

AsthmaNet ALfA Data Documentation for BioLINCC

ALfA Study Forms, Data sets and Variables

The file ALfA_forms.pdf on the enclosed CD includes the annotated ALfA 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 'P9_' prefix are specific to the ALfA protocol; data associated with these ALfA-specific forms are stored in a corresponding data file of the same name with the 'P9_' 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 ALfA 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 ALfA 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_1200, ter_1210, ter_1220, ter_1230 from the Termination of Study Participation (P9_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 phone contacts denoted with vnum_c of 2A and 2B. 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>
2A	2.001	Phone Contact #1
2B	2.002	Phone Contact #2

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

Of the 137 enrolled in ALfA at Visit 1, 78 were randomized at Visit 2 to receive alendronate or matching placebo along with fluticasone propionate 250mcg and salmeterol 50mcg. Between Visits 2 and 3, participants were contacted twice by phone. After 8 weeks treatment, participants returned for Visit 3, their final visit of the study.

The primary hypothesis of the ALfA trial was: Alendronate prevents the loss of bronchoprotection against methacholine induced bronchoconstriction that occurs with regular use of ICS/LABA.

Visit numbers for the ALfA data generally match the numbers outlined in the protocol (i.e., Visits 1 – 3); exceptions are described above.

Table 1. ALfA Forms and Datasets

Form Name Abbreviation	Dataset Name	Variable Prefix	Form Name or Description	Field Changes/ Comments
ACT	act.sas7bdat	act	Asthma Control Test	
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)
	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)
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)

Form Name Abbreviation	Dataset Name	Variable Prefix	Form Name or Description	Field Changes/ Comments
PADVAIR_SPIRO	padvair_spiro.sas7bat	pas	Post-Advair (2 puffs) Spirometry Testing	<ul style="list-style-type: none"> • pas_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)
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)
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

Form Name Abbreviation	Dataset Name	Variable Prefix	Form Name or Description	Field Changes/ Comments
REGISTRY	registry.sas7bdat	reg	AsthmaNet Registry information, including 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
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)
SPIRO	spiro.sas7bdat	spi	Spirometry Testing	<ul style="list-style-type: none"> • spi_6000 was deleted (comment field)
P9_ASTHMA_LOG	asthma_log.sas7bdat	asl	ALFA Asthma Monitoring Log	<ul style="list-style-type: none"> • ddate (date) was altered as described above
P9_BASELINE	baseline.sas7bdat	bas	ALFA Baseline PEF and Rescue Use Values	<ul style="list-style-type: none"> • bas_6000 was deleted (comment field)
	b2ar.sas7bdat		Peripheral blood mononuclear cells B2AR cell surface density	<p>File contains the following variables:</p> <ul style="list-style-type: none"> • part • vnum • b2ar

Form Name Abbreviation	Dataset Name	Variable Prefix	Form Name or Description	Field Changes/ Comments
	camp.sas7bdat	camp	Peripheral blood mononuclear cells cAMP concentrations	File contains the following variables: <ul style="list-style-type: none"> • part • vnum • camp_forsk (µM) • camp_iso (µM) • camp_pbs (µM)
P9_COMPLY	comply.sas7bdat	com	ALFA Compliance Checklist	• com_6000 was deleted (comment field)
	comply_mems.sas7bdat	mems	Capsule Compliance calculated from raw MEMS data	File contains the following variables: <ul style="list-style-type: none"> • part • vnum • vdate • mems_taken • mems_taken_inwindow
P9_CTXQX	ctxqx.sas7bdat	ctx	ALFA Coordinator Study Treatment Questionnaire	• ctx_1020D was deleted (description field) • ctx_1030, ctx_1040 were deleted (source doc fields)
P9_ELIG1	elig1.sas7bdat	e1	ALFA Eligibility Checklist 1	• e1_1010 (date) was altered as described above • e1_1160, e1_1170 were deleted (source doc fields) • e1_6000 was deleted (comment field)
P9_ELIG2	elig2.sas7bdat	e2	ALFA Eligibility Checklist 2	• e2_1000D was deleted (description field) • e2_1340, e2_1350 were deleted (source doc fields) • e2_6000 was deleted (comment field)
P9_ELIG3	elig3.sas7bdat	e3	ALFA Eligibility Checklist 3	• e3_1050D was deleted (description field) • e3_6000 was deleted (comment field)
P9_ELIG4	elig4.sas7bdat	e4	ALFA Eligibility Checklist 4	• e4_1110D was deleted (description field) • e4_6000 was deleted (comment field)
P9_LAB	lab.sas7bdat	lab	ALFA Laboratory Results	• lab_6000 was deleted (comment field)

