

AsthmaNet INFANT and AVICA STUDY FORMS AND DATASETS

Referencing the INFANT/AVICA Study Forms and Datasets

Annotated INFANT/AVICA case report forms (CRFs) are included on the enclosed CD in pdf format (INFANT_AVICA_forms.pdf). Each CRF has an abbreviated name that is located in a shaded box in the lower right-hand corner of the form. Some of these abbreviated names begin with a 'P4_' prefix, and some do not. As a general rule, data corresponding to each CRF are stored in a data file of the same name. If the CRF abbreviation begins with a 'P4_' prefix, the name of the corresponding data file will have the 'P4_' prefix removed. All data file names must be 8 or less characters in length to be included in the transport file. If the CRF abbreviation has more than 8 characters, the name of the corresponding data file will be adjusted to only have 8 characters. This is specified in Table 1. Variable names for a particular CRF begin with the prefix that is assigned to that form followed by an underscore and the number of the field. 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 INFANT/AVICA 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.

Table 1 below outlines the relationship between each form name, dataset, and variable prefix. Where no form name is given, no CRF existed for collection of the relevant information during study implementation. Where no dataset name is given, the corresponding "form" was simply a reference card that was used to explain some element of data collection.

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 INFANT/AVICA 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 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.

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, heq_1000D, heq_1160D, heq_1250D from the Home Environment Questionnaire (HEQ 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. Any additional changes made to a given dataset are summarized in Table 1 below.

Background

This study was comprised of two separate but linked clinical trials: INFANT and AVICA. Participants entered INFANT and AVICA simultaneously. Although these trials had separate protocols and consents, and were registered separately on clinicaltrials.gov, they share clinical data which was collected on common CRFs. For this reason, they are submitted to BioLINCC as a single package.

The Individualized Therapy for Asthma in Toddlers (INFANT) trial was a multicenter, randomized, double-blind, double-dummy, clinical trial in children 12-59 months (n=300) with persistent asthma. Participants completed a 2-8 week run-in period followed by three crossover periods with either daily inhaled corticosteroid (ICS), daily leukotriene receptor antagonist (LTRA), and as-needed ICS treatment. The primary outcome was differential response to asthma medication based on a composite measure of asthma control. The primary analysis involved two stages: determination of differential response, and assessment of whether three pre-specified features (aeroallergen sensitization, previous exacerbations, and sex) predicted differential response.

The Acetaminophen Versus Ibuprofen in Children with Asthma (AVICA) trial enrolled 300 children aged 12-59 months with mild persistent asthma in a multicenter, prospective, randomized, double-blind, parallel arm trial comparing the use of acetaminophen with ibuprofen as needed for fever or pain over 48 weeks. The primary outcome was the number of asthma exacerbations requiring systemic corticosteroids per participant annualized per year.

Table 1. INFANT/AVICA Forms and Datasets

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_PED	astmahx.sas7bdat	aha	Pediatric Asthma and Allergy History	<ul style="list-style-type: none"> • aha_1400D, aha_1410D, aha_1420D, aha_1460D, and aha_1560D were omitted (description fields) • Comment field in aha_6000 was deleted

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)
HEQ	heq.sas7bdat	heq	Home Environment Questionnaire	<ul style="list-style-type: none"> • heq_1710, heq_1720 were omitted (source doc fields) • heq_1000D, heq_1160D, heq_1250D, heq_1340D, heq_1410D, heq_1420D, heq_1460D, heq_1620D were omitted (description fields) • Comment field in heq_6000 was deleted
HOUSEHOLD__SEI	sei.sas7bdat	sei	Household Socio-Economic Information	<ul style="list-style-type: none"> • sei_1000D was omitted (description field) • Comment field in sei_6000 was deleted • Due to sparseness, sei_1030 was recoded such that all responses coded ≥ 6 were set to 6.

Form Name Abbreviation	Dataset Name	Variable Prefix	Form Name or Description	Field Changes/ Comments
IMMUNOCAP	immune.sas7bdat		ImmunoCap Data	<ul style="list-style-type: none"> Includes IgE, cat, dog, cockroach, mite, egg white, rat, ragweed, milk mouse, peanut, weed, tree, mold and grass.
PRIOR_COND_ALL	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 omitted (description fields) Comment field in pal_6000 was deleted
PRIOR_TRT	priortrt.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 omitted (description fields) Comment field in ptr_6000 was deleted 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).

