

AsthmaNet SIENA Data Documentation for BioLINCC

SIENA Study Forms, Data sets and Variables

The file SIENA_forms.pdf on the enclosed CD includes the annotated SIENA Case Report Forms (CRFs). Each CRF has an abbreviated name located in a shaded box in the lower right-hand corner of the form. Abbreviated CRF names beginning with a 'P6_' prefix are specific to the SIENA protocol; data associated with these SIENA-specific forms are stored in a corresponding data file of the same name with the 'P6_' prefix removed. A listing of each CRF and data set name is included in Table 1.

Variable names for a particular CRF begin with a prefix assigned to that form followed by an underscore and the number of the field; prefixes for each form can be found in Table 1. Fields within each CRF are usually numbered sequentially and are located (in most cases) in parentheses on the left hand side of the responses to each question.

For example, data regarding adverse events experienced by the SIENA subjects are collected on the Clinical Adverse Events form (form name AECLIN). Corresponding data are stored in file aeclin.sas7bdat. The variable name corresponding to the ICD9 code for a particular adverse event (field #1010) on the Clinical Adverse Events form is aec_1010.

Where no form name is given in Table 1, no CRF existed for collection of the relevant information during study implementation.

Table 2 below shows the CRFs that were completed at each study visit, either routinely or only on an as-needed basis.

Standard Data Edits

Each SIENA CRF includes a set of key variables in the upper right-hand corner. These variables may include: Participant ID (part_id), participant initials, visit number (vnum), visit/current date (vdate), and interviewer/technician/supervisor/coordinator ID. For the purpose of de-identifying the dataset, the following standard changes were applied to the key variables for all public use datasets:

- Participant initials were omitted.
- All visit dates were converted to intervals representing the number of days from the participant's Visit 1 (initial screen visit).
- All interviewer/technician/supervisor/coordinator IDs were omitted.

In addition, the following changes were made to all public use data sets:

- All dates collected within a given CRF were converted to days from Visit 1. Unless otherwise noted, converted dates were stored in the original variable names given on the CRFs.
- Data collected in source documentation boxes or fields (for example, ter_1210, ter_1220, ter_1230, ter_1240 from the Termination of Study Participation (P6_TERM) form) were omitted from the public datasets. Variables in the source documentation boxes remain annotated on the forms but they were not included in the datasets.
- Comment fields and text descriptions related to a given question were deleted. These fields contain free text which may include dates or other participant-related details that risk possible identification.

Note the 'vnum_c' variable is a character variable representing the visit numbers as outlined in the protocol, with Supervised Washout visits denoted with vnum_c of 0A and 0B. Variable 'vnum' is a corresponding numeric variable that was assigned for ease of sorting the data in chronological order. Mapping of 'vnum' to 'vnum_c' is as follows:

<u>vnum_c</u>	<u>vnum</u>	<u>Visit Name</u>
0A	0.001	Visit 0A (Supervised Washout)
0B	0.002	Visit 0B (Supervised Washout)
2A	2.001	Visit 2A (for participants who need third sputum)
90A*	90.001*	Visit 90A (Asthma Exacerbation Visit)
90B*	90.002*	Visit 90B (Asthma Exacerbation Phone Contact #1)
90C*	90.003*	Visit 90C (Asthma Exacerbation Phone Contact #2)
90D*	90.004*	Visit 90D (Asthma Exacerbation Phone Contact #3)

* These visits are part of the post-randomization Asthma Exacerbation Protocol. Visit 90 collects data at the phone contact at start of prednisone, Visit 90A collects data in clinic 3 days after prednisone start, and Visits 90B, 90C and 90D collect data at phone contacts 10, 14 and 21 days after prednisone start.

For the remainder of the visits, 'vnum_c' and 'vnum' values are identical.

Any additional changes made to a given dataset are summarized in Table 1 below.

