ACRN SLiMSIT Variable List

Variable	Dataset	Description
ACQ Variables	acq.sas7bdat	ACQ is copyright protected (Elizabeth Juniper, Tel: +44(0)1243 572124, E-mail: juniper@qoltech.co.uk). Data from this questionnaire is available in the repository data package.
AEC_1000	aeclin.sas7bdat	DESCRIPTION OF ADVERSE EVENT
AEC_1010	aeclin.sas7bdat	1.ICD9 CODE
AEC_1020	aeclin.sas7bdat	2. DATE STARTED (Top Line) MONTH / DAY / YEAR
AEC_1030	aeclin.sas7bdat	3. DATE STOPPED (Bottom Line) MONTH / DAY / YEAR
AEC_1040	aeclin.sas7bdat	4. ONGOING at current visit
AEC_1050	aeclin.sas7bdat	5. DURATION Complete ONLY if duration is less than 24 hours. HOUR(S)
AEC_1060	aeclin.sas7bdat	6. TYPE 1 – INTERMITTENT 2- CONTINUOUS
AEC_1070	aeclin.sas7bdat	7.SEVERITY 1- MILD 2 - MODERATE 3 - SEVERE
AEC_1080	aeclin.sas7bdat	8.SERIOUS 1- YES * 2- 0 - NO
AEC_1090	aeclin.sas7bdat	9. LIKELIHOOD OF RELATIONSHIP TO STUDY DRUG 1 - NONE 2 - UNLIKELY (REMOTE) 3 - POSSIBLE 4 - PROBABLE 5 - HIGHLY PROBABLE

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Variable	Dataset	Description
AEC_1100	aeclin.sas7bdat	10. CHANGE IN STUDY MEDICATIONS 1 - DISCONTINUED 2 - REDUCED 3 - INTERRUPTED, BUT RESUMED AT CURRENT DOSE 4 - UNCHANGED 5 - INCREASED
AEC_1110	aeclin.sas7bdat	11. OUTCOME *(Skip if #3 is missing.)* 1 – COMPLETELY RECOVERED 2 - RECOVERED, BUT WITH LASTING EFFECTS 3 - DEATH *
AEC_1120	aeclin.sas7bdat	12. TREATMENT REQUIRED 1- NONE 2 - MEDICATION ** 3 - HOSPITALIZATION * 4 - OTHER
SUBJID	aeclin.sas7bdat	SUBJECT ID
VDATE	aeclin.sas7bdat	VISIT DATE
VNUM	aeclin.sas7bdat	VISIT NUMBER
AM1_1000	am1qc.sas7bdat	1. Serial Number of AM1® being tested
AM1_1020	am1qc.sas7bdat	2. Serial Number of turbine being tested
AM1_1030	am1qc.sas7bdat	3. Test date
AM1_1040	am1qc.sas7bdat	4. Is a new AM1®device being tested? 1 Yes 0 No
AM1_1050	am1qc.sas7bdat	If ***YES***, indicate the primary reason. 1 First issuing 2 “Old” device failed QC testing 3 “Old” device had display problems 4 “Old” device experienced battery failure 5 “Old” device was recalled 6 “Old” device was lost 7 Other
AM1_1060	am1qc.sas7bdat	5. Trial 1 **AM1® (L/Min)**

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Variable	Dataset	Description
AM1_1070	am1qc.sas7bdat	**Jones FVC** **(L/Min)**
AM1_1080	am1qc.sas7bdat	6. Trial 2 **AM1® (L/Min)**
AM1_1090	am1qc.sas7bdat	**Jones FVC** **(L/Min)**
AM1_1100	am1qc.sas7bdat	7. Trial 3 **AM1® (L/Min)**
AM1_1110	am1qc.sas7bdat	**Jones FVC** **(L/Min)**
AM1_1120	am1qc.sas7bdat	8. Trial 4 **AM1® (L/Min)**
AM1_1130	am1qc.sas7bdat	**Jones FVC** **(L/Min)**
AM1_1140	am1qc.sas7bdat	9. Trial 5 **AM1® (L/Min)**
AM1_1150	am1qc.sas7bdat	**Jones FVC** **(L/Min)**
AM1_1160	am1qc.sas7bdat	10. Did the AM1® pass? 1 Yes 0 No
AM1_1170	am1qc.sas7bdat	If ***NO***, is this the second test with this turbine at this visit? 1 Yes 0 No *If **NO**, retest the AM1® with the same turbine and complete another AM1® Quality Control form.* ➜ *If **YES**, issue a new turbine and complete another AM1®Quality Control form. If 2 turbines have been tested* *with this device, issue a new device and turbine and complete another AM1®Quality Control form.*
PAGE	am1qc.sas7bdat	PAGE
SUBJID	am1qc.sas7bdat	SUBJECT ID
VDATE	am1qc.sas7bdat	VISIT DATE
VNUM	am1qc.sas7bdat	VISIT NUMBER
AQLQ Variables	aqlq.sas7bdat	AQLQ is copyright protected (Elizabeth Juniper, Tel: +44(0)1243 572124, E-mail: juniper@qoltech.co.uk). Data from this questionnaire is available in the repository data package.

ACRN SLiMSIT Variable List

Variable	Dataset	Description
ASUI Variables	asui.sas7bdat	ASUI is copyright protected (Dennis Revicki, United BioSource Corporation). Data from this questionnaire is available in the repository data package.
CCB_1000	ccblind.sas7bdat	1 I am certain the inhaler contained placebo.
CCB_1010	ccblind.sas7bdat	3 I have no idea which type of inhaler the subject received, but my best guess would be: 1 Placebo 2 Active Drug
CCB_1020	ccblind.sas7bdat	1 I am certain the tablets contained placebo.
CCB_1030	ccblind.sas7bdat	3 I have no idea which type of tablets the subject received, but my best guess would be: 1 Placebo 2 Active Drug
SUBJID	ccblind.sas7bdat	SUBJECT ID
VDATE	ccblind.sas7bdat	VISIT DATE
VNUM	ccblind.sas7bdat	VISIT NUMBER
CMA_1000	cmed_as.sas7bdat	NAME OF MEDICATION
CMA_1020	cmed_as.sas7bdat	FREQUENCY
CMA_1060	cmed_as.sas7bdat	STOP DATE
CMA_1070	cmed_as.sas7bdat	ONGOING AT CURRENT VISIT
MED_CODE	cmed_as.sas7bdat	CODE
START_DT	cmed_as.sas7bdat	START DATE
SUBJID	cmed_as.sas7bdat	SUBJECT ID
VDATE	cmed_as.sas7bdat	VISIT DATE
VNUM	cmed_as.sas7bdat	VISIT NUMBER
COM_1000	comply.sas7bdat	1a. Number of tablets dispensed in eDEM™ vial ___ ___ tablets
COM_1010	comply.sas7bdat	1b. Number of tablets returned in eDEM™ vial ___ ___ tablets
COM_1020	comply.sas7bdat	1c. Actual number of tablets taken (Question #1a - Question #1b) ___ ___ tablets
COM_1030	comply.sas7bdat	1d. Number of prescribed doses ___ ___ doses
COM_1040	comply.sas7bdat	1e. Percent compliance = *Question #1d/* *Question #1c* x *100* ___ ___ ___ . ___ % ➜ ***If the percent compliance for the Tablet Count is less than 85%, re-emphasize*** ***the importance of maintaining the daily dosing schedule.***
COM_1050	comply.sas7bdat	2a. Number of monitored days ___ ___ days
COM_1060	comply.sas7bdat	2b. Number of doses taken ___ ___ doses

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Variable	Dataset	Description
COM_1070	comply.sas7bdat	2c. % Prescribed number of doses taken ___ ___ ___ . ___ %
COM_1080	comply.sas7bdat	2d. Doses in time window/prescribed doses ___ ___ ___ . ___ % (Percent compliance) ➜ ***If the percent compliance for the eDEM is less than 85%, re-emphasize the importance of maintaining the daily dosing schedule.***
COM_1090	comply.sas7bdat	3a. Total number of scheduled puffs since the last visit ___ ___ ___ puffs ➜ Value obtained from Question #1 on P11_COMPLY_WKS
COM_1100	comply.sas7bdat	3b. Total number of puffs in Doser™ history ___ ___ ___ puffs ➜ Value obtained from Question #2 on P11_COMPLY_WKS
COM_1110	comply.sas7bdat	3c. Percent compliance = *Question #3b/ Question #3a x 100* ___ ___ ___ . ___ % ➜ ***If the percent compliance for the Doser™ is less than 85%, re-emphasize the importance of maintaining the daily dosing schedule.***
COM_1120	comply.sas7bdat	4a. Number of scheduled puffs since the last visit ___ ___ ___ puffs
COM_1130	comply.sas7bdat	4b. Number of remaining puffs reflected on Serevent® Diskus® counter ___ ___ ___ puffs ➜ At Visits 5, 6, 9, 10: Total the values reflected on two returned Serevent® Diskus®
COM_1140	comply.sas7bdat	4c. Number of puffs taken ___ ___ ___ puffs ➜ At Visits 4, 8: 60 - Question #4b ➜ At Visits 5, 6, 9, 10: 120 - Question #4b
COM_1150	comply.sas7bdat	4d. Percent compliance = *Question #4c/ Question #4a x 100* ___ ___ ___ . ___ % ➜ ***If the percent compliance for the Serevent® Diskus® is less than 85%, re-emphasize the importance of maintaining the daily dosing schedule.***
SUBJID	comply.sas7bdat	SUBJECT ID
VDATE	comply.sas7bdat	VISIT DATE
VNUM	comply.sas7bdat	VISIT NUMBER
DIARYDT	diary.sas7bdat	DIARY CARD
DRY_1000	diary.sas7bdat	1. Number of times that you woke up last night due to asthma
DRY_1010	diary.sas7bdat	2. Time of AM Peak Flow (within 15 minutes of awakening)
DRY_1020	diary.sas7bdat	3. AM Peak Flow liters
DRY_1025	diary.sas7bdat	/min
DRY_1040	diary.sas7bdat	Total number of puff(s) from Scheduled Inhaler **(AM)**
DRY_1045	diary.sas7bdat	Total number of puff(s) from Serevent® Diskus® **(AM)**

ACRN SLiMSIT Variable List

Variable	Dataset	Description
DRY_1050	diary.sas7bdat	6. Shortness of Breath
DRY_1060	diary.sas7bdat	7. Chest Tightness
DRY_1070	diary.sas7bdat	8. Wheezing
DRY_1080	diary.sas7bdat	9. Cough
DRY_1090	diary.sas7bdat	10. Phlegm/Mucus
DRY_1100	diary.sas7bdat	11. Time of PM Peak Flow (between 8 PM and 1 AM)
DRY_1110	diary.sas7bdat	12. PM Peak Flow liters
DRY_1115	diary.sas7bdat	/min
DRY_1130	diary.sas7bdat	13. Total number of puff(s) from Scheduled Inhaler **(PM)**
DRY_1135	diary.sas7bdat	14. Total number of puff(s) from Serevent® Diskus®
DRY_1140	diary.sas7bdat	15. Number of scheduled tablet(s) taken **(PM)**
DRY_1150	diary.sas7bdat	16. Shortness of Breath
DRY_1160	diary.sas7bdat	17. Chest Tightness
DRY_1170	diary.sas7bdat	18. Wheezing
DRY_1180	diary.sas7bdat	19. Cough
DRY_1190	diary.sas7bdat	20. Phlegm/Mucus
DRY_1200	diary.sas7bdat	21. Total number of **puffs** from albuterol **(RESCUE)** inhaler over a 24 hour period. *(Do not record* *preventive use.)*
SUBJID	diary.sas7bdat	SUBJECT ID
VDATE	diary.sas7bdat	VISIT DATE
VNUM	diary.sas7bdat	VISIT NUMBER
DRUG_ARM	drugarms.sas7bdat	DRUG_ARM
SUBJID	drugarms.sas7bdat	SUBJECT ID
EDE_1000	edemqc.sas7bdat	1. Serial Number of eDEM monitor being tested
EDE_1010	edemqc.sas7bdat	2. Test date
EDE_1040	edemqc.sas7bdat	4. Record battery voltage
EDE_1050	edemqc.sas7bdat	5. Is a new eDEM monitor being tested? 1 Yes 0 No

