	Baseline through Week 12

Analysis Population Description
Intent-to-Treat population.

Reporting Groups

	Description
SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	50/100ug - one inhalation twice daily
FP 100: Fluticasone Propionate	100ug - one inhalation twice daily

Measured Values

	SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	FP 100: Fluticasone Propionate
Overall Number of Participants Analyzed	33	41
Change From Baseline in FEV1 Reversibility Through Week 12 (Using Last Observation Carried Forward [LOCF] Approach) Mean (Standard Deviation) Unit of measure: Percent change	-9.46 (16.47)	-4.05 (11.97)

5. Secondary Outcome Measure:

Measure Title	Change From Baseline in Pre-dose Forced Expiratory Vital Capacity (FVC) Through Week 12 (Using Last Observation Carried Forward [LOCF] Approach)
Measure Description	FVC is the total amount of air that can forcibly be blown out after full inspiration, measured in liters. A spirometer is the device used to measure FVC. Age, height and gender is used to determine what is normal. Change from baseline could have been measured at any time during the study (up to Week 12), using the LOCF. In the LOCF approach, for each individual, missing values are replaced by the last observed value of that variable.
Time Frame	Baseline through Week 12

Analysis Population Description
Intent-to-Treat

Reporting Groups

	Description
SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	50/100ug - one inhalation twice daily

	Description
FP 100: Fluticasone Propionate	100ug - one inhalation twice daily

Measured Values

	SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	FP 100: Fluticasone Propionate
Overall Number of Participants Analyzed	33	42
Change From Baseline in Pre-dose Forced Expiratory Vital Capacity (FVC) Through Week 12 (Using Last Observation Carried Forward [LOCF] Approach) Mean (Standard Deviation) Unit of measure: Liters	0.18 (0.44)	0.14 (0.49)

6. Secondary Outcome Measure:

Measure Title	Change From Baseline (BL) in Pre-dose FEF 25-75% (Forced Expiratory Flow) Through Week 12 (Using Last Observation Carried Forward [LOCF] Approach)
Measure Description	Forced Expiratory Flow 25-75% (measured by a spirometer) is the average flow (or speed) of air coming out of the lung during the middle portion of the expiration. Age, height, and gender is used to determine what is normal. Change from BL could have been measured at any time during the study (up to Week 12), using the LOCF (for each individual, missing values are replaced by the last observed value of that variable). Change from BL is measured as percentage of predicted value, with height, gender, age, and race as variables (percentage of predicted value at endpoint minus value at BL).
Time Frame	Baseline through Week 12

Analysis Population Description

Intent-to-Treat population.

Reporting Groups

	Description
SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	50/100ug - one inhalation twice daily
FP 100: Fluticasone Propionate	100ug - one inhalation twice daily

Measured Values

	SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	FP 100: Fluticasone Propionate
Overall Number of Participants Analyzed	33	42
Change From Baseline (BL) in Pre-dose FEF 25-75% (Forced Expiratory Flow) Through Week 12 (Using Last Observation Carried Forward [LOCF] Approach) Mean (Standard Deviation) Unit of measure: Percentage of predicted value	7.24 (24.07)	4.28 (17.30)

7. Secondary Outcome Measure:

Measure Title	Number of Participants With at Least One Exacerbation During 12-Week Treatment Period
Measure Description	Subjects will record exacerbations (defined as temporary PEF decrease, increase in salbutamol use) in a Daily Record Card (DRC). The number of events are categorized as those that showed a deterioration in asthma requiring administration of oral corticosteroids and/or a deterioration in asthma requiring emergency room visit and/or hospitalization (hosp.).
Time Frame	12-Week Treatment Period (Week 1 through Week 12)

Analysis Population Description
Intent-to-Treat population.