Background

This protocol was a randomized, stratified, 3-period double-blind placebo-controlled crossover study of patients with symptomatic

mild-to-moderate asthma, not already taking an inhaled corticosteroid, in whom the effect of “medium-dose” inhaled corticosteroid (mometasone) was compared with the effect of placebo and with a long-acting muscarinic antagonist (tiotropium). Sputum induction was performed up to 3 times during the run-in in order to collect two acceptable sputum samples, and sputum eosinophil percentages were quantified. Based on a "cut point" of $\geq 2\%$ eosinophils and two measures of sputum eosinophil percentage during the run-in, participants were categorized as "eosinophilic" (either persistently or intermittently eosinophilic) or "persistently non-eosinophilic" and stratified on this basis at randomization. The goal was to determine if asthmatic participants who are persistently non-eosinophilic require a different treatment strategy than those with sputum eosinophilia.

The co-primary hypotheses of the SIENA trial were: (1) Among asthmatic participants who are persistently non-eosinophilic, the preference for ICS will be greater than placebo; and (2) Among asthmatic participants who are persistently non-eosinophilic, the preference for LMA will be greater than placebo.

Of the 564 enrolled in SIENA at Visit 1, 295 were randomized at Visit 3 and 241 completed the study.

Visit numbers for the SIENA data generally match the numbers outlined in the protocol (i.e., Visits 1 – 9); exceptions are described above.

Table 1. SIENA Forms and Datasets

Form Name Abbreviation	Dataset Name	Variable Prefix	Form Name or Description	Field Changes/ Comments
AAAQ	aaaq.sas7bdat	aaq	Acute Asthma Assessment Questionnaire	<ul style="list-style-type: none"> • aaq_1060D was deleted (description field) • aaq_1070, aaq_1080, aaq_1090 were deleted (source doc fields)
ABP	abp.sas7bdat	abp	Asthma Bother Profile	<ul style="list-style-type: none"> • abp_1240, abp_1250, abp_1260 were deleted (source doc fields)
ACT	act.sas7bdat	act	Asthma Control Test	

Form Name Abbreviation	Dataset Name	Variable Prefix	Form Name or Description	Field Changes/ Comments
AECLIN	aeclin.sas7bdat	aec	Clinical Adverse Events	<ul style="list-style-type: none"> • aec_1020, aec_1030 (dates) were altered as described above • aec_1000 is a sequential number assigned to each adverse event within a participant (starting from 01 up to 99) • Variables added to this dataset include: <ul style="list-style-type: none"> ○ icd9_cat: ICD-9 category ○ icd9long: Full description of ICD-9 code ○ icd9shrt: abbreviated description of ICD-9 code • The dataset used to code adverse events and link to descriptions was downloaded from www.cms.gov. ICD-9-CM Diagnosis and Procedure Codes: Abbreviated and Full Code Titles effective October 1, 2009 were used.
ASTHMA_HX_ADULT	asthma_hx_adult.sas7bdat	aha	Adult Asthma and Allergy History	<ul style="list-style-type: none"> • aha_1400D, aha_1410D, aha_1420D, aha_1460D were deleted (description fields) • aha_6000 was deleted (comment field)
ASUI	asui.sas7bdat	asu	Adult Symptom Utility Index	<ul style="list-style-type: none"> • asu_1080D was deleted (description field) • asu_1100, asu_1110, asu_1120 were deleted (source doc fields)
	bmi.sas7bdat		Body Mass Index	<p>File contains the following variables:</p> <ul style="list-style-type: none"> • 'part_id' = participant ID number • 'bmi' = body mass index computed from height and weight measured at Visit 1