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Variable	Dataset	Description
EDE_1060	edemqc.sas7bdat	If ***YES***, indicate the primary reason. 1 First issuing 2 “Old” device was recalled 3 “Old” device experiencing low voltage (< 2.90 volts) 4 “Old” device had downloading problems 5 “Old” device experienced AC adaptor failure 6 “Old” device experienced battery failure 7 “Old” device was lost 8 “Old” device validity expired 9 Other
EDE_1070	edemqc.sas7bdat	6. Did the eDEM monitor pass? 1 Yes 0 No ➜ *If **NO**, issue a new eDEM monitor and complete another eDEM□ □Monitor Quality Control form.*
PAGE	edemqc.sas7bdat	PAGE
SUBJID	edemqc.sas7bdat	SUBJECT ID
VDATE	edemqc.sas7bdat	VISIT DATE
VNUM	edemqc.sas7bdat	VISIT NUMBER
E1_1000	elig1.sas7bdat	*1. **Did the subject sign the Informed Consent?*** *1 Yes* *0 No*
E1_1010	elig1.sas7bdat	1a. If ***YES***, record the date the form was signed.
E1_1020	elig1.sas7bdat	2. Is the subject between 12 and 65, inclusive? 1 Yes 0 No
E1_1030	elig1.sas7bdat	3. Are you planning to move away from this clinical center in the next 12 months such that your ability to complete the study will be jeopardized? 1 Yes 0 No
E1_1040	elig1.sas7bdat	4. Have you used any smokeless tobacco products (chew, snuff) in the past year? 1 Yes 0 No
E1_1050	elig1.sas7bdat	5. Have you smoked cigarettes, a pipe, cigar, marijuana or any other substance in the past year? 1 Yes 0 No

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Variable	Dataset	Description
E1_1060	elig1.sas7bdat	6. Do you have a smoking history less than 10 pack-years? 1 Yes 0 No
E1_1070	elig1.sas7bdat	Record history in pack-years. (Enter '00.0' if none)
E1_1080	elig1.sas7bdat	7. Have you had a respiratory tract infection in the past 6 weeks? 1 Yes 0 No
E1_1090	elig1.sas7bdat	8. Have you experienced a significant asthma attack in the past 6 weeks? 1 Yes 0 No
E1_1100	elig1.sas7bdat	9. Have you experienced a life-threatening asthma attack requiring treatment with intubation and mechanical ventilation in the past 10 years? 1 Yes 0 No
E1_1110	elig1.sas7bdat	Do you work night shift or have an altered day/night cycle for other reasons? 1 Yes 0 No
E1_1120	elig1.sas7bdat	11. Is the subject eligible? ***If any of the shaded boxes are filled in, the subject is ineligible.*** 1 Yes 0 No ➜ ***If NO, please complete the Termination of Study Participation (P11_TERM) form.***
SUBJID	elig1.sas7bdat	SUBJECT ID
VDATE	elig1.sas7bdat	VISIT DATE
VNUM	elig1.sas7bdat	VISIT NUMBER
E2_1000	elig2.sas7bdat	1.Does the subject have current evidence of any of the conditions listed on the Exclusionary Medical Conditions reference card (EXCLMED)? 1 Yes 0 No If ***YES***, describe
E2_1010	elig2.sas7bdat	2. Has the subject taken any medications listed on the Exclusionary Drugs reference card (EXCLDRUG) within the specified time periods? 1 Yes 0 No If ***YES***, describe

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Variable	Dataset	Description
E2_1020	elig2.sas7bdat	3.Is the subject currently taking Pulmicort Respules for treatment of his or her asthma? 1 Yes 0 No
E2_1030	elig2.sas7bdat	4. Is the subject currently taking prescription or over-the-counter medication(s) other than those listed on the Allowed Medications reference card (MEDALLOW)? 1 Yes 0 No If ***YES***, describe
E2_1040	elig2.sas7bdat	5. Is the subject currently receiving hyposensitization therapy other than an established maintenance regimen implemented continuously for a minimum of 3 months? 1 Yes 0 No
E2_1050	elig2.sas7bdat	6. Is the subject currently using intranasal steroids, or does the subject anticipate using intranasal steroids during their participation in the study? 1 Yes 0 No
E2_1060	elig2.sas7bdat	If ***YES***, please choose one of the following: 0 The subject agrees to stop use of all intranasal steroids for the duration of the study. 1 The subject agrees to adhere to a course of intranasal fluticasone propionate at a dose not to exceed 2 sprays (50 g each spray) in each nostril daily throughout the duration of the study. ➜ ***Please complete the Concomitant Medications for Asthma and Allergies (P11_CMED_AS) form.*** 2 The subject does not agree to adhere to the criteria regarding intranasal steroid use as outlined in the SLiMSIT Manual of Operations.
E2_1070	elig2.sas7bdat	7. Is the subject potentially able to bear children? (If subject is male, check N/A and skip to Question #8.) 1 Yes 0 No 9 N/A
E2_1080	elig2.sas7bdat	7a. If ***YES,*** is the subject currently pregnant or lactating? 1 Yes 0 No

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Variable	Dataset	Description
E2_1090	elig2.sas7bdat	7b. If ***YES,*** is the subject using one of the approved methods indicated on the Birth Control Methods reference card (P11_BIRCTRL)? 1 Yes 0 No
E2_1100	elig2.sas7bdat	7c. If ***YES***, record results of the urine pregnancy test. 1 Positive 2 Negative
E2_1110	elig2.sas7bdat	8. Is the subject eligible? ***If any of the shaded boxes are filled in, the subject is ineligible.*** 1 Yes 0 No ➜ ***If YES, please continue with Visit 1.*** ➜ ***If NO, please complete the Termination of Study Participation (P11_TERM) form.***
SUBJID	elig2.sas7bdat	SUBJECT ID
VDATE	elig2.sas7bdat	VISIT DATE
VNUM	elig2.sas7bdat	VISIT NUMBER
E3_1000	elig3.sas7bdat	1. Is the subject currently using inhaled corticosteroids/leukotriene modifiers on a regular basis? 1 Yes 0 No
E3_1010	elig3.sas7bdat	1a. If ***YES***, is the subject's prebronchodilator FEV1 > 40% of predicted? 1 Yes 0 No
E3_1020	elig3.sas7bdat	1b. If ***NO***, is the subject's prebronchodilator FEV1 > 40% and ⩽ 80% of predicted? 1 Yes 0 No
E3_1030	elig3.sas7bdat	2. Is the subject's prebronchodilator FEV1 > 55% of predicted? 1 Yes 0 No
E3_1040	elig3.sas7bdat	2a. If ***YES*** *(FEV1 > 55%),* does the subject have source documentation of a methacholine PC20 ≤8 mg/ml (ACRN systems only) within the past 6 months? 1 Yes 0 No
E3_1050	elig3.sas7bdat	➜ ***If YES, record values below:*** PC20 _ ._ _ _ _ mg/ml
E3_1060	elig3.sas7bdat	Source Documentation Date

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Variable	Dataset	Description
E3_1070	elig3.sas7bdat	2b. If ***NO*** *(FEV1 < 55%)*, does the subject have source documentation of a > 12% increase in FEV1 in response to aerosolized albuterol (ACRN systems only) within the past 6 months? 1 Yes 0 No
E3_1080	elig3.sas7bdat	➜ ***If YES, record values below:*** Prebronchodilator FEV1 _. _ _ L
E3_1090	elig3.sas7bdat	Postbronchodilator FEV1 _. _ _ L
E3_1100	elig3.sas7bdat	Source Documentation Date
E3_1110	elig3.sas7bdat	3. Is the subject able to use a metered dose inhaler (MDI) properly, as evidenced by achieving a score of 6 on two consecutive, separate inhalations using the MDI Inhalation Technique Checklists (P11_SCORE, P11_TECH_MDI)? 1 Yes 0 No
E3_1120	elig3.sas7bdat	4. Is the subject able to use the AM1® device correctly, as evidenced by achieving a satisfactory rating on the AM1® Performance Checklist (P11_PERF_AM1)? 1 Yes 0 No
E3_1130	elig3.sas7bdat	5. Is the subject eligible? ***If any of the shaded boxes are filled in, the subject is ineligible.*** 1 Yes 0 No ➜ ***If NO, please complete the Termination of Study Participation (P11_TERM) form***.
SUBJID	elig3.sas7bdat	SUBJECT ID
VDATE	elig3.sas7bdat	VISIT DATE
VNUM	elig3.sas7bdat	VISIT NUMBER
E4_1000	elig4.sas7bdat	1. Since Visit 1, has the subject experienced a significant asthma exacerbation as defined in the protocol? 1 Yes 0 No ➜ ***Review information on Treatment Failure Assessment (P11_TXFAIL_V2_3) form.***

ACRN SLiMSIT Variable List

Variable	Dataset	Description
E4_1010	elig4.sas7bdat	2. Since Visit 1, has the subject been deemed a treatment failure as defined in the protocol? 1 Yes 0 No ➜ ***Review information on Treatment Failure Assessment (P11_TXFAIL_V2_3) form.***
E4_1020	elig4.sas7bdat	3. Since Visit 1, has the subject received treatment with any excluded medications (EXCLDRUG)? 1 Yes 0 No
E4_1030	elig4.sas7bdat	4. Is the subject's prebronchodilator FEV1 ⩾ 55% of predicted? 1 Yes 0 No
E4_1040	elig4.sas7bdat	5. Is the subject's prebronchodilator FEV1 ⩾ 85% of the prebronchodilator FEV1 obtained at Visit 1? 1 Yes 0 No
E4_1050	elig4.sas7bdat	6. Using the history stored in the Doser□, did the subject take at least 85% of the required puffs from his or her scheduled inhaler during the last two weeks of the run-in period? 1 Yes 0 No
E4_1060	elig4.sas7bdat	7. Using the eDEM Monitor, did the subject take at least 85% of the required tablets from his or her eDEM Monitor during the last two weeks of the run-in period? 1 Yes 0 No
E4_1070	elig4.sas7bdat	8. During the last two weeks of the run-in period, did the subject 8. During the last two weeks of the run-in period, did the subject on his or her Diary Card (P11_DIARY) an average of at least six days per week? 1 Yes 0 No
E4_1080	elig4.sas7bdat	9. During the last two weeks of the run-in period, did the subject measure his or her AM and PM peak flow on schedule and accurately transcribe the measurements onto the Diary Cards (P11_DIARY) an average of at least six days per week? 1 Yes 0 No

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Variable	Dataset	Description
E4_1090	elig4.sas7bdat	10. During the last week of the run-in period, did the subject use an average of ≥ 16 puffs/24 hours from his or her RESCUE (albuterol) inhaler? 1 Yes 0 No
E4_1100	elig4.sas7bdat	11. Does the subject wish to withdraw consent from the study? 1 Yes 0 No
E4_1110	elig4.sas7bdat	12. Is there any new information that makes the subject ineligible according to the eligibility criteria? 1 Yes 0 No If ***YES***, describe
E4_1120	elig4.sas7bdat	13. Is there any other reason why this subject should not be included in the study? 1 Yes 0 No If ***YES***, describe
E4_1130	elig4.sas7bdat	14. Is the subject eligible? ***If any of the shaded boxes are filled in, the subject is ineligible.*** 1 Yes 0 No ➜ ***If the subject is eligible and will participate in SLiMSIT, randomize the subject.*** ***Otherwise, please complete the Termination of Study Participation (P11_TERM) form.***
E4_1140	elig4.sas7bdat	15. Drug Packet Number **(record on LOG)**
SUBJID	elig4.sas7bdat	SUBJECT ID
VDATE	elig4.sas7bdat	VISIT DATE
VNUM	elig4.sas7bdat	VISIT NUMBER
FLU_1000	fluid.sas7bdat	ECP _ _ _ _ _ mcg/L
FLU_1010	fluid.sas7bdat	Non-detectable limit
FLU_1020	fluid.sas7bdat	Quantity not sufficient to dilute
FLU_1030	fluid.sas7bdat	Tryptase _ _ _ _ _ mcg/L
FLU_1040	fluid.sas7bdat	Non-detectable limit