Form Name Abbreviation	Dataset Name	Variable Prefix	Form Name or Description	Field Changes/ Comments
	regimen.sas7bdat		Randomized treatment assignments	File contains the following variables: <ul style="list-style-type: none"> • part_id • avi_reg (AVICA regimen – stays the same through entire study) <ul style="list-style-type: none"> - Coded as either “Ibuprofen” or “Acetominophen” • inf_reg (INFANT regimen – treatments listed in order assigned, 6 combinations) <ul style="list-style-type: none"> - Coded as “Daily : As-needed : LTRA” or “Daily : LTRA : As-needed” or “As-needed : Daily : LTRA” or “As-needed : LTRA : Daily” or “LTRA : Daily : As-needed” or “LTRA : As-needed : Daily”
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 omitted; the participant’s age at visit 0 was calculated and is stored in variable ‘age’ (as a whole number) • ethnicity and individual race variables have been omitted 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 for the ‘other’ race category) was omitted

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 omitted (description fields) • Comment field in ser_6000 was deleted
LEXAM	lexam.sas7bdat	lx	Pediatric Long Physical Exam	<ul style="list-style-type: none"> • lx_1120D was omitted (description field) • Comment field in lx_6000 was deleted
SEXAM	sexam.sas7bdat	sx	Pediatric Short Physical Exam	<ul style="list-style-type: none"> • sx_1120D was omitted (description field) • Comment field in sx_6000 was deleted
P4_AVICA_COMPLY	a_comply.sas7bdat	acp	AVICA Compliance Checklist	<ul style="list-style-type: none"> • Comment field in acmp_6000 was deleted
P4_AVICA_DIARY	a_diary.sas7bdat	adr	Diary of AVICA use	<ul style="list-style-type: none"> • Create date of use (usedate) from adry_1010, adry_1020, and adry_1030 • Comment field in adry_6000 was deleted
P4_AVICA_TERM	a_term.sas7bdat	atr	Termination of AVICA	<ul style="list-style-type: none"> • atrm_1020, atrm_1030, atrm_1040 and atrm_1050 were omitted (source doc fields) • atrm_1010D was omitted (description field) • Comment field in atrm_6000 was deleted
P4_AVICA_TRTQX	a_txqx.sas7bdat	atq	AVICA Study Treatment Questionnaire	<ul style="list-style-type: none"> • atxqx_1040D was omitted (description field) • Comment field in atxqx_6000 was deleted

Form Name Abbreviation	Dataset Name	Variable Prefix	Form Name or Description	Field Changes/ Comments
P4_ELIG1	elig1.sas7bdat	e1	INFANT/AVICA Eligibility Checklist 1	<ul style="list-style-type: none"> • e1_1010 (date) was altered as described above • e1_1030 (date) was altered as described above • e1_1320D was omitted (description field) • Comment field in e1_6000 was deleted
P4_ELIG2	elig2.sas7bdat	e2	INFANT/AVICA Eligibility Checklist 2	<ul style="list-style-type: none"> • e2_1170D was omitted (description field) • Comment field in e2_6000 was deleted
P4_ELIG3	elig3.sas7bdat	e3	INFANT/AVICA Eligibility Checklist 3	<ul style="list-style-type: none"> • e3_1090D was omitted (description field) • Comment field in e3_6000 was deleted
P4_ELIG4	elig4.sas7bdat	e4	INFANT/AVICA Eligibility Checklist 4	<ul style="list-style-type: none"> • e4_1190D was omitted (description field) • Comment field in e4_6000 was deleted
P4_ELIG5	elig5.sas7bdat	e5	INFANT/AVICA Eligibility Checklist 5	<ul style="list-style-type: none"> • e5_1150D was omitted (description field) • Comment field in e5_6000 was deleted
P4_INFANT_COMPLY	i_comply.sas7bdat	icp	INFANT Compliance Checklist	<ul style="list-style-type: none"> • Comment field in icmp_6000 was deleted
P4_INFANT_FAIL	i_fail.sas7bdat	ifl	INFANT Failure Form	<ul style="list-style-type: none"> • ifail_1040 (date) was altered as described above • ifail_1050, ifail_1060 and ifail_1070 were omitted (source doc fields) • Comment field in ifail_6000 was deleted
P4_INFANT_TERM	i_term.sas7bdat	itr	Termination of INFANT	<ul style="list-style-type: none"> • itrm_1020, itrm_1030, itrm_1040 and itrm_1050 were omitted (source doc fields) • itrm_1010D was omitted (description field) • Comment field in itrm_6000 was deleted