Reporting Groups

	Description
SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	50/100ug - one inhalation twice daily
FP 100: Fluticasone Propionate	100ug - one inhalation twice daily

Measured Values

	SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	FP 100: Fluticasone Propionate
Overall Number of Participants Analyzed	34	43

	SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	FP 100: Fluticasone Propionate
Number of Participants With at Least One Exacerbation During 12-Week Treatment Period Measure Type: Number Unit of measure: Participants		
Any exacerbation (Exac.)	1	5
Exac. needing oral corticosteroids and/or hosp.	0	0

8. Secondary Outcome Measure:

Measure Title	Number of Participants Who Achieved Well-Controlled Asthma During Weeks 5-12
Measure Description	Well-controlled asthma is defined as 2 or more of the following: symptoms on no more than 2 days with symptom score of >1; no more than 2 days of rescue meds (maximum of 4 per week); >=80% predicted morning PEF. And no night time awakenings, exacerbations, emergency room visits, and treatment related adverse effects requiring a change to therapy. The number of participants who achieved "well-controlled" asthma at any time during Week 5-12 of the study period will be summarized by treatment groups. The difference between treatment groups will be assessed using logistic regression.
Time Frame	Weeks 5 -12

Analysis Population Description
Intent-to-Treat population.

Reporting Groups

	Description
SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	50/100ug - one inhalation twice daily
FP 100: Fluticasone Propionate	100ug - one inhalation twice daily

Measured Values

	SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	FP 100: Fluticasone Propionate
Overall Number of Participants Analyzed	29	35

	SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	FP 100: Fluticasone Propionate
Number of Participants Who Achieved Well-Controlled Asthma During Weeks 5-12 Measure Type: Number Unit of measure: Participants		
Yes	13	11
No	16	24

9. Secondary Outcome Measure:

Measure Title	Median Number of Weeks to First Achieve Well-Controlled Asthma During Weeks 5-12
Measure Description	Well-controlled asthma is defined as 2 or more of the following: symptoms on no more than 2 days with symptom score of >1; no more than 2 days of rescue meds (maximum of 4 per week); >=80% predicted morning PEF. And no night time awakenings, exacerbations, emergency room visits, and treatment related adverse effects requiring a change to therapy. The median number of weeks to first achieve "well-controlled" asthma during Week 5-12 of the study period will be summarized by treatment groups. The difference between treatment groups will be assessed using logistic regression.
Time Frame	Weeks 5 - 12

Analysis Population Description

Intent-to-Treat population.

Reporting Groups

	Description
SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	50/100ug - one inhalation twice daily
FP 100: Fluticasone Propionate	100ug - one inhalation twice daily

Measured Values

	SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	FP 100: Fluticasone Propionate
Overall Number of Participants Analyzed	34	43

	SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	FP 100: Fluticasone Propionate
Median Number of Weeks to First Achieve Well-Controlled Asthma During Weeks 5-12 Median (Full Range) Unit of measure: Weeks	3.1 (0.1 to 15.6)	4.1 (0.1 to 14.1)

10. Secondary Outcome Measure:

Measure Title	Number of Participants Who Achieved Total-controlled Asthma During Weeks 5-12
Measure Description	Totally-controlled asthma is defined as no daily symptoms, no night-time awakenings, no exacerbations, no rescue medication, no emergency visits, no treatment related adverse events resulting in change in asthma therapy, >=80% predicted PEF. The number of subjects who achieved "total-controlled" asthma at any time during Week 5-12 of the study period will be summarized by treatment groups. The difference between treatment groups will be assessed using logistic regression.
Time Frame	Weeks 5 - 12

Analysis Population Description
Intent-to-Treat population.