Form Name Abbreviation	Dataset Name	Variable Prefix	Form Name or Description	Field Changes/ Comments
CMED	cmed.sas7bdat	cme	Concomitant Medications for Asthma/Allergy and Adverse Events	<ul style="list-style-type: none"> • cme_1060, cme_1070 (dates) have been altered as described above • cme_1000 is a sequential number assigned to each medication within a participant (starting from 01 up to 99) • Variables added to this dataset include: <ul style="list-style-type: none"> ○ class: drug class text ○ class_id: class ID number ○ gen_name: generic drug name ○ Units (cme_1040), frequency (cme_1050) and route (cme_1055) contain formatted values • Drug codes and classes were obtained from the American Society of Health-System Pharmacists, Inc. drug coding system (AsthmaNet purchased a license to use and update the data annually)
ENO	eno.sas7bat	eno	Exhaled Nitric Oxide	<ul style="list-style-type: none"> • eno_6000 was deleted (comment field)
HEQ	heq.sas7bdat	heq	Home Environment Questionnaire	<ul style="list-style-type: none"> • heq_1710, heq_1720 were deleted (source doc fields) • heq_1000D, heq_1160D, heq_1250D, heq_1340D, heq_1410D, heq_1420D, heq_1460D, heq_1620D were deleted (description fields) • heq_6000 was deleted (comment field)
HOUSEHOLD_SEI	household_sei.sas7bdat	sei	Household Socio-Economic Information	<ul style="list-style-type: none"> • sei_1000D was deleted (description field) • sei_6000 was deleted (comment field)
LEXAM_PED	lexam_ped.sas7bdat	ple	Pediatric Long Physical Exam	<ul style="list-style-type: none"> • ple_1120D was deleted (description field) • ple_6000 was deleted (comment field)
METHA	metha.sas7bdat	mth	Methacholine Challenge Testing	<ul style="list-style-type: none"> • mth_6000 was deleted (comment field)

Form Name Abbreviation	Dataset Name	Variable Prefix	Form Name or Description	Field Changes/ Comments
METHACHK_ADULT	methachk_adult.sas7bdat	mca	Adult Methacholine Challenge Testing Checklist	<ul style="list-style-type: none"> • mca_1100D was deleted (description field) • mca_6000 was deleted (comment field)
METHACHK_PED	methachk_ped.sas7bdat	mcp	Pediatric Methacholine Challenge Testing Checklist	<ul style="list-style-type: none"> • mcp_1100D was deleted (description field) • mcp_6000 was deleted (comment field)
METHA_ADD_TRT	metha_add_trt.sas7bdat	mad	Additional Treatment Post Methacholine Challenge Testing	<ul style="list-style-type: none"> • mad_1240, mad_1250, mad_1260 were deleted (source doc fields) • mad_1060D, mad_1190D were deleted (description fields) • mad_6000 was deleted (comment field)
PALB4_SPIRO	palb4_spiro.sas7bdat	pa4	Post-Albuterol (4 puffs) Spirometry Testing	<ul style="list-style-type: none"> • pa4_6000 was deleted (comment field)
PIPRA4_SPIRO	pipra4_spiro.sas7bdat	pi4	Post-Ipratropium (4 puffs) Spirometry Testing	<ul style="list-style-type: none"> • pi4_6000 was deleted (comment field)
PREG_TEST	preg_test.sas7bdat	prg	Urine Pregnancy Test	<ul style="list-style-type: none"> • prg_1050, prg_1060 were deleted (source doc fields) • prg_6000 was deleted (comment field)
PRIOR_COND_ADULT	prior_cond_adult.sas7bdat	pad	Prior Conditions for Adult Participants	<ul style="list-style-type: none"> • pad_1000D, pad_1010D, pad_1020D, pad_1030D, pad_1040D, pad_1050D, pad_1060D, pad_1070D, pad_1080D, pad_1090D, pad_1100D, pad_1110D, pad_1120D were deleted (description fields) • pad_6000 was deleted (comment field)
PRIOR_COND_ALL	prior_cond_all.sas7bdat	pal	Prior Conditions for All Participants	<ul style="list-style-type: none"> • pal_1000D, pal_1010D, pal_1060D, pal_1110D, pal_1130D, pal_1150D, pal_1170D, pal_1180D were deleted (description fields) • pal_6000 was deleted (comment field)