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Variable	Dataset	Description
FLU_1050	fluid.sas7bdat	Quantity not sufficient to dilute
READ_DT	fluid.sas7bdat	READ_DT
SUBJID	fluid.sas7bdat	SUBJECT ID
VNUM	fluid.sas7bdat	VISIT NUMBER
IGE	ige.sas7bdat	IGE
SUBJID	ige.sas7bdat	SUBJECT ID
IMP_PC20	imp_pc20.sas7bdat	IMP_PC20
SUBJID	imp_pc20.sas7bdat	SUBJECT ID
VNUM	imp_pc20.sas7bdat	VISIT NUMBER
LAB_1000	lab.sas7bdat	***1.(Complete Question #1 for Visit 1 Only.)*** Eosinophils (absolute count) _ _ _ _ /mm3 ➜ ***Attach a photocopy of the lab report to this form before submitting it to the DCC. Ensure that any identifying information on the report is completely masked.***
LAB_1010	lab.sas7bdat	*2.* ***(Complete Question #2 for Visits 2, 3, 6, 7 Only.)*** Pregnancy test results *(Check N/A if subject is male or unable to bear children.)* 1Positive 2 Negative 9 N/A
SUBJID	lab.sas7bdat	SUBJECT ID
VDATE	lab.sas7bdat	VISIT DATE
VNUM	lab.sas7bdat	VISIT NUMBER
BMI	lexam.sas7bdat	BMI
LEX_1000	lexam.sas7bdat	1.Resting blood pressure _ _ _ systolic
LEX_1010	lexam.sas7bdat	/ _ _ _ mm Hg diastolic
LEX_1020	lexam.sas7bdat	2. Pulse _ _ _beats/min
LEX_1030	lexam.sas7bdat	3. Respiratory rate _ _ breaths/min

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Variable	Dataset	Description
LEX_1040	lexam.sas7bdat	4. Body temperature _ _ _. _ F
LEX_1080	lexam.sas7bdat	7. Hair and Skin 2 Not Done 1 Normal 0 Abnormal
LEX_1090	lexam.sas7bdat	8. Lymph nodes 2 Not Done 1 Normal 0 Abnormal
LEX_1100	lexam.sas7bdat	9. Eyes (excluding corrective lenses) 2 Not Done 1 Normal 0 Abnormal
LEX_1110	lexam.sas7bdat	10. Ears, Nose, and Throat 2 Not Done 1 Normal 0 Abnormal
LEX_1120	lexam.sas7bdat	11. Respiratory (excluding asthma) 2 Not Done 1 Normal 0 Abnormal
LEX_1130	lexam.sas7bdat	12. Cardiovascular 2 Not Done 1 Normal 0 Abnormal
LEX_1140	lexam.sas7bdat	13. Gastrointestinal 2 Not Done 1 Normal 0 Abnormal
LEX_1150	lexam.sas7bdat	14. Musculoskeletal 2 Not Done 1 Normal 0 Abnormal

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Variable	Dataset	Description
LEX_1160	lexam.sas7bdat	15. Neurological 2 Not Done 1 Normal 0 Abnormal
LEX_1170	lexam.sas7bdat	16. Mental 2 Not Done 1 Normal 0 Abnormal Status
LEX_1180	lexam.sas7bdat	17. Other (check Not Done if non-applicable 2 Not Done 1 Normal 0 Abnormal
LEX_1190	lexam.sas7bdat	18. Indicate subject's condition. *(Check one box only)* 1 No wheezing 2 Wheeze on inspiration or expiration 3 Adventitious sounds other than Wheezing If applicable, describe sounds:
SUBJID	lexam.sas7bdat	SUBJECT ID
VDATE	lexam.sas7bdat	VISIT DATE
VNUM	lexam.sas7bdat	VISIT NUMBER
MED_1000	med.sas7bdat	1.Type of scheduled medications dispensed 1 Regular 2 Backup ➜ ***If backup medications were dispensed, immediately fax this form to the Project Coordinator at the*** ***DCC at (717) 531-4359. Explain circumstances:***
MED_1010	med.sas7bdat	2. Number of Scheduled MDIs dispensed. 0 None 1 One
MED_1020	med.sas7bdat	3. Number of Serevent® Diskus® DPIs dispensed. 0 None 1 One 2 Two
MED_1030	med.sas7bdat	4. Number of tablets dispensed.

ACRN SLiMSIT Variable List

Variable	Dataset	Description
SUBJID	med.sas7bdat	SUBJECT ID
VDATE	med.sas7bdat	VISIT DATE
VNUM	med.sas7bdat	VISIT NUMBER
AGE	medhx.sas7bdat	AGE
DATE_Q11	medhx.sas7bdat	Date Non-long-acting Inhaled Beta Agonists were last taken
DATE_Q12	medhx.sas7bdat	Date Long-acting Inhaled Beta-Agonists were last taken
DATE_Q13	medhx.sas7bdat	Date Asthma medication via a Nebulizer Machine was last taken
DATE_Q14	medhx.sas7bdat	Date Oral Beta-Agonists were last taken
DATE_Q15	medhx.sas7bdat	Date Short-Acting Oral Theophylline was last taken
DATE_Q16	medhx.sas7bdat	Date Sustained release Oral Theophylline was last taken
DATE_Q17	medhx.sas7bdat	Date Inhaled Anticholinergic was last taken
DATE_Q18	medhx.sas7bdat	Date Anti-allergic Inhaled Medications were last taken
DATE_Q19	medhx.sas7bdat	Date Anti-allergic Nasal Medications were last taken
DATE_Q20	medhx.sas7bdat	Date Anti-allergic Oral Medications were last taken
DATE_Q21	medhx.sas7bdat	Date Leukotriene Antagonist / 5L0 Inhibitors were last taken
DATE_Q22	medhx.sas7bdat	Date Topical Steroids (Prescription) were last taken
DATE_Q23	medhx.sas7bdat	Date Topical Steroids (OTC) were last taken
DATE_Q24	medhx.sas7bdat	Date Nasal Steroids were last taken
DATE_Q25	medhx.sas7bdat	Date Oral Steroids were last taken
DATE_Q26	medhx.sas7bdat	Date Inhaled Steroids were last taken
MHX_1010	medhx.sas7bdat	2. Subject's gender 1 Male 2 Female
MHX_1100	medhx.sas7bdat	5. Approximately how old were you when your asthma first appeared? (*Check one box only*) 1 less than 10 years old 2 10-19 years old 3 20-29 years old 4 30-39 years old 5 40-49 years old 6 50 years or more 8 unknown

ACRN SLiMSIT Variable List

Variable	Dataset	Description
MHX_1110	medhx.sas7bdat	6. How many years have you had asthma? (*Check one box only)* 1 less than 1 year 2 1-4 years 3 5-9 years 4 10-14 years 5 15 years or more 8 unknown
MHX_1120	medhx.sas7bdat	7. What season is your asthma the worst? (*Check one box only*) 1 Winter 2 Spring 3 Summer 4 Fall 5 Same all year
MHX_1130	medhx.sas7bdat	8. In the last 12 months, how many: (*Enter '00' if none*) 8a. Asthma episodes have you had that required (1130) emergency care or an unscheduled office visit?
MHX_1140	medhx.sas7bdat	8b. Hospitalizations have you had due to asthma?
MHX_1150	medhx.sas7bdat	8c. Courses of oral corticosteroid therapy for asthma (1150) (such as prednisone or Medrol) have you taken?
MHX_1160	medhx.sas7bdat	9. Have you missed any days of work or school due to asthma in the last 12 months? 1 Yes 0 No 9 N/A
MHX_1170	medhx.sas7bdat	9a. If ***YES***, record your best estimate of the number of days missed
MHX_1180	medhx.sas7bdat	10. Have any of your immediate blood relatives been told by a physician that they have asthma? (*Check the 'N/A' box if the subject does not have siblings or children.*) 10a. Mother 1 Yes 0 No 8 Don't Know
MHX_1190	medhx.sas7bdat	10b. Father 1 Yes 0 No 8 Don't Know
MHX_1200	medhx.sas7bdat	10c. Brothers or Sisters 1 Yes 0 No 8 Don't Know 9 N/A

ACRN SLiMSIT Variable List

Variable	Dataset	Description
MHX_1210	medhx.sas7bdat	10d. Child(ren) 1 Yes 0 No 8 Don't Know 9 N/A
MHX_1220	medhx.sas7bdat	11. Non-long-acting Inhaled Beta-Agonists (**Bronkaid Mist, Duo-Medihaler, Medihaler-Epi, Primatene Mist, Alupent, Brethaire, Brethine, Bronkometer, Maxair, Metaprel, Proventil, Tornalate, Ventolin, Xopenex and others)** 1 Yes 0 No 8Unknown If Yes, indicate date month / day / year medication was last taken__ /__ /____
MHX_1260	medhx.sas7bdat	11a. If ***YES***, indicate average daily puffs in the past month. (Enter '00' if none used.) _ _ puffs
MHX_1270	medhx.sas7bdat	12. Long-acting Inhaled Beta-Agonists (**Serevent, Foradil, Advair Diskus**) 1 Yes 0 No 8 Unknown If Yes, indicate date month / day / year medication was last taken__ /__ /____
MHX_1310	medhx.sas7bdat	12a. If ***YES***, indicate average daily puffs in the past month. (Enter '00' if none used.) _ _ puffs
MHX_1320	medhx.sas7bdat	13. Asthma medication via a Nebulizer Machine 1 Yes 0 No 8 Unknown If Yes, indicate date month / day / year medication was last taken__ /__ /____

ACRN SLiMSIT Variable List

Variable	Dataset	Description
MHX_1360	medhx.sas7bdat	14. Oral Beta-Agonists (**Alupent, Brethine, Bricanyl, Metaprel, Proventil, Ventolin, Repetabs, Volmax and others**) 1 Yes 0 No 8 Unknown If Yes, indicate date month / day / year medication was last taken__ /__ /____
MHX_1400	medhx.sas7bdat	15. Short-acting Oral Theophylline (**Aminophylline, Slo-Phyllin and others**) 1 Yes 0 No 8 Unknown If Yes, indicate date month / day / year medication was last taken__ /__ /____
MHX_1440	medhx.sas7bdat	16. Sustained release Oral Theophylline (**Slo-bid, Theo-Dur, Uniphyl and others**) 1 Yes 0 No 8 Unknown If Yes, indicate date month / day / year medication was last taken__ /__ /____
MHX_1480	medhx.sas7bdat	17. Inhaled Anticholinergic (**Atrovent, Combivent**) 1 Yes 0 No 8 Unknown If Yes, indicate date month / day / year medication was last taken__ /__ /____
MHX_1520	medhx.sas7bdat	18. Anti-allergic Inhaled Medications (**Intal, Tilade and others**) 1 Yes 0 No 8 Unknown If Yes, indicate date month / day / year medication was last taken__ /__ /____

ACRN SLiMSIT Variable List

Variable	Dataset	Description
MHX_1560	medhx.sas7bdat	19. Anti-allergic Nasal Medications (**Nasalcrom, Astelin and others**) 1 Yes 0 No 8 Unknown If Yes, indicate date month / day / year medication was last taken__ /__ /____
MHX_1600	medhx.sas7bdat	20. Anti-allergic Oral Medications (**Allegra, Claritin, Zyrtec, Chlor-Trimeton** **and others**) 1 Yes 0 No 8 Unknown If Yes, indicate date month / day / year medication was last taken__ /__ /____
MHX_1640	medhx.sas7bdat	21. Leukotriene Antagonist / 5L0 Inhibitors (**Accolate, Zyflo, Singulair**) 1 Yes 0 No 8 Unknown If Yes, indicate date month / day / year medication was last taken__ /__ /____
MHX_1680	medhx.sas7bdat	22. Topical Steroids – Prescription (**Synalar, Lidex, Dermacin, Fluocinonide and others**) 1 Yes 0 No 8 Unknown If Yes, indicate date month / day / year medication was last taken__ /__ /____
MHX_1720	medhx.sas7bdat	23. Topical Steroids – OTC (**Hydrocortisone - multiple strengths and products)** 1 Yes 0 No 8 Unknown If Yes, indicate date month / day / year medication was last taken__ /__ /____