Form Name Abbreviation	Dataset Name	Variable Prefix	Form Name or Description	Field Changes/ Comments
METHA	metha.sas7bdat	mth	ALfA Methacholine Challenge Testing	<ul style="list-style-type: none"> • mth_6000 was deleted (comment field)
METHA_ADD_TRT	metha_add_trt.sas7bdat	mad	ALfA 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)
P9_PARTTXQX	parttxqx.sas7bdat	ptx	ALfA Participant Study Treatment Questionnaire	<ul style="list-style-type: none"> • ptx_1020D was deleted (description field) • ptx_1030, ptx_1040 were deleted (source doc fields)
	phadiatop.sas7bdat		Phadiatop Result	<p>File contains the following variables:</p> <ul style="list-style-type: none"> • part • phadiatop
P9_PULMONARYCHK	pulmonarychk.sas7bdat	pch	ALfA Pulmonary Procedure Checklist	<ul style="list-style-type: none"> • pch_1130 (date) was altered as described above • pch_1170D was deleted (description field) • pch_1190 (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 (either "Placebo" or "Alendronate")
	saa.sas7bdat	saa	Saliva Collection Results (from Salimetrics)	<p>File contains the following variables:</p> <ul style="list-style-type: none"> • part_id • vnum • saa_preadv • saa_postadv
P9_SALIVACHK	salivachk.sas7bdat	sal	ALfA Saliva Collection Checklist	<ul style="list-style-type: none"> • sal_6000 was deleted (comment field)

Form Name Abbreviation	Dataset Name	Variable Prefix	Form Name or Description	Field Changes/ Comments
P9_SIGEX	sigex.sas7bdat	sig	ALfA Significant Asthma Exacerbation	<ul style="list-style-type: none"> • sig_1060 (date) was altered as described above • sig_1230D was deleted (description field) • sig_6000 was deleted (comment field)
P9_TERM	term.sas7bdat	ter	ALfA Termination of Study Participation	<ul style="list-style-type: none"> • ter_1030D, ter_1180D were deleted (description fields) • ter_1060 (date) was altered as described above • ter_1200, ter_1210, ter_1220, ter_1230 were deleted (source doc fields)

Table 2. Forms/Procedures Completed at each Study Visit (Visits 1-3)
 (•^a=regular visit procedure; ○^b=completed only as needed)

	Visit Number				
	1	2	2.001	2.002	3
ACT	• ^a	• ^a	• ^a	• ^a	• ^a
AECLIN	○ ^b	○ ^b			○ ^b
ASTHMA_HX_ADULT	• ^a				
CMED	○ ^b	○ ^b			○ ^b
ENO		• ^a			• ^a
HEQ	• ^a				
HOUSEHOLD_SEI	• ^a				
METHACHK_ADULT	○ ^b	• ^a			• ^a
PADVAIR_SPIRO		• ^a			• ^a
PALB4_SPIRO	○ ^b				
PREG_TEST	• ^a	• ^a			• ^a
PRIOR_COND_ADULT	• ^a				
PRIOR_COND_ALL	• ^a				
PRIOR_TRT	• ^a				
Randomization		• ^a			
REGISTRY	• ^a				
SERIOUS	○ ^b	○ ^b			○ ^b
SPIRO	• ^a	• ^a			• ^a
P9_ASTHMA_LOG		• ^a			• ^a
P9_BASELINE	• ^a	• ^a			
P9_COMPLY	○ ^b	• ^a			• ^a
P9_CTXQX		○ ^b			• ^a

	Visit Number				
	1	2	2.001	2.002	3
P9_ELIG1	• a				
P9_ELIG2	• a				
P9_ELIG3	• a				
P9_ELIG4		• a			
P9_LAB	• a				
METHA	○ b	• a			• a
METHA_ADD_TRT	○ b	○ b			○ b
P9_PARTTXQX		○ b			• a
P9_PULMONARYCHK	• a	• a			• a
P9_SALIVACHK		• a			• a
P9_SIGEX	○ b	○ b			○ b
P9_TERM	○ b	○ b			• a