Form Name Abbreviation	Dataset Name	Variable Prefix	Form Name or Description	Field Changes/ Comments
PRIOR_TRT	prior_trt.sas7bdat	ptr	Prior Asthma/Allergy Treatment	<ul style="list-style-type: none"> ptr_1000D, ptr_1470D, ptr_1500D, ptr_1600D, ptr_1830D, ptr_1870D, ptr_1910D were deleted (description fields) ptr_6000 was deleted (comment field) Date intervals for the medication dates in Questions 2-22 were stored in variables date_q02-date_q22. If day was missing, but month and year were present, we calculated the date using the 1st of the month. If only the year was present, no date interval was computed (i.e., missing data).
PSS_10	pss_10.sas7bdat	p10	Perceived Stress Scale	<ul style="list-style-type: none"> p10_1100, p10_1110, p10_1120 were deleted (source doc fields)
RAND_IAQL_12	rand_iaql_12.sas7bdat	iaq	RAND Impact of Asthma on QOL SF-12	<ul style="list-style-type: none"> iaq_1120, iaq_1130, iaq_1140 were deleted (source doc fields)
REGISTRY	registry.sas7bdat	reg	AsthmaNet Registry Form (includes demographics)	<ul style="list-style-type: none"> reg_1020, reg_1040, reg_1060 (dates) were altered as described above reg_1070 (birth date) was deleted; the participant's age at visit 1 was calculated and is stored in variable 'age' (as a whole number) ethnicity and individual race variables have been deleted due to sparseness (reg_1090, reg_1100, reg_1110, reg_1120, reg_1130, reg_1140) reg_1150 (primary racial identification) has been re-coded such that those who were in categories 1, 2 and 6 were included in the 'other' category (code 6) reg_1160 (description field) was deleted

Form Name Abbreviation	Dataset Name	Variable Prefix	Form Name or Description	Field Changes/ Comments
SERIOUS	serious.sas7bdat	ser	Serious Adverse Event Reporting Form	<ul style="list-style-type: none"> • ser_1000, ser_1080, ser_1090 (dates) were altered as described above • ser_1010D, ser_1180D, ser_1210D, ser_1220D were deleted (description fields) • ser_6000 was deleted (comment field)
SEXAM_PED	sexam_ped.sas7bdat	pse	Pediatric Short Physical Exam	<ul style="list-style-type: none"> • pse_1120D was deleted (description field) • pse_6000 was deleted (comment field)
SNQ	snq.sas7bdat	snq	Sinonasal Questionnaire	<ul style="list-style-type: none"> • snq_1050, snq_1060, snq_1070 were deleted (source doc fields)
SPIRO	spiro.sas7bdat	spi	Spirometry Testing	<ul style="list-style-type: none"> • spi_6000 was deleted (comment field)
SPUTLAB	sputlab.sas7bdat	sla	Sputum Induction Lab Values	<ul style="list-style-type: none"> • sla_1000 (date) was altered as described above • sla_6000 was deleted (comment field)
SPUTREAD	sputread.sas7bdat	sre	Sputum Induction Read	<ul style="list-style-type: none"> • sre_1000 (date) was altered as described above • sre_6000 was deleted (comment field)
SPUTUM	sputum.sas7bdat	spu	Sputum Induction	<ul style="list-style-type: none"> • spu_6000 was deleted (comment field)
SPUTUM_ADD_TRT	sputum_add_trt.sas7bdat	sad	Additional Treatment Post Sputum Induction	<ul style="list-style-type: none"> • sad_1080, sad_1090, sad_1100 were deleted (source doc fields)
SPUTUMCHK	sputumchk.sas7bdat	sch	Sputum Induction Checklist	<ul style="list-style-type: none"> • sch_1060D was deleted (description field) • sch_6000 was deleted (comment field)
WPAI_ASTHMA	wpai_asthma.sas7bdat	wpa	Asthma-Specific Work Productivity and Activity Impairment Questionnaire	<ul style="list-style-type: none"> • wpa_1090, wpa_1100, wpa_1110 were deleted (source doc fields)
WURSS_21	wurss_21.sas7bdat		Wisconsin Upper Respiratory Symptom Survey – 21	<ul style="list-style-type: none"> • wdate (date) was altered as described above
P6_BASELINE	baseline.sas7bdat	bas	SIENA Baseline PEF and Rescue Use Values	<ul style="list-style-type: none"> • bas_6000 was deleted (comment field)