Form Name Abbreviation	Dataset Name	Variable Prefix	Form Name or Description	Field Changes/ Comments
P4_INFANT_TRTFAIL	i_txfail.sas7bdat	itx	INFANT Treatment Arm Failure	<ul style="list-style-type: none"> • itxf_1010 (date) was altered as described above • itxf_1020, itxf_1030 and itxf_1040 were omitted (source doc fields) • Comment field in itxf_6000 was deleted
P4_INFANT_TRTQX	i_trtqx.sas7bdat	itq	INFANT Study Treatment Questionnaire	<ul style="list-style-type: none"> • itxqx_1050D, itxqx_1100D and itxqx_1170D were omitted (description fields) • Comment field in itxqx_6000 was deleted
P4_LAB	lab.sas7bdat	lab	INFANT Laboratory Results	<ul style="list-style-type: none"> • Comment field in lab_6000 was deleted
P4_PHONE_CONTACT	phone.sas7bdat	phn	INFANT Phone/Visit Symptom Assessment	<ul style="list-style-type: none"> • Comment field in phn_6000 was deleted
P4_PRED	pred.sas7bdat	pr	INFANT Prednisolone Medication Form	<ul style="list-style-type: none"> • pred_1000 (date) was altered as described above • Comment field in pred_6000 was deleted

Form Name Abbreviation	Dataset Name	Variable Prefix	Form Name or Description	Field Changes/ Comments
P4_SPIROTEL_CREF	spirotel.sas7bdat	dry	INFANT spirotel® Coordinator Reference Card	<ul style="list-style-type: none"> • This dataset contains the diary data collected by the Spirotel device. Participants were asked to complete diary questions once per day. • Diary variables begin with the dry prefix. They are numbered according to the questions on the reference card. For example, spr_1 corresponds to “Did your child have any asthma symptoms today?” • 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 downloaded)
P4_TERMR	termr.sas7bdat	trr	INFANT Run-In Termination	<ul style="list-style-type: none"> • trmr_1010, trmr_1020, trmr_1030 and trmr_1040 were omitted (source doc fields) • trmr_1000D was omitted (description field) • Comment field in trmr_6000 was deleted

Table 2. Forms/Procedures Completed at each Study Visit (Visits 1-8, PC)
(a=regular visit procedure; b=completed only as needed)

Form Abbreviation or Procedure Description	Visit Number								
	1	2	3	4	5	6	7	8	PC
AECLIN	b	b	b	b	b	b	b	b	b
ASTHMA_HX_PED	a								
CMED	b	b	b	b	b	b	b	b	b
HEQ	a								
HOUSEHOLD_SEI	a								
IMMUNOCAP		a							
PRIOR_COND_ALL	a								
PRIOR_TRT	a								
Randomization		a							
REGISTRY	a								
SERIOUS	b	b	b	b	b	b	b	b	
LEXAM_PED	a								
SEXAM_PED		a	a	a	a	a	a	a	
P4_AVICA_COMPLY			a	a	a	a	a	a	
P4_AVICA_DIARY			a	a	a	a	a	a	
P4_AVICA_TERM		b	b	b	b	b	b	b	
P4_AVICA_TRTQX		b	b	b	b	b	b	b	
P4_ELIG1	a								
P4_ELIG2	a								
P4_ELIG3	a								

Form Abbreviation or Procedure Description	Visit Number								
	1	2	3	4	5	6	7	8	PC
P4_ELIG4		a							
P4_ELIG5		a							
P4_INFANT_COMPLY		a	a	a	a	a	a	a	
P4_INFANT_FAIL		b	b	b	b	b	b	b	
P4_INFANT_TERM		b	b	b	b	b	b	b	
P4_INFANT_TRTFAIL		b	b	b	b	b	b	b	
P4_INFANT_TRTQX		b	b	b	b	b	b	b	
P4_LAB		a	b	b	b	b	b	b	
P4_PHONE_CONTACT			a	a	a	a	a	a	a
P4_PRED			b	b	b	b	b	b	b
P4_SPIROTEL (e-diary data)		a	a	a	a	a	a	a	
P4_TERMR	a	a							