ACRN SLiMSIT Variable List

Variable	Dataset	Description
MHX_1760	medhx.sas7bdat	24. Nasal Steroids (**Beconase, Vancenase, Flonase, Nasacort, Nasalide, Nasarel, Rhinocort, Nasonex and others)** 1 Yes 0 No 8 Unknown If Yes, indicate date month / day / year medication was last taken__ /__ /____
MHX_1800	medhx.sas7bdat	25. Oral Steroids (**Prednisone, Medrol and others**) 1 Yes 0 No 8 Unknown If Yes, indicate date month / day / year medication was last taken__ /__ /____
MHX_1840	medhx.sas7bdat	26. Inhaled Steroids (**Azmacort, Beclovent, Vanceril, AeroBid, QVAR, Flovent, Pulmicort, Advair Diskus and others**) 1 Yes 0 No 8 Unknown If Yes, indicate date month / day / year medication was last taken__ /__ /____ ➜ ***If NO or unknown, skip to Question #27.*** ➜ ***If YES, complete Questions #26a - 26c.***

ACRN SLiMSIT Variable List

Variable	Dataset	Description
MHX_1880	medhx.sas7bdat	26a. Indicate most recent type. 1 beclomethasone MDI (1 puff = 42 µ g) (**e.g., Beclovent, Vanceril**) 2 beclomethasone MDI (1 puff = 84 µg) (**e.g., Vanceril-DS**) 3 beclomethasone HFA (1 puff = 40 µg) (**e.g., QVAR**) 4 beclomethasone HFA (1 puff = 80 µg) (**e.g., QVAR**) 5 budesonide DPI (1 puff = 200 µg) (**e.g., Pulmicort Turbuhaler**) 6 flunisolide MDI (1 puff = 250 µg) (**e.g., Aerobid, Aerobid - M**) 7 fluticasone MDI (1 puff = 44 µg) (**e.g., Flovent**) 8 fluticasone MDI (1 puff = 110 µg) (**e.g., Flovent**) 9 fluticasone MDI (1 puff = 220 µg) (**e.g., Flovent**) 10 fluticasone DPI (1 puff = 50 µg) (**e.g., Flovent Rotadisk)**
MHX_1880 (contd)	medhx.sas7bdat	11 fluticasone DPI (1 puff = 100 □g) (**e.g., Advair Diskus**) 12 fluticasone DPI (1 puff = 250 □g) (**e.g., Advair Diskus**) 13 fluticasone DPI (1 puff = 500 □g) (**e.g., Advair Diskus**) 14 triamcinolone acetonide MDI (1 puff = 100 □g) (**e.g., Azmacort**) 15 other
MHX_1890	medhx.sas7bdat	26b. Indicate total number of puffs used in the past week. (Enter ‘00’ if none used.) _ _ puffs
MHX_1900	medhx.sas7bdat	26c. Indicate most recent duration. 1 less than 1 month 2 1 - 6 months 3 greater than 6 months
MHX_1910	medhx.sas7bdat	27. Skin 1 Yes 0 No **If Yes, Comment**
MHX_1920	medhx.sas7bdat	28. Blood, Lymph, or Immune Systems 1 Yes 0 No **If Yes, Comment**

ACRN SLiMSIT Variable List

Variable	Dataset	Description
MHX_1930	medhx.sas7bdat	29. Eyes 1 Yes 0 No **If Yes, Comment**
MHX_1940	medhx.sas7bdat	30. Ears, Nose, or Throat 1 Yes 0 No **If Yes, Comment**
MHX_1950	medhx.sas7bdat	31. Breasts 1 Yes 0 No **If Yes, Comment**
MHX_1960	medhx.sas7bdat	32. Endocrine Systems 1 Yes 0 No **If Yes, Comment**
MHX_1970	medhx.sas7bdat	33. Lung - other than asthma 1 Yes 0 No **If Yes, Comment**
MHX_1980	medhx.sas7bdat	34. Heart and Blood Vessels 1 Yes 0 No **If Yes, Comment**
MHX_1990	medhx.sas7bdat	35. Liver or Pancreas 1 Yes 0 No **If Yes, Comment**
MHX_2000	medhx.sas7bdat	36. Kidneys or Urinary Tract System 1 Yes 0 No **If Yes, Comment**
MHX_2010	medhx.sas7bdat	37. Reproductive System 1 Yes 0 No **If Yes, Comment**

ACRN SLiMSIT Variable List

Variable	Dataset	Description
MHX_2020	medhx.sas7bdat	38. Stomach or Intestines 1 Yes 0 No **If Yes, Comment**
MHX_2030	medhx.sas7bdat	39. Muscles or Bones 1 Yes 0 No **If Yes, Comment**
MHX_2040	medhx.sas7bdat	40. Nervous System 1 Yes 0 No **If Yes, Comment**
MHX_2050	medhx.sas7bdat	41. Psychiatric 1 Yes 0 No **If Yes, Comment**
MHX_2060	medhx.sas7bdat	42. Other 1 Yes 0 No **If Yes, Comment**
MINORITY	medhx.sas7bdat	MINORITY
SUBJID	medhx.sas7bdat	SUBJECT ID
VDATE	medhx.sas7bdat	VISIT DATE
VNUM	medhx.sas7bdat	VISIT NUMBER
BRAND	mediact.sas7bdat	BRAND
GENERIC	mediact.sas7bdat	GENERIC
MED_CODE	mediact.sas7bdat	MED_CODE
ROUTE	mediact.sas7bdat	ROUTE
MTH_1000	metha.sas7bdat	1.Has the subject had any severe acute illness in the past 4 weeks? 1 Yes 0 No

ACRN SLiMSIT Variable List

Variable	Dataset	Description
MTH_1010	metha.sas7bdat	If ***YES***, has the subject received permission from the supervising physician to proceed with the methacholine challenge testing? 1 Yes 0 No Name of physician:
MTH_1015	metha.sas7bdat	2. Has the subject been deemed a SLiMSIT treatment failure at this the subject been deemed a SLiMSIT treatment failure at this visit? 1 Yes 0 No
MTH_1016	metha.sas7bdat	If ***YES***, has the subject received permission from the supervising physician to proceed with the methacholine challenge testing? 1 Yes 0 No Name of physician:
MTH_1020	metha.sas7bdat	3. Does the subject have a baseline (pre-diluent) FEV1 less than 55% of predicted? 1 Yes 0 No ***At Visit 2: Use the prebronchodilator FEV1 value from the Spirometry Testing (P11_SPIRO) form as the baseline reference.*** ***At Visits 3, 6, 7, 10: Use the 1-hour post-salmeterol FEV1 value from the Post-Salmeterol Spirometry Testing (P11_PS_SPIRO) form as the baseline reference.***
MTH_1025	metha.sas7bdat	4. Does the subject have a history of urinary retention? 1 Yes 0 No ***If YES, the subject may not proceed with the methacholine challenge testing without written medical clearance from the study physician.*** ***If YES, and the subject is not randomized, the subject is ineligible to participate in the study and a Termination of Study Participation (P11_TERM) form should be completed.***
MTH_1030	metha.sas7bdat	5. Is there any other reason the subject should not proceed with the methacholine challenge testing? 1 Yes 0 No If ***YES,*** explain

ACRN SLiMSIT Variable List

Variable	Dataset	Description
MTH_1040	metha.sas7bdat	6. Is the subject eligible to proceed with the diluent (solution #0) pulmonary function testing for the methacholine challenge? ***If any of the shaded boxes are filled in, the subject is ineligible.*** 1 Yes 0 No ➜ ***If NO, do NOT complete the rest of this form.*** If possible, pulmonary function testing and the methacholine challenge should be rescheduled within the visit window.
MTH_1050	metha.sas7bdat	7. PC20 _ _ _ . _ _ _ _ mg/ml
MTH_1060	metha.sas7bdat	7a. Time PC20 was achieved (*based on 24-hour clock)*
MTH_1070	metha.sas7bdat	8. Subject's FEV1 after standard reversal from methacholine challenge ***If subject is continuing with sputum induction, standard reversal = 4 puffs albuterol.*** ***If subject is not continuing with sputum induction, standard reversal = 2 puffs albuterol.*** 8a. FEV1 _. _ _ L
MTH_1080	metha.sas7bdat	8b. FEV1 (% predicted)
MTH_1090	metha.sas7bdat	8c. Time of FEV1 in Question #8a (*based on 24-hour clock*)
MTH_1100	metha.sas7bdat	8d. Was the FEV1 from Question #8a ≥ the methacholine reversal 8d. Was the FEV1 from Question #8a ≥ the methacholine reversal 1 Yes 0 No ➜ ***If YES, STOP HERE and continue with remaining visit procedures.***
MTH_1110	metha.sas7bdat	9. Was additional treatment used in the first hour? 1 Yes 0 No ➜ ***If NO, skip to Question #11.*** ➜ ***If YES, please complete the Concomitant Medications for Asthma and Allergies (P11_CMED_AS) form.***
MTH_1120	metha.sas7bdat	9a. Additional albuterol by MDI 1 Yes 0 No ➜ ***If NO, skip to Question #9b.***

ACRN SLiMSIT Variable List

Variable	Dataset	Description
MTH_1130	metha.sas7bdat	9ai. Number of additional puffs of albuterol administered 1 two 2 four 3 > four
MTH_1140	metha.sas7bdat	9b. Nebulized Beta-agonist 1 Yes 0 No
MTH_1150	metha.sas7bdat	9c. Subcutaneous epinephrine 1 Yes 0 No
MTH_1160	metha.sas7bdat	9d. Implementation of clinic emergency protocol or algorithm 1 Yes 0 No
MTH_1170	metha.sas7bdat	9e. Other 1 Yes 0 No
MTH_1180	metha.sas7bdat	10. Subject's FEV1 after additional treatment within first hour. 10a. FEV1 _. _ _L
MTH_1190	metha.sas7bdat	10b. FEV1 (% predicted)
MTH_1200	metha.sas7bdat	10c. Time of FEV1 in Question #10a (*based on 24-hour clock*)
MTH_1210	metha.sas7bdat	10d. Was the FEV1 from Question #10a ⩾ the methacholine reversal reference value in the gray box on page 2 of this form? 1 Yes 0 No ➜ ***If YES, STOP HERE and continue with remaining visit procedures.***
MTH_1220	metha.sas7bdat	11. Was additional treatment used after one hour? 1 Yes 0 No ➜ ***If NO, skip to Question #12.*** ➜ ***If YES, please complete the appropriate Concomitant Medications for Asthma and Allergies (P11_CMED_AS) form.***
MTH_1230	metha.sas7bdat	11a. Additional albuterol by MDI 1 Yes 0 No ➜ ***If NO, skip to Question #11b.***

ACRN SLiMSIT Variable List

Variable	Dataset	Description
MTH_1240	metha.sas7bdat	11ai. Number of additional puffs of albuterol administered 1 two 2 four 3 > four
MTH_1250	metha.sas7bdat	11b. Nebulized Beta-agonist 1 Yes 0 No
MTH_1260	metha.sas7bdat	11c. Subcutaneous epinephrine 1 Yes 0 No
MTH_1270	metha.sas7bdat	11d. Implementation of clinic emergency protocol or algorithm 1 Yes 0 No
MTH_1280	metha.sas7bdat	11e. Treatment in the emergency room 1 Yes 0 No
MTH_1290	metha.sas7bdat	11f. Overnight hospitalization 1 Yes 0 No ➜ ***If YES, please complete the Serious Adverse Event Reporting (P11_SERIOUS) form.***
MTH_1300	metha.sas7bdat	11g. Other 1 Yes 0 No
MTH_1310	metha.sas7bdat	12. Subject's final FEV1 after methacholine challenge. 12a. FEV1 _ . _ _ L
MTH_1320	metha.sas7bdat	12b. FEV1(% predicted)
MTH_1330	metha.sas7bdat	12c. Time of FEV1 from Question #12a (*based on 24-hour clock*)
MTH_1340	metha.sas7bdat	12d. Was the FEV1 from Question #12a ≥ the methacholine reversal reference value in the gray box on page 2 of this form? 1 Yes 0 No ➜ ***If NO, complete the source documentation box below.***
SUBJID	metha.sas7bdat	SUBJECT ID
VDATE	metha.sas7bdat	VISIT DATE