Reporting Groups

	Description
SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	50/100ug - one inhalation twice daily
FP 100: Fluticasone Propionate	100ug - one inhalation twice daily

Measured Values

	SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	FP 100: Fluticasone Propionate
Overall Number of Participants Analyzed	29	36
Number of Participants Who Achieved Total-controlled Asthma During Weeks 5-12 Measure Type: Number Unit of measure: Participants		
Yes	1	1
No	28	35

11. Secondary Outcome Measure:

Measure Title	Change From Baseline in Asthma Control Test (ACT) Score at Week 12
Measure Description	5 question test with various responses rating frequency of asthma events over 4-week period. Questions include occurrence of asthma affecting work/school; causing shortness of breath; symptoms (wheezing, coughing, shortness of breath, chest tightness, pain) wake you up at night; causing need for rescue medication; asthma control. Scale: 1=all of time, 2=most of time, 3=some of the time, 4=a little of the time, 5=none of the time. Possible ACT scores range from 5 to 25.
Time Frame	Baseline, Week 12

Analysis Population Description

Intent-to-Treat population.

Reporting Groups

	Description
SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	50/100ug - one inhalation twice daily
FP 100: Fluticasone Propionate	100ug - one inhalation twice daily

Measured Values

	SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	FP 100: Fluticasone Propionate
Overall Number of Participants Analyzed	33	42
Change From Baseline in Asthma Control Test (ACT) Score at Week 12 Mean (Standard Deviation) Unit of measure: Score on a scale	5.64 (5.00)	5.90 (4.81)

12. Secondary Outcome Measure:

Measure Title	ACT Score in Classes at Week 12
Measure Description	Score is ranged from 5 (poor control) to 25 (complete control).
Time Frame	Week 12

Analysis Population Description
Intent-to-Treat population.

Reporting Groups

	Description
SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	50/100ug - one inhalation twice daily
FP 100: Fluticasone Propionate	100ug - one inhalation twice daily

Measured Values

	SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	FP 100: Fluticasone Propionate
Overall Number of Participants Analyzed	33	42
ACT Score in Classes at Week 12 Measure Type: Number Unit of measure: Particpants		
< 15 score	5	2
15-19 score	12	15
>=20 score	16	25

13. Secondary Outcome Measure:

Measure Title	Change From Baseline in Overall Asthma Quality of Life Questionnaire (AQLQ) Score at Week 12
Measure Description	7-point scale where 1=total impairment and 7=no impairment. Questions contain 32 items in four domains. Domains include Activity Limitation (11 items), Symptoms (12 items), Emotional Function (5 items), and Environmental Stimuli (4 items). 32 items produce one overall quality of life score. The 7 points scoring are different and depend on the item : they are the translation in French of the original questionnaire from Juniper. Possible AQLQ scores range from 1 to 7 (the mean of all the questions).
Time Frame	Baseline, Week 12

Analysis Population Description
Intent-to-Treat population.

Reporting Groups

	Description
SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	50/100ug - one inhalation twice daily
FP 100: Fluticasone Propionate	100ug - one inhalation twice daily

Measured Values

	SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	FP 100: Fluticasone Propionate
Overall Number of Participants Analyzed	33	41
Change From Baseline in Overall Asthma Quality of Life Questionnaire (AQLQ) Score at Week 12 Mean (Standard Deviation) Unit of measure: Score on a scale	0.99 (0.92)	1.11 (1.02)

Reported Adverse Events

Time Frame	[Not specified]
Adverse Event Reporting Description	[Not specified]

Reporting Groups

	Description
SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined	50/100ug - one inhalation twice daily
FP 100: Fluticasone Propionate	100ug - one inhalation twice daily

All-Cause Mortality

	SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined		FP 100: Fluticasone Propionate	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total All-Cause Mortality	/		/	

Serious Adverse Events

	SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined		FP 100: Fluticasone Propionate	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total	0/37 (0%)		0/44 (0%)	

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	SFC 100: Salmeterol Xinafoate/ Fluticasone Propionate Combined		FP 100: Fluticasone Propionate	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total	0/		2/	
Infections and infestations				
Bronchitis [A] †	0/37 (0%)	0	2/44 (4.55%)	2

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA 10.0

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.

GSK agreements may vary with individual investigators, but will not prohibit any investigator from publishing. GSK supports the publication of results from all centres of a multi-centre trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

Results Point of Contact:

Name/Official Title: GSK Response Center
Organization: GlaxoSmithKline
Phone: 866-435-7343
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