Form Name Abbreviation	Dataset Name	Variable Prefix	Form Name or Description	Field Changes/ Comments
P6_CHANGE_MEDS	change_meds.sas7bdat	chg	SIENA Change in Scheduled Study Medications	<ul style="list-style-type: none"> • chg_1000D was deleted (description field) • chg_1030 (date) was altered as described above • chg_6000 was deleted (comment field)
P6_COMPLY	comply.sas7bdat	com	SIENA Compliance Checklist	<ul style="list-style-type: none"> • com_6000 was deleted (comment field)
P6_CTXQX	ctxqx.sas7bdat	ctx	SIENA Coordinator Study Treatment Questionnaire	<ul style="list-style-type: none"> • ctx_1020D, ctx_1050D were deleted (description fields) • ctx_1060, ctx_1070 were deleted (source doc fields)
P6_ELIG0A	elig0a.sas7bdat	e0a	SIENA Eligibility Checklist 0A	<ul style="list-style-type: none"> • e0a_1010 (date) was altered as described above • e0a_1160D was deleted (description field) • e0a_1200, e0a_1210 were deleted (source doc fields) • e0a_6000 was deleted (comment field)
P6_ELIG0B	elig0b.sas7bdat	e0b	SIENA Eligibility Checklist 0B	<ul style="list-style-type: none"> • e0b_6000 was deleted (comment field)
P6_ELIG1	elig1.sas7bdat	e1	SIENA Eligibility Checklist 1	<ul style="list-style-type: none"> • e1_1010 (date) was altered as described above • e1_1150, e1_1160 were deleted (source doc fields) • e1_6000 was deleted (comment field)
P6_ELIG2	elig2.sas7bdat	e2	SIENA Eligibility Checklist 2	<ul style="list-style-type: none"> • e2_1000D was deleted (description field) • e2_1220, e2_1230 were deleted (source doc fields) • e2_6000 was deleted (comment field)
P6_ELIG3	elig3.sas7bdat	e3	SIENA Eligibility Checklist 3	<ul style="list-style-type: none"> • e3_1040 (date) was altered as described above • e3_1120D was deleted (description field) • e3_6000 was deleted (comment field)

Form Name Abbreviation	Dataset Name	Variable Prefix	Form Name or Description	Field Changes/ Comments
P6_ELIG4	elig4.sas7bdat	e4	SIENA Eligibility Checklist 4	• e4_6000 was deleted (comment field)
P6_ELIG5	elig5.sas7bdat	e5	SIENA Eligibility Checklist 5	• e5_1170D was deleted (description field) • e5_6000 was deleted (comment field)
	ige.sas7bdat		ImmunoCAP Results	File contains the following variables: • part • ige • re1 (cat) • re5 (dog) • re72 (mouse) • re74 (rat) • rmx1 (mold mix) • ri6 (cockroach) • rgx2 (grass mix 2) • rtx4 (tree mix 4) • rtx6 (tree mix 6) • rwx1 (weed mix) • rw3 (giant ragweed) • rd2 (mite, d. farinae) • rd1 (mite, d. pteronyssinus)
P6_LAB	lab.sas7bdat	lab	SIENA Laboratory Results	• lab_6000 was deleted (comment field)
P6_PARTTXQX	parttxqx.sas7bdat	ptx	SIENA Participant Study Treatment Questionnaire	• ptx_1000D, ptx_1030D, ptx_1060D were deleted (description fields) • ptx_1070, ptx_1080 were deleted (source doc fields)
	periostin.sas7bdat		Periostin Results	File contains the following variables: • part • vnum • vdate (altered as described above) • periostin