ACRN SLiMSIT Variable List

Variable	Dataset	Description
VNUM	metha.sas7bdat	VISIT NUMBER
NO_1000	no.sas7bdat	ANORA number:
NO_1010	no.sas7bdat	**Balloon Id**
NO_1020	no.sas7bdat	**Time Collected** *(based on 24-hour clock)*
NO_1030	no.sas7bdat	**Time Read** *(based on 24-hour clock)*
NO_1040	no.sas7bdat	**Measurement (ppb)**
NO_1050	no.sas7bdat	**Balloon Id**
NO_1060	no.sas7bdat	**Time Collected** *(based on 24-hour clock)*
NO_1070	no.sas7bdat	**Time Read** *(based on 24-hour clock)*
NO_1080	no.sas7bdat	**Measurement (ppb)**
NO_1090	no.sas7bdat	**Balloon Id**
NO_1100	no.sas7bdat	**Time Collected** *(based on 24-hour clock)*
NO_1110	no.sas7bdat	**Time Read** *(based on 24-hour clock)*
NO_1120	no.sas7bdat	**Measurement (ppb)**
NO_1130	no.sas7bdat	Date balloons were read:
SUBJID	no.sas7bdat	SUBJECT ID
VDATE	no.sas7bdat	VISIT DATE
VNUM	no.sas7bdat	VISIT NUMBER
FEF25_75	predict.sas7bdat	FEF25_75
FEV_1	predict.sas7bdat	FEV_1
FVC	predict.sas7bdat	FVC
PEFR	predict.sas7bdat	PEFR
SUBJID	predict.sas7bdat	SUBJECT ID
PSS_1000	ps_spiro.sas7bdat	1. Time salmeterol administered *(based on 24-hour clock*
PSS_1010	ps_spiro.sas7bdat	2. Time post-salmeterol spirometry started *(based on 24-hour clock)*
PSS_1020	ps_spiro.sas7bdat	3. Results of best effort post-salmeterol: 3a. FVC _ . _ _ L
PSS_1030	ps_spiro.sas7bdat	3b. FEV1 _ . _ _ L
PSS_1040	ps_spiro.sas7bdat	3c. FEV1 (% predicted)

ACRN SLiMSIT Variable List

Variable	Dataset	Description
PSS_1050	ps_spiro.sas7bdat	3d. PEFR _ _ . _ _ L/S
PSS_1060	ps_spiro.sas7bdat	3e. FEF25-75 _ _ . _ _ L/S
SUBJID	ps_spiro.sas7bdat	SUBJECT ID
VDATE	ps_spiro.sas7bdat	VISIT DATE
VNUM	ps_spiro.sas7bdat	VISIT NUMBER
SER_1000	serious.sas7bdat	1. Date of Adverse Event
SER_1010	serious.sas7bdat	2. Description of Adverse Event (ICD9 Code) Describe:
SER_1020	serious.sas7bdat	3. Time interval between taking the study drug (last dose before symptoms) and subsequent onset of symptoms.
SER_1030	serious.sas7bdat	4. Unit of time for above interval 1 second(s) 2 minute(s) 3 hour(s) 4 day(s)
SER_1040	serious.sas7bdat	5. Why was the event serious? 5a. Fatal Event? 1 Yes 0 No
SER_1050	serious.sas7bdat	5b. Life-threatening event? 1 Yes 0 No
SER_1060	serious.sas7bdat	5c. Inpatient hospitalization required? 1 Yes 0 No ➜ ***If NO, skip to Question #5d.***
SER_1070	serious.sas7bdat	5c1. Admission date
SER_1080	serious.sas7bdat	5c2. Discharge date
SER_1090	serious.sas7bdat	5d. Hospitalization prolonged? 1 Yes 0 No
SER_1100	serious.sas7bdat	5e. Disabling or incapacitating? 1 Yes 0 No

ACRN SLiMSIT Variable List

Variable	Dataset	Description
SER_1110	serious.sas7bdat	5f. Overdose? 1 Yes 0 No
SER_1120	serious.sas7bdat	5g. Cancer? 1 Yes 0 No
SER_1130	serious.sas7bdat	5h. Congenital anomaly? 1 Yes 0 No
SER_1140	serious.sas7bdat	5i. Serious laboratory abnormality with clinical symptoms? 1 Yes 0 No
SER_1150	serious.sas7bdat	5j. Other 1 Yes 0 No
SER_1160	serious.sas7bdat	6. What, in your opinion, caused the event? 6a. Toxicity of study drug(s)? 1 Yes 0 No
SER_1170	serious.sas7bdat	6b. Withdrawal of study drug(s)? 1 Yes 0 No
SER_1180	serious.sas7bdat	6c. Concurrent medication? 1 Yes 0 No If ***YES***, describe
SER_1190	serious.sas7bdat	6d. Concurrent disorder? 1 Yes 0 No If ***YES***, describe
SER_1200	serious.sas7bdat	6e. Other event? 1 Yes 0 No If ***YES***, describe
SUBJID	serious.sas7bdat	SUBJECT ID

ACRN SLiMSIT Variable List

Variable	Dataset	Description
VDATE	serious.sas7bdat	VISIT DATE
VNUM	serious.sas7bdat	VISIT NUMBER
SKN_1000	skin.sas7bdat	A. Has the subject had a previous skin test using ACRN procedures within three years of the visit date? 1 Yes 0 No
SKN_1010	skin.sas7bdat	If ***YES***, Date of previous skin test
SKN_1030	skin.sas7bdat	B. Skin test site 1 back 2 forearm
SKN_1040	skin.sas7bdat	Method 1 prick 2 puncture
SKN_1050	skin.sas7bdat	Time test sites pricked/punctured (based on 24-hour clock)
SKN_1060	skin.sas7bdat	Time test sites evaluated (based on 24-hour clock)
SKN_1070	skin.sas7bdat	1. Diluting Fluid Was there a reaction? 0 No 1 Yes
SKN_1080	skin.sas7bdat	Largest Wheal Diameter _ _ _ mm
SKN_1090	skin.sas7bdat	Perpendicular Wheal Diameter _ _ _ mm
SKN_1100	skin.sas7bdat	2. Tree Mix Was there a reaction? 0 No 1 Yes
SKN_1110	skin.sas7bdat	Largest Wheal Diameter _ _ _ mm
SKN_1120	skin.sas7bdat	Perpendicular Wheal Diameter _ _ _ mm
SKN_1130	skin.sas7bdat	3. Grass Mix Was there a reaction? 0 No 1 Yes

ACRN SLiMSIT Variable List

Variable	Dataset	Description
SKN_1140	skin.sas7bdat	Largest Wheal Diameter _ _ _ mm
SKN_1150	skin.sas7bdat	Perpendicular Wheal Diameter _ _ _ mm
SKN_1160	skin.sas7bdat	4. Ragweed Was there a reaction? 0 No 1 Yes
SKN_1170	skin.sas7bdat	Largest Wheal Diameter _ _ _ mm
SKN_1180	skin.sas7bdat	Perpendicular Wheal Diameter _ _ _ mm
SKN_1190	skin.sas7bdat	5. Weed Mix Was there a reaction? 0 No 1 Yes
SKN_1200	skin.sas7bdat	Largest Wheal Diameter _ _ _ mm
SKN_1210	skin.sas7bdat	Perpendicular Wheal Diameter _ _ _ mm
SKN_1220	skin.sas7bdat	6. Dogs Was there a reaction? 0 No 1 Yes
SKN_1230	skin.sas7bdat	Largest Wheal Diameter _ _ _ mm
SKN_1240	skin.sas7bdat	Perpendicular Wheal Diameter _ _ _ mm
SKN_1250	skin.sas7bdat	7. Cats Was there a reaction? 0 No 1 Yes
SKN_1260	skin.sas7bdat	Largest Wheal Diameter _ _ _ mm

ACRN SLiMSIT Variable List

Variable	Dataset	Description
SKN_1270	skin.sas7bdat	Perpendicular Wheal Diameter _ _ _ mm
SKN_1280	skin.sas7bdat	8. Alternaria Was there a reaction? 0 No 1 Yes
SKN_1290	skin.sas7bdat	Largest Wheal Diameter _ _ _ mm
SKN_1300	skin.sas7bdat	Perpendicular Wheal Diameter _ _ _ mm
SKN_1310	skin.sas7bdat	9. Cladosporium Was there a reaction? 0 No 1 Yes
SKN_1320	skin.sas7bdat	Largest Wheal Diameter _ _ _ mm
SKN_1330	skin.sas7bdat	Perpendicular Wheal Diameter _ _ _ mm
SKN_1340	skin.sas7bdat	10. Aspergillus Was there a reaction? 0 No 1 Yes
SKN_1350	skin.sas7bdat	Largest Wheal Diameter _ _ _ mm
SKN_1360	skin.sas7bdat	Perpendicular Wheal Diameter _ _ _ mm
SKN_1370	skin.sas7bdat	11. D. Farinae
SKN_1380	skin.sas7bdat	Largest Wheal Diameter _ _ _ mm
SKN_1390	skin.sas7bdat	Perpendicular Wheal Diameter _ _ _ mm
SKN_1400	skin.sas7bdat	12. D. Pteryn Was there a reaction? 0 No 1 Yes

ACRN SLiMSIT Variable List

Variable	Dataset	Description
SKN_1410	skin.sas7bdat	Largest Wheal Diameter _ _ _ mm
SKN_1420	skin.sas7bdat	Perpendicular Wheal Diameter _ _ _ mm
SKN_1430	skin.sas7bdat	13. Cockroach Was there a reaction? 0 No 1 Yes
SKN_1440	skin.sas7bdat	Largest Wheal Diameter _ _ _ mm
SKN_1450	skin.sas7bdat	Perpendicular Wheal Diameter _ _ _ mm
SKN_1460	skin.sas7bdat	14. Histamine Was there a reaction? 0 No 1 Yes
SKN_1470	skin.sas7bdat	Largest Wheal Diameter _ _ _ mm
SKN_1480	skin.sas7bdat	Perpendicular Wheal Diameter _ _ _ mm
SUBJID	skin.sas7bdat	SUBJECT ID
VDATE	skin.sas7bdat	VISIT DATE
VNUM	skin.sas7bdat	VISIT NUMBER
SPR_1010	spiro.sas7bdat	2. Time spirometry started *(based on 24-hour clock)*
SPR_1020	spiro.sas7bdat	3. Results of best effort: 3a. FVC _. _ _ L
SPR_1030	spiro.sas7bdat	3b. FEV1 _. _ _ L
SPR_1040	spiro.sas7bdat	3c. FEV1 (% predicted)
SPR_1050	spiro.sas7bdat	3d. PEFR _ _ . _ _ L/S
SPR_1060	spiro.sas7bdat	3e. FEF25-75 _ _ . _ _ L/S
SUBJID	spiro.sas7bdat	SUBJECT ID

ACRN SLiMSIT Variable List

Variable	Dataset	Description
VDATE	spiro.sas7bdat	VISIT DATE
VNUM	spiro.sas7bdat	VISIT NUMBER
SCK_1000	spirochk.sas7bdat	1. Have you consumed caffeine in the past 6 hours? ***Examples**: Caffeinated colas (Pepsi, Coke), Coffee, Mello-Yello, Mountain Dew, Tea, Barq's Rootbeer,* *Red Bull* 1 Yes 0 No
SCK_1010	spirochk.sas7bdat	2. Have you used medications with caffeine in the past 6 hours? ***Examples**: Anacin, Darvon compound, Esgic, Excedrin,* *Fiorinal, Fioricet, No Doz, Norgesic, Vivarin* 1 Yes 0 No
SCK_1020	spirochk.sas7bdat	3. Have you consumed any food containing alcohol or beverages containing alcohol in the past 6 hours? 1 Yes 0 No
SCK_1030	spirochk.sas7bdat	4a. Have you used any antihistamines [e.g., Allegra or Chlor-Trimeton] in the past 48 hours? 1 Yes 0 No
SCK_1040	spirochk.sas7bdat	***(***4b. Have you used any oral decongestants or cold remedies [e.g., pseudoephedrine (Sudafed) or oxymetazoline (Afrin)] in the past 48 hours? 1 Yes 0 No
SCK_1050	spirochk.sas7bdat	4c. Have you used any nasal steroids in the past 48 hours? 1 Yes 0 No
SCK_1060	spirochk.sas7bdat	4d. Have you used a rescue intermediate-acting inhaled beta-agonist [e.g., albuterol (Ventolin or Proventil)] in the past 6 hours? 1 Yes 0 No
SCK_1070	spirochk.sas7bdat	***If Visit 1, 2, 3, 6A - 6F or 7, do not complete Question #4e)*** Have you used your Serevent® Diskus® in the past 12 hours? 1 Yes 0 No

ACRN SLiMSIT Variable List

Variable	Dataset	Description
SCK_1080	spirochk.sas7bdat	4f. Have you taken any other medications (see the EXCLDRUG reference card) to treat your asthma or allergies in the past 6 weeks? 1 Yes 0 No ➜ ***If YES, complete the Concomitant Medications for Asthma and Allergies (P11_CMED_AS) form.***
SCK_1090	spirochk.sas7bdat	5. At this time, is your asthma worse because of recent exposure to triggers (e.g., cold air, smoke, allergens, or recent exercise)? 1 Yes 0 No
SCK_1100	spirochk.sas7bdat	Have you had a respiratory tract infection or any other pulmonary infection since the last visit? 1 Yes 0 No
SCK_1110	spirochk.sas7bdat	7. Is there any other reason you should not proceed with the pulmonary function testing? 1 Yes 0 No If ***YES***, explain
SCK_1120	spirochk.sas7bdat	8. Does the subject have evidence of oral candidiasis? 1 Yes 0 No ➜ ***If YES, complete the Clinical Adverse Events (P11_AECLIN) form and contact study investigator.***
SCK_1130	spirochk.sas7bdat	9. Is the subject eligible to proceed with the pulmonary function testing? 1 Yes 0 No ***If any of the shaded boxes are filled in, the subject is ineligible.*** ***Exception: An ineligible subject may proceed with pulmonary function testing if this is an FEV1 re-assessment visit for evaluation of treatment failure (i.e., this is the continuation of a regular visit) AND physician approval has been obtained.*** ***Exception: An ineligible subject may proceed with pulmonary function testing if he or she is already known to be a treatment failure at this visit.***
SUBJID	spirochk.sas7bdat	SUBJECT ID
VDATE	spirochk.sas7bdat	VISIT DATE
VNUM	spirochk.sas7bdat	VISIT NUMBER
SLB_1000	sputlab.sas7bdat	1.Total Cell Count _ _ . _ _ x 10 5/ml

ACRN SLiMSIT Variable List

Variable	Dataset	Description
SLB_1010	sputlab.sas7bdat	2. Squamous Cells _ _ _ . _ %
SLB_1020	sputlab.sas7bdat	3. Did the subject's sputum sample reveal ⩾ 80% squamous cells? 1 Yes 0 No ➜ ***If NO, please complete Question #4 through Question #9 and send the sputum sample for overreading***. ➜ ***If YES, STOP HERE and do not send the sputum sample for overreading***.
SLB_1030	sputlab.sas7bdat	4. Total Cell Count _ _ . _ _ x 10 5/ml
SLB_1040	sputlab.sas7bdat	5. Epithelial Cells _ _ _ . _ %
SLB_1050	sputlab.sas7bdat	6. Macrophages _ _ _ . _ %
SLB_1060	sputlab.sas7bdat	7. Neutrophils _ _ _ . _ %
SLB_1070	sputlab.sas7bdat	8. Eosinophils _ _ _ . _ %
SLB_1080	sputlab.sas7bdat	9. Lymphocytes _ _ _ . _ %
SUBJID	sputlab.sas7bdat	SUBJECT ID
VDATE	sputlab.sas7bdat	VISIT DATE
VNUM	sputlab.sas7bdat	VISIT NUMBER
SOV_1000	sputover.sas7bdat	1. Date of Over-Read
SOV_1010	sputover.sas7bdat	2. Is the slide quality acceptable? 1 Yes 0 No ➜ If ***NO***, please comment below.
SOV_1020	sputover.sas7bdat	3. Squamous Cells _ _ _ . _ %
SOV_1030	sputover.sas7bdat	4. Epithelial Cells _ _ _ . _ %
SOV_1040	sputover.sas7bdat	5. Macrophages _ _ _ . _ %
SOV_1050	sputover.sas7bdat	6. Neutrophils _ _ _ . _ %

ACRN SLiMSIT Variable List

Variable	Dataset	Description
SOV_1060	sputover.sas7bdat	7. Eosinophils _ _ _ . _ %
SOV_1070	sputover.sas7bdat	8. Lymphocytes _ _ _ . _ %
SUBJID	sputover.sas7bdat	SUBJECT ID
VDATE	sputover.sas7bdat	VISIT DATE
VNUM	sputover.sas7bdat	VISIT NUMBER
SPT_1000	sputum.sas7bdat	1. ***(If Visit 3, do not complete Question #1)*** At Visit 3, was the subject able to continue sputum induction for more than 4 minutes and able to produce a satisfactory induced sputum sample (☐☐ 30% squamous cells)? 1 Yes 0 No
SPT_1010	sputum.sas7bdat	2. Did the subject complete the methacholine challenge? 1 Yes 0 No ➜ ***If YES, complete Question #3.*** ➜ ***If NO, skip to Question #4.***
SPT_1020	sputum.sas7bdat	***(For subjects who completed the methacholine challenge)*** 3a. Subject's FEV1 after reversal from methacholine challenge _ _ . _ L
SPT_1030	sputum.sas7bdat	3b. Subject's FEV1 (% predicted) after reversal from methacholine challenge
SPT_1040	sputum.sas7bdat	3c. Was the subject's FEV1 from Question #3a ≥ the methacholine reversal reference value on page 2 of the Methacholine Challenge Testing (P11_METHA) form? 1 Yes 0 No ➜ ***Skip to Question #5.***
SPT_1050	sputum.sas7bdat	***(For subjects who did NOT complete the methacholine challenge)*** 4a. Subject's FEV1 15 minutes after 4 puffs of albuterol _ . _ _ L
SPT_1060	sputum.sas7bdat	4b. Subject's FEV1 15 minutes after 4 puffs of albuterol (% predicted)
SPT_1070	sputum.sas7bdat	5. Was the subject's FEV1 (% predicted) from Question #3b or Question #4b ≥60% predicted? 1 Yes 0 No

ACRN SLiMSIT Variable List

Variable	Dataset	Description
SPT_1080	sputum.sas7bdat	6. Is there any other reason the subject should not proceed with sputum induction? 1 Yes 0 No If ***YES***, explain
SPT_1090	sputum.sas7bdat	7. Is the subject eligible for sputum induction? 1 Yes 0 No ***If any of the shaded boxes are filled in, the subject is ineligible.*** ➜ ***If NO, do NOT complete the rest of this form.***
SPT_1100	sputum.sas7bdat	***(If Visit 3, do not complete Question #8)*** What was the duration of sputum induction the first time it exceeded 4 minutes, not including the current visit? ***(Duration of sputum induction at the current visit should not exceed this value.) _ _ . _ minutes***
SPT_1110	sputum.sas7bdat	9. Subject's FEV1 immediately after completion of sputum induction 9a. FEV1 _ . _ _ L
SPT_1120	sputum.sas7bdat	9b. FEV1 (% predicted)
SPT_1130	sputum.sas7bdat	9c. Time of FEV1 in Question #9a (*based on 24-hour clock*)
SPT_1140	sputum.sas7bdat	9d. Percent difference in FEV1 *(Question #3a or #4a - Question #9a)/ Question #3a or #4a* x 100
SPT_1150	sputum.sas7bdat	10. Duration of sputum induction at this visit _ _ . _ minutes
SPT_1160	sputum.sas7bdat	11. Volume of sputum sample at this visit _ _ . _ ml
SPT_1170	sputum.sas7bdat	12. Did the subject tolerate sputum induction for 4 minutes at this visit? 1 Yes 0 No
SPT_1180	sputum.sas7bdat	13. Is the sample adequate for analysis of squamous cells? 1 Yes 0 No ***If the shaded box in Question #12 is filled in, the sputum sample is inadequate and should not be sent for analysis of squamous cell counts.***

ACRN SLiMSIT Variable List

Variable	Dataset	Description
SPT_1190	sputum.sas7bdat	14. Did the subject's FEV1 immediately after completion of sputum induction drop > 20% (from post-albuterol baseline) as indicated in Question #9d? 1 Yes 0 No ➜ ***If YES, proceed with Question #15 on the next page.*** ➜ ***If NO, STOP HERE and continue with remaining visit procedures.***
SPT_1200	sputum.sas7bdat	Subject's FEV1 after initial 2 puffs of albuterol following sputum induction 15a. FEV1 _ . _ _ L
SPT_1210	sputum.sas7bdat	15b. FEV1 (% predicted)
SPT_1220	sputum.sas7bdat	15c. Time of FEV1 from Question #15a (*based on 24-hour clock*)
SPT_1230	sputum.sas7bdat	15d. Was the FEV1 from Question #15a ≥ the sputum induction reversal 1 Yes 0 No ➜ ***If YES, stop here and continue with remaining visit procedures.*** ➜ ***If NO, proceed with additional procedures as instructed in the MOP and complete Question #16.***
SPT_1240	sputum.sas7bdat	16. Subject's final FEV1 after sputum induction 16a. FEV1 _ . _ _ L
SPT_1250	sputum.sas7bdat	16b. FEV1 (% predicted)
SPT_1260	sputum.sas7bdat	16c. Time of FEV1 from Question #16a (*based on 24-hour clock*)
SPT_1270	sputum.sas7bdat	16d. Was the FEV1 from Question #16a ⩾ the sputum induction reversal reference value in the gray box on page 3 of this form? 1 Yes 0 No ➜ ***If NO, complete the source documentation box below.***
SUBJID	sputum.sas7bdat	SUBJECT ID
VDATE	sputum.sas7bdat	VISIT DATE
VNUM	sputum.sas7bdat	VISIT NUMBER
SUBJID	subblind.sas7bdat	SUBJECT ID
SUB_1000	subblind.sas7bdat	1 I am certain the inhaler contained placebo.
SUB_1010	subblind.sas7bdat	3 I have no idea which type of tablets I received, but my best guess would be: 1 Placebo

ACRN SLiMSIT Variable List

Variable	Dataset	Description
SUB_1020	subblind.sas7bdat	As a SLiMSIT study participant you were randomized to receive either active (i.e. real) tablets or look-alike placebo (i.e. inactive) tablets. Please check the box that most closely represents your feelings about the **tablets** you took **over the past 14 weeks.** 1 I am certain the tablets contained placebo.
SUB_1030	subblind.sas7bdat	1 Placebo
SUB_1060	subblind.sas7bdat	3. Please comment with respect to the taste of the medication you received from your **scheduled inhaler over the past 14 weeks.** 1 Tasted good (*Describe*)
SUB_1070	subblind.sas7bdat	4. Please comment with respect to the smell of the medication you received from your **scheduled inhaler over the past 14 weeks.** 1 Smelled good (*Describe*)
SUB_1080	subblind.sas7bdat	5. Please comment with respect to any physical sensations produced by the medication you you received from your **scheduled inhaler over the past 14 weeks.** 1 Pleasant sensations (*Describe*)
SUB_1090	subblind.sas7bdat	6. Please comment with respect to any other observations you may have made regarding your **scheduled inhaler**. 1 I have no further comments
SUB_1100	subblind.sas7bdat	7. Please comment with respect to the taste of the tablets you received **over the past 14 weeks.** 1 Tasted good
SUB_1110	subblind.sas7bdat	8. Please comment with respect to the smell of the **tablets** you received **over the past 14 weeks.** 1 Smelled good (*Describe*)
SUB_1120	subblind.sas7bdat	9. Please comment with respect to any physical sensations produced by the **tablets** you received **over the past 14 weeks.** 1 Pleasant sensations (*Describe*)
SUB_1130	subblind.sas7bdat	10. Please comment with respect to any other observations you may have made regarding the **tablets** you received. 1 I have no further comments
VDATE	subblind.sas7bdat	VISIT DATE
VNUM	subblind.sas7bdat	VISIT NUMBER
SUBJID	term.sas7bdat	SUBJECT ID
TRM_1000	term.sas7bdat	1. ***(Visit 10 Only)*** Pregnancy test results *(Check N/A if the subject is male or unable to bear children.)* 1 Positive 2 Negative 9 N/A