Form Name Abbreviation	Dataset Name	Variable Prefix	Form Name or Description	Field Changes/ Comments
P6_PULMONARYCHK	pulmonarychk.sas7bdat	pch	SIENA Pulmonary Procedure Checklist	<ul style="list-style-type: none"> • pch_1130D was deleted (description field) • pch_1150 (height) was deleted • pch_6000 was deleted (comment field)
	regimen.sas7bdat		Randomized treatment assignments	<p>File contains the following variables:</p> <ul style="list-style-type: none"> • part_id • regimen_period_1 (Mometasone, Tiotropium or Placebo) • regimen_period_2 (Mometasone, Tiotropium or Placebo) • regimen_period_3 (Mometasone, Tiotropium or Placebo)
P6_SIGEX	sigex.sas7bdat	sig	SIENA Significant Asthma Exacerbation	<ul style="list-style-type: none"> • sig_1070 (date) was altered as described above • sig_1240D, sig_1250D were deleted (description fields) • sig_1260, sig_1270, sig_1280 were deleted (source doc fields) • sig_6000 was deleted (comment field)
P6_SIGEX_FOLLOW	sigex_follow.sas7bdat	sfu	SIENA Significant Asthma Exacerbation Phone Follow-up	<ul style="list-style-type: none"> • sfu_1170D was deleted (description field) • sfu_1180, sfu_1190, sfu_1200 were deleted (source doc fields) • sfu_6000 was deleted (comment field)

Form Name Abbreviation	Dataset Name	Variable Prefix	Form Name or Description	Field Changes/ Comments
P6_SPIROTEL_CREF	spirotel.sas7bdat	dry	SIENA spirotel® Coordinator Reference Card	<ul style="list-style-type: none"> • ddate (date) was altered as described above • Dataset contains the diary and peak flow (PEF) maneuver data collected by the Spirotel device. FEF25-75, FET, FEV1, and FVC maneuver data are also included. Participants were asked to complete diary questions and perform three PEF maneuvers each morning and evening (scheduled sessions). They also had the option to perform unscheduled peak flows to monitor their lung function, but the data from these unscheduled maneuvers are not included in this dataset. • Variables corresponding to this reference card begin with the dry_ prefix and are numbered according to the questions on the reference card. For example, dry_1 corresponds to “Number of times the participant woke up last night due to asthma symptoms”, which is evaluated at the AM session. • Two date intervals are present in the diary data: <ul style="list-style-type: none"> ○ ddate: date on which the diary was completed ○ vdate: date of the participant’s next clinic visit (at which data were typically downloaded)

Form Name Abbreviation	Dataset Name	Variable Prefix	Form Name or Description	Field Changes/ Comments
P6_SPIROTEL_CREF	spirotel.sas7bdat	dry	SIENA spirotel® Coordinator Reference Card	<ul style="list-style-type: none"> • Variables representing the various maneuvers are as follows (and are not found on the reference card): <ul style="list-style-type: none"> ○ am_fef2575: morning session FEF25-75 ○ am_fet: morning session FET ○ am_fev1: morning session FEV1 ○ am_fvc: morning session FVC ○ am_pef: morning session PEF ○ pm_fef2575: evening session FEF25-75 ○ pm_fet: evening session FET ○ pm_fev1: evening session FEV1 ○ pm_fvc: evening session FVC ○ pm_pef: evening session PEF • This dataset has been modified such that the morning and evening scheduled sessions on the same day have been combined into a single observation. This is true for days other than those in which the participant had a clinic visit. The morning and evening scheduled sessions on the day of a clinic visit remain separated into two observations (since the vnum and vdate variables are different due to the vnum being reset in the spirotel device at each visit.)
P6_TERM	term.sas7bdat	ter	SIENA Termination of Study Participation	<ul style="list-style-type: none"> • ter_1030D, ter_1190D (description fields) were deleted • ter_1060 (date) was altered as described above • ter_1210, ter_1220, ter_1230, ter_1240 (source doc fields) were deleted