ACRN SLiMSIT Variable List

Variable	Dataset	Description
TRM_1030	term.sas7bdat	2. ***(Visit 10 Only)*** Has the subject completed the study? 1 Yes 0 No ➜ ***If YES, skip to the SIGNATURES section on page 2.***
TRM_1040	term.sas7bdat	3. Is the subject withdrawing from the study due to pregnancy? 1 Yes 0 No 9 N/A *(Check N/A if the subject is male.)*
TRM_1050	term.sas7bdat	4. ***(Visit 1 - Visit 3)*** During the initial run-in period, has the subject been deemed a treatment failure as defined in the protocol? 1 Yes 0 No If ***YES***, indicate criteria that were met below.
TRM_1060	term.sas7bdat	5. ***(Visit 1 - Visit 3)*** Has the subject been deemed ineligible according to any eligibility criteria **other than** treatment failure? 1 Yes 0 No If ***YES***, indicate criteria that were met below.
TRM_1070	term.sas7bdat	6. Has the subject withdrawn consent? 1 Yes 0 No
TRM_1080	term.sas7bdat	If ***YES***, indicate the **primary** reason. 1 no longer interested in participating 2 no longer willing to follow protocol 3 access to clinic is difficult (location, transportation, parking) 4 unable to make visits during clinic hours 5 moving out of the area 6 unable to continue in study due to personal constraints 7 dissatisfied with asthma control 8 unable to continue due to medical condition unrelated to asthma 9 side effects of study medications 10 treatment failure 11 other
TRM_1090	term.sas7bdat	7. Has the subject been lost to follow-up? 1 Yes 0 No

ACRN SLiMSIT Variable List

Variable	Dataset	Description
TRM_1100	term.sas7bdat	8. Has the subject experienced a serious adverse event (e.g., an adverse event resulting in death or hospitalization, etc.)? 1 Yes 0 No ➜ ***If YES, complete the Serious Adverse Event Reporting (P11_SERIOUS) form.***
TRM_1110	term.sas7bdat	9. Did a physician initiate subject termination? 1 Yes 0 No If ***YES***, explain
VDATE	term.sas7bdat	VISIT DATE
VNUM	term.sas7bdat	VISIT NUMBER
SUBJID	txf_2_3.sas7bdat	SUBJECT ID
TFR_1000	txf_2_3.sas7bdat	1. Did the subject experience a fall in **pre**bronchodilator PEFR to < 65% of baseline on two out of three consecutive scheduled measurements? 1 Yes 0 No ➜ ***Refer to P11_BASELINE form.***
TFR_1010	txf_2_3.sas7bdat	2. Did the subject experience a fall in **post**bronchodilator PEFR (any time of day) to < 80% of baseline despite 60 minutes of rescue beta-agonist treatment (> 6 puffs of albuterol in one hour)? 1 Yes 0 No ➜ ***Refer to P11_BASELINE form.***
TFR_1020	txf_2_3.sas7bdat	2a. If ***YES***, record the **post**bronchodilator PEFR value that qualified the subject as a treatment failure. _ _ _ L/min
TFR_1030	txf_2_3.sas7bdat	3. Did the subject experience an increase in symptoms (e.g., cough, phlegm/mucus, chest tightness, wheezing, or shortness of breath) associated with any of the following conditions? 3a. An increase in rescue inhaler use of > 8 puffs per 24 hours over baseline rescue inhaler use for a period of 48 hours? 1 Yes 0 No ➜ ***Refer to P11_BASELINE form.***
TFR_1040	txf_2_3.sas7bdat	3b. Rescue inhaler use of > 16 puffs per 24 hours for a period of 48 hours? 1 Yes 0 No

ACRN SLiMSIT Variable List

Variable	Dataset	Description
TFR_1050	txf_2_3.sas7bdat	3c. PEFR which did not increase to > 65% of baseline after 60 minutes of rescue beta-agonist use? 1 Yes 0 No ➜ ***Refer to P11_BASELINE form.***
TFR_1060	txf_2_3.sas7bdat	3ci. If ***YES***, record the subject's **post**bronchodilator PEFR value after 60 minutes of RESCUE use. _ _ _ L/ min
TFR_1070	txf_2_3.sas7bdat	3d. Symptoms persisting after 60 minutes of rescue beta-agonist reatment? 1 Yes 0 No ➜ ***If YES (to any question in #3), the subject has experienced a significant asthma exacerbation in addition to treatment failure. Please complete the Clinical Adverse Events (P11_AECLIN) form.***
TFR_1080	txf_2_3.sas7bdat	4. Did the subject experience **pre**bronchodilator FEV1 values < 80% of the prebronchodilator value recorded at Visit 1 on two consecutive spirometric determinations made on different days? 1 Yes 0 No
TFR_1090	txf_2_3.sas7bdat	5. Did the subject require emergency treatment or an urgent care visit (at a medical facility) that was related to his/her asthma and which resulted in corticosteroid treatment or hospitalization for an acute asthma exacerbation? 1 Yes 0 No ➜ ***If YES, please complete the Serious Adverse Event Reporting (P11_SERIOUS) form if hospitalized and the Concomitant Medications for Asthma and Allergies (P11_CMED_AS) form, if applicable.***
TFR_1100	txf_2_3.sas7bdat	6. Did the subject require treatment with oral, parenteral, or non-study-related inhaled corticosteroids for an asthma related condition? 1 Yes 0 No ➜ ***If YES, please complete the Concomitant Medications for Asthma and Allergies (P11_CMED_AS) form.*** ➜ ***If YES, the subject has experienced a significant asthma exacerbation in addition to treatment failure. Please complete the Clinical Adverse Events (P11_AECLIN) form.***

ACRN SLiMSIT Variable List

Variable	Dataset	Description
TFR_1110	txf_2_3.sas7bdat	7. Based on clinical judgement, did the physician deem this subject a treatment failure for safety reasons? 1 Yes 0 No
TFR_1120	txf_2_3.sas7bdat	8. Is the subject a treatment failure? ***If any of the shaded boxes in Questions #1 - 7 are filled in, the subject is a treatment failure.*** 1 Yes 0 No ➜ ***If YES, please complete the rest of this form and the Termination of Study Participation (P11_TERM) form.*** ➜ ***If NO, STOP HERE and continue with remaining visit procedures.***
TFR_1130	txf_2_3.sas7bdat	9. Date treatment failure conditions were met
TFR_1140	txf_2_3.sas7bdat	10. Has the subject taken any of the following medications (excluding study drug) since treatment failure conditions started? 10a. Inhaled corticosteroids 1 Yes 0 No
TFR_1150	txf_2_3.sas7bdat	10b. Oral corticosteroids 1 Yes 0 No
TFR_1160	txf_2_3.sas7bdat	10c. Parenteral corticosteroids 1 Yes 0 No
TFR_1170	txf_2_3.sas7bdat	10d. Theophylline 1 Yes 0 No
TFR_1180	txf_2_3.sas7bdat	10e. Beta-Agonist via nebulizer 1 Yes 0 No
TFR_1190	txf_2_3.sas7bdat	10f. Cromolyn 1 Yes 0 No
TFR_1200	txf_2_3.sas7bdat	10g. Nedocromil 1 Yes 0 No

ACRN SLiMSIT Variable List

Variable	Dataset	Description
TFR_1210	txf_2_3.sas7bdat	10h. Ipratropium bromide 1 Yes 0 No
TFR_1220	txf_2_3.sas7bdat	10i. Leukotriene modifiers 1 Yes 0 No
TFR_1230	txf_2_3.sas7bdat	10j. Other: 1 Yes 0 No ➜ ***If YES (to any question in #10), please complete the Concomitant Medications for Asthma and Allergies (P11_CMED_AS) form.***
TFR_1240	txf_2_3.sas7bdat	11. Did the subject seek care for treatment failure conditions? 1 Yes 0 No ➜ ***If NO, skip to Question #14.***
TFR_1250	txf_2_3.sas7bdat	12. What type of care was sought? 12a. Study Investigator or Clinic Coordinator? 1 Yes 0 No
TFR_1260	txf_2_3.sas7bdat	If ***YES***, indicate type of contact. 1 Scheduled clinic visit 2 Unscheduled clinic visit 3 Phone contact
TFR_1270	txf_2_3.sas7bdat	12b. Primary Care or Other Physician? 1 Yes 0 No
TFR_1280	txf_2_3.sas7bdat	If ***YES***, indicate type of contact. 1 Scheduled clinic visit 2 Unscheduled clinic visit 3 Phone contact
TFR_1290	txf_2_3.sas7bdat	12c. Emergency Room visit? 1 Yes 0 No Name of hospital:

ACRN SLiMSIT Variable List

Variable	Dataset	Description
TFR_1300	txf_2_3.sas7bdat	13. Was the subject hospitalized? 1 Yes 0 No ➜ ***If YES, please complete the Serious Adverse Event Reporting (P11_SERIOUS) form.*** If ***YES***, 13a. Name of hospital:
TFR_1310	txf_2_3.sas7bdat	13b. Duration of hospital stay? _ _ days
TFR_1320	txf_2_3.sas7bdat	13c. Was intubation or ventilation assistance required? 1 Yes 0 No
TFR_1330	txf_2_3.sas7bdat	14. Were the subject's treatment failure conditions treated as outlined in the protocol? 1 Yes 0 No If ***NO***, describe
TFR_1340	txf_2_3.sas7bdat	15. Were treatment failure conditions related to the routine pulmonary function testing? *(Check one box only)* 1 Definitely related 2 Probably related 3 Relationship undetermined 4 Probably not related 5 Definitely not related
TFR_1350	txf_2_3.sas7bdat	16. Were treatment failure conditions related to the methacholine challenge testing? *(Check one box only)* 1 Definitely related 2 Probably related 3 Relationship undetermined 4 Probably not related 5 Definitely not related
TFR_1360	txf_2_3.sas7bdat	17. Physician Narrative Assessment and Follow-Up Plan
VDATE	txf_2_3.sas7bdat	VISIT DATE
VNUM	txf_2_3.sas7bdat	VISIT NUMBER
SUBJID	txf_4_10.sas7bdat	SUBJECT ID
TFT_1000	txf_4_10.sas7bdat	1. ***(Visits 91- 99 Only)*** Complete the number of the last regular visit completed.
TFT_1010	txf_4_10.sas7bdat	Did the subject experience a fall in **pre**bronchodilator PEFR to < 65% of baseline on two out of three consecutive scheduled measurements?

ACRN SLiMSIT Variable List

Variable	Dataset	Description
TFT_1020	txf_4_10.sas7bdat	Did the subject experience a fall in **post**bronchodilator PEFR (any time of day) to < 80% of baseline despite 60 minutes of rescue beta-agonist treatment (> 6 puffs of albuterol in one hour)?
TFT_1030	txf_4_10.sas7bdat	If ***YES***, record the **post**bronchodilator PEFR value that qualified the subject as a treatment failure.
TFT_1040	txf_4_10.sas7bdat	Did the subject experience an increase in symptoms (e.g., cough, phlegm/mucus, chest tightness, wheezing, or shortness of breath) associated with any of the following conditions? An increase in rescue inhaler use of > 8 puffs per 24 hours over baseline rescue inhaler use for a period of 48 hours?
TFT_1050	txf_4_10.sas7bdat	Rescue inhaler use of > 16 puffs per 24 hours for a period of 48 hours?
TFT_1060	txf_4_10.sas7bdat	PEFR which did not increase to > 65% of baseline after 60 minutes of rescue beta-agonist use?
TFT_1070	txf_4_10.sas7bdat	If ***YES***, record the subject's **post**bronchodilator PEFR value after 60 minutes of RESCUE use.
TFT_1080	txf_4_10.sas7bdat	Symptoms persisting after 60 minutes of rescue beta-agonist treatment?
TFT_1090	txf_4_10.sas7bdat	Did the subject experience **pre**bronchodilator FEV1 values < 80% of the prebronchodilator value recorded at Visit 3 on two consecutive spirometric determinations made on different days?
TFT_1100	txf_4_10.sas7bdat	Did the subject experience a **post**-salmeterol FEV1 value < 80% of the post-salmeterol baseline value recorded at Visit 3?
TFT_1110	txf_4_10.sas7bdat	Did the subject require emergency treatment or an urgent care visit (at a medical facility) that was related to his/her asthma and which resulted in corticosteroid treatment or hospitalization for an acute asthma exacerbation?
TFT_1120	txf_4_10.sas7bdat	Did the subject require treatment with oral, parenteral, or non-study-related inhaled corticosteroids for an asthmarelated condition?
TFT_1130	txf_4_10.sas7bdat	Based on clinical judgement, did the physician deem this subject a treatment failure for safety reasons?
TFT_1140	txf_4_10.sas7bdat	Is the subject a treatment failure? ***If any of the shaded boxes in Questions #3 - 10 are filled in, the subject is a treatment failure.***
TFT_1150	txf_4_10.sas7bdat	Date treatment failure conditions were met
TFT_1160	txf_4_10.sas7bdat	Has the subject taken any of the following medications (excluding study drug) since treatment failure conditions started? Inhaled corticosteroids
TFT_1170	txf_4_10.sas7bdat	Oral corticosteroids
TFT_1180	txf_4_10.sas7bdat	Parenteral corticosteroids
TFT_1190	txf_4_10.sas7bdat	Theophylline
TFT_1200	txf_4_10.sas7bdat	Beta-Agonist via nebulizer
TFT_1210	txf_4_10.sas7bdat	Cromolyn

ACRN SLiMSIT Variable List

Variable	Dataset	Description
TFT_1220	txf_4_10.sas7bdat	Nedocromil
TFT_1230	txf_4_10.sas7bdat	Ipratropium bromide
TFT_1240	txf_4_10.sas7bdat	Leukotriene modifiers
TFT_1250	txf_4_10.sas7bdat	Other
TFT_1260	txf_4_10.sas7bdat	Did the subject seek care for treatment failure conditions?
TFT_1270	txf_4_10.sas7bdat	What type of care was sought? Study Investigator or Clinic Coordinator?
TFT_1280	txf_4_10.sas7bdat	If ***YES***, indicate type of contact.
TFT_1290	txf_4_10.sas7bdat	Primary Care or Other Physician?
TFT_1300	txf_4_10.sas7bdat	If ***YES***, indicate type of contact.
TFT_1310	txf_4_10.sas7bdat	Emergency Room visit?
TFT_1320	txf_4_10.sas7bdat	Was the subject hospitalized?
TFT_1330	txf_4_10.sas7bdat	Duration of hospital stay?
TFT_1340	txf_4_10.sas7bdat	Was intubation or ventilation assistance required?
TFT_1350	txf_4_10.sas7bdat	Were the subject's treatment failure conditions treated as outlined in the protocol?
TFT_1360	txf_4_10.sas7bdat	Were treatment failure conditions related to the routine pulmonary function testing?
TFT_1370	txf_4_10.sas7bdat	Were treatment failure conditions related to the methacholine challenge testing?
TFT_1380	txf_4_10.sas7bdat	Were treatment failure conditions related to the sputum induction procedure?
TFT_1390	txf_4_10.sas7bdat	From a clinical perspective, would you have considered this subject to be a "treatment failure" if he/she were not participating in this double-blind trial and, instead, you were seeing him/her in your outpatient clinic?
TFT_1400	txf_4_10.sas7bdat	Based on the subject's clinical status at the time he/she met one of the treatment failure criteria, when do you think the subject reached this status?
TFT_1410	txf_4_10.sas7bdat	What was the subject's opinion of his/her asthma at the time he/she reached treatment failure?
TFT_1420	txf_4_10.sas7bdat	Based on your experience with this subject, are you satisfied with the SLiMSIT treatment failure criteria?
TFT_1430	txf_4_10.sas7bdat	Physician Narrative Assessment and Follow-Up Plan
TFT_1470	txf_4_10.sas7bdat	2. ***(Visits 4 - 10 Only)*** List the dates that contact was made with the subject to assess for treatment failure status since the last regular visit. List them in order from oldest to most recent. 2a. Date of contact:
TFT_1480	txf_4_10.sas7bdat	Type of contact: 1 Successful Phone Contact

ACRN SLiMSIT Variable List

Variable	Dataset	Description
TFT_1490	txf_4_10.sas7bdat	2b. Date of contact:
TFT_1500	txf_4_10.sas7bdat	Type of contact: 1 Successful Phone Contact
TFT_1510	txf_4_10.sas7bdat	2c. Date of contact:
TFT_1520	txf_4_10.sas7bdat	Type of contact: 1 Successful Phone Contact
VDATE	txf_4_10.sas7bdat	VISIT DATE
VNUM	txf_4_10.sas7bdat	VISIT NUMBER
SUBJID	v7sched1.sas7bdat	SUBJECT ID
V71_1000	v7sched1.sas7bdat	1. Did the subject achieve treatment failure status during the first treatment period? 1 Yes 0 No
V71_1010	v7sched1.sas7bdat	1a. If **YES**, record the date of the subject's *latest* treatment failure from the Treatment Failure Assessment (P11_TXFAIL_V4_10)
V71_1020	v7sched1.sas7bdat	1b. If **YES**, did the subject achieve treatment failure status at least two weeks prior to today's date? 1 Yes 0 No
V71_1030	v7sched1.sas7bdat	2. Has the subject taken prednisone during the SLiMSIT trial? 1 Yes 0 No
V71_1040	v7sched1.sas7bdat	2a. If **YES**, record the date of the subject's last dose of prednisone from the appropriate Concomitant Medications (P11_CMED_AS or P11_CMED_NON)
V71_1050	v7sched1.sas7bdat	2b. If **YES**, was the subject's last dose of prednisone taken at least two weeks prior to today's date? 1 Yes 0 No
V71_1060	v7sched1.sas7bdat	3. Has the subject taken open-label inhaled corticosteroids (ICS) (any dose, any brand, for any reason) during the SLiMSIT trial? 1 Yes 0 No
V71_1070	v7sched1.sas7bdat	3a. If **YES**, record the date of the subject's last dose of open-label ICS from the Concomitant Medications for Asthma and Allergies (P11_CMED_AS)

ACRN SLiMSIT Variable List

Variable	Dataset	Description
V71_1080	v7sched1.sas7bdat	3b. If **YES**, was the subject's last dose of open-label ICS taken prior to today's date? 1 Yes 0 No
V71_1090	v7sched1.sas7bdat	3bi. If **NO**, will the subject discontinue use of these medications today? 1 Yes 0 No
V71_1100	v7sched1.sas7bdat	4. Is the subject prepared to schedule Visit 7 at this time? ***If any of the shaded boxes are filled in, the subject is NOT prepared to schedule Visit 7.*** 1 Yes 0 No
VDATE	v7sched1.sas7bdat	VISIT DATE
VNUM	v7sched1.sas7bdat	VISIT NUMBER
SUBJID	v7sched2.sas7bdat	SUBJECT ID
V72_1000	v7sched2.sas7bdat	1. Has the subject achieved treatment failure status during the SLiMSIT trial? 1 Yes 0 No
V72_1010	v7sched2.sas7bdat	1a. If **YES**, record the date of the subject's *latest* treatment failure from the Treatment Failure Assessment (P11_TXFAIL_V4_10)
V72_1020	v7sched2.sas7bdat	1b. If **YES**, did the subject achieve treatment failure status at least four weeks prior to today's date? 1 Yes 0 No
V72_1030	v7sched2.sas7bdat	2. Has the subject taken prednisone during the SLiMSIT trial? 1 Yes 0 No
V72_1040	v7sched2.sas7bdat	2a. If **YES**, record the date of the subject's last dose of prednisone from the appropriate Concomitant Medications (P11_CMED_AS or P11_CMED_NON)
V72_1050	v7sched2.sas7bdat	2b. If **YES**, was the subject's last dose of prednisone taken at least four weeks prior to today's date? 1 Yes 0 No
V72_1060	v7sched2.sas7bdat	3. Has the subject taken open-label inhaled corticosteroids (ICS) (any dose, any brand, for any reason) during the SLiMSIT trial? 1 Yes 0 No

ACRN SLiMSIT Variable List

Variable	Dataset	Description
V72_1070	v7sched2.sas7bdat	3a. If **YES**, record the date of the subject's last dose of open-label ICS from the Concomitant Medications for Asthma and Allergies (P11_CMED_AS)
V72_1080	v7sched2.sas7bdat	3b. If **YES**, was the subject's last dose of open-label ICS taken at least two weeks prior to today's date? 1 Yes 0 No
V72_1090	v7sched2.sas7bdat	4. Has a study investigator assessed the subject at this visit? 1 Yes 0 No
V72_1100	v7sched2.sas7bdat	4a. If **YES**, does the study investigator allow the subject to schedule Visit 7 at this time? 1 Yes 0 No
V72_1110	v7sched2.sas7bdat	5. Is the subject prepared to schedule Visit 7 at this time? ***If any of the shaded boxes are filled in, the subject is NOT prepared to schedule Visit 7.*** 1 Yes 0 No ➜ ***If YES, schedule the subject for Visit 7 to occur two weeks from today.*** ➜ ***If NO, schedule the subject for another intermediate visit (e.g., 6b, 6c, etc.) to occur two weeks from today.***
VDATE	v7sched2.sas7bdat	VISIT DATE
VNUM	v7sched2.sas7bdat	VISIT NUMBER
SUBJID	v7sched3.sas7bdat	SUBJECT ID
V73_1000	v7sched3.sas7bdat	1. Has the subject achieved treatment failure status during the SLiMSIT trial? 1 Yes 0 No
V73_1010	v7sched3.sas7bdat	1a. If **YES**, record the date of the subject's *latest* treatment failure from the Treatment Failure Assessment (P11_TXFAIL_V4_10)
V73_1020	v7sched3.sas7bdat	1b. If **YES**, did the subject achieve treatment failure status at least six weeks prior to today's date? 1 Yes 0 No
V73_1030	v7sched3.sas7bdat	2. Has the subject taken prednisone during the SLiMSIT trial? 1 Yes 0 No

ACRN SLiMSIT Variable List

Variable	Dataset	Description
V73_1040	v7sched3.sas7bdat	2a. If **YES**, record the date of the subject's last dose of prednisone from the appropriate Concomitant Medications (P11_CMED_AS or P11_CMED_NON)
V73_1050	v7sched3.sas7bdat	2b. If **YES**, was the subject's last dose of prednisone taken at least six weeks prior to today's date? 1 Yes 0 No
V73_1060	v7sched3.sas7bdat	3. Has the subject taken open-label inhaled corticosteroids (ICS) (any dose, any brand, for any reason) during the SLiMSIT trial? 1 Yes 0 No
V73_1070	v7sched3.sas7bdat	3a. If **YES**, record the date of the subject's last dose of open-label ICS from the Concomitant Medications for Asthma and Allergies (P11_CMED_AS)
V73_1080	v7sched3.sas7bdat	3b. If **YES**, was the subject's last dose of open-label ICS taken at least four weeks prior to today's date? 1 Yes 0 No
V73_1090	v7sched3.sas7bdat	4. Is the subject prepared to complete Visit 7 at this time? ***If any of the shaded boxes are filled in, the subject is NOT prepared to complete Visit 7.*** 1 Yes 0 No ➜ ***If YES, complete Visit 7 today.*** ➜ ***If NO, complete an intermediate visit (e.g., 6a, 6b, 6c) today.***
VDATE	v7sched3.sas7bdat	VISIT DATE
VNUM	v7sched3.sas7bdat	VISIT NUMBER