Form Name Abbreviation	Dataset Name	Variable Prefix	Form Name or Description	Field Changes/ Comments
P6_TXFAIL_CHK	txfail_chk.sas7bdat	tch	SIENA Treatment Failure Checklist	<ul style="list-style-type: none"> • tch_1070 (date) was altered as described above • tch_1110D was deleted (description field) • tch_6000 was deleted (comment field)
P6_TXFAIL	txfail.sas7bdat	txf	SIENA Treatment Failure Information	<ul style="list-style-type: none"> • txf_1120D was deleted (description field) • txf_6000 was deleted (comment field)
P6_WASHOUT	washout.sas7bdat	wsh	SIENA Washout Form	<ul style="list-style-type: none"> • wsh_6000 was deleted (comment field)

Table 2. Forms/Procedures Completed at each Study Visit (Visits 0A – 9, 90, 90A – 90D)
 (•=regular visit procedure; ○=completed only as needed)

	0A†	0B†	1	2	2A‡	3	4	5	6	7	8	9	90§	90A§	90B§	90C§	90D§
AAAQ						•							•	•	•	•	•
ABP			•			•		•		•		•					
ACT			•	•		•	•	•	•	•	•	•					
AECLIN	○	○	○	○	○	○	○	○	○	○	○	○					
ASTHMA_HX_ADULT			•														
ASUI			•	•		•	•	•	•	•	•	•					
CMED	○	○	○	○	○	○	○	○	○	○	○	○					
ENO			•	•	•												
HEQ				•													
HOUSEHOLD_SEI				•													
LEXAM_PED	•		•									•		•			
METHA			○														
METHACHK_ADULT			○														
METHACHK_PED			○														
METHA_ADD_TRT			○														
PALB4_SPIRO			•		•												
PIPRA4_SPIRO				•													
PREG_TEST			•									•					
PRIOR_COND_ADULT			•														
PRIOR_COND_ALL			•														
PRIOR_TRT			•														
PSS_10						•											
Randomization						•											
RAND_IAQL_12			•			•		•		•		•					
REGISTRY	•		•														
SERIOUS	○	○	○	○	○	○	○	○	○	○	○	○					
SEXAM_PED		•	○	•	•	•	•	•	•	•	•						

	0A [†]	0B [†]	1	2	2A [‡]	3	4	5	6	7	8	9	90 [§]	90A [§]	90B [§]	90C [§]	90D [§]
SNQ						•		•		•		•					
SPIRO	•	•	•	•	•	•	•	•	•	•	•	•					
SPUTLAB			•	•	•												
SPUTREAD			•	•	•												
SPUTUM			•	•	•												
SPUTUMCHK			•	•	•												
SPUTUM_ADD_TRT			○	○	○												
WPAI_ASTHMA						•		•		•		•	•		•	•	•
WURSS_21																	•
P6_BASELINE	•	•	•	•													
P6_CHANGEMEDS						○	○	○	○	○	○	○		○			
P6_COMPLY		•	○	•	•	•	•	•	•	•	•	•					
P6_CTXQX						○	○	•	○	•	○	•					
P6_ELIG0A	•																
P6_ELIG0B		•															
P6_ELIG1			•														
P6_ELIG2			•														
P6_ELIG3			•														
P6_ELIG4				•	•												
P6_ELIG5						•											
P6_LAB			•	•	•												
P6_PARTTXQX						○	○	•	○	•	○	•					
P6_PULMONARYCHK	•	•	•	•	•	•	•	•	•	•	•	•					
P6_SIGEX			○	○										•			
P6_SIGEX_FOLLOW															•	•	•
P6_TERM	○	○	○	○	○	○	○	○	○	○	○	•					
P6_TXFAIL			○	○	○	○	○	○	○	○	○	○					
P6_TXFAIL_CHK			○	•	•	•	•	•	•	•	•	•					
P6_WASHOUT								•		•		•					

† Visits 0A and 0B were only completed by those who entered the study on ICS. Visit 0A and 0B data are only included for participants who successfully completed Visit 1 (i.e., entered SIENA run-in).

‡ Visit 2A was only completed if the participant needed a third try to produce a second acceptable sputum sample.

§ Visits 90, 90A – 90D were only completed by those who experienced a significant asthma exacerbation during the randomized treatment period.