AsthmaNet BARD STUDY FORMS AND DATASETS

Referencing the BARD Study Forms and Datasets

Annotated BARD case report forms (CRFs) are included on the enclosed CD in pdf format (BARD_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 'P5_' prefix, and some do not. As a general rule, data corresponding to each CRF are stored in a data file of the same name. 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 BARD 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 BARD 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_c), visit/current date (vdate), and technician/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 0A (initial screen visit).
- All technician/coordinator IDs were omitted.

All dates collected within a given CRF were converted to intervals representing the number of days from the participant's Visit 0A. 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, aaq_1070, aaq_1080, aaq_1090 from the Acute Asthma Assessment Questionnaire (AAAQ 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.

The 'vnum_c' variable is a character variable representing the visit numbers as outlined in the protocol. 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:

vnum_c	vnum	Visit Name
0A	0.1	Screen Visit A
0A1	0.11	Screen Visit A1
0B	0.2	Screen Visit B
0C	0.3	Screen Visit C
0D	0.4	Screen Visit D

For the remainder of the visits (Visit 1 and beyond), the 'vnum_c' and 'vnum' values are identical.

Background

This protocol was a prospective, randomized 66-week cross-over trial in both individuals 12 years of age and older and children (5-11 years of age) with inadequately-controlled asthma on low dose ICS. In individuals aged 12 and older, we compared the effectiveness of a) adding a LABA or b) increasing ICS dose 2.5 fold or c) increasing ICS dose 5 fold or d) adding a LABA and increasing ICS dose 2.5 fold**.** In children aged 5-11, we compared the effectiveness of a) increasing ICS 2 fold b) increasing ICS

2 fold and adding a LABA c) increasing ICS 5 fold and d) increasing ICS 5 fold and adding a LABA**.** Our goal was to identify the best option for add-on therapy in Blacks and to determine whether the response in Black individuals aged 12 or greater differs from that of Black children aged 5-11. These trials were not precisely the same due to dosage restrictions in children and medication availability. Our goal was to create core parallels that would allow us to examine whether these age groups differ significantly in their patterns of response to add-on therapy, specifically the dose response of ICS and the impact of adding LABA to increased ICS therapy.

The primary hypotheses of the BARD trial for adults/adolescents ≥ 12 were:

1. In Black adults and adolescents with inadequately controlled asthma on low-dose ICS alone, the addition of LABA will not be more efficacious than increased doses of ICS in improving asthma control, regardless of the dose of ICS used with the LABA.
2. A preference for LABA vs. ICS in Blacks in the study will be associated with a lesser degree of African ancestry (%African Black versus %European White) as determined by genetic markers of African ancestry.

The primary hypotheses of the BARD trial for children 5-11 years ≥ 12 were:

1. In Black children with inadequately controlled asthma on low-dose ICS alone, the addition of LABA will not be more efficacious than increased doses of ICS in improving asthma control.
2. A preference for LABA vs. ICS in Black children will be associated with a lesser degree of African ancestry (%African Black versus %European White) as determined by genetic markers of African ancestry.

Five hundred and thirty-six adolescents/adults and four hundred and eighty-two children were enrolled in the run-in period. Two hundred and ninety-four adolescents/adults and two hundred and eighty children were randomized at Visit 1.

The ‘age_track’ variable (available in most datasets) identifies which age group track an individual was enrolled in (‘Children (5-11)’ vs ‘Adolescent (12-17)’ vs ‘Adult (18+)’).

Table 1. BARD Forms and Datasets

Form Name Abbreviation	Dataset Name	Prefix	Form Name or Description	Field Changes/ Comments
AAAQ	aaaq.sas7bdat	aaq	Acute Asthma Assessment Questionnaire	• aaq_1060D was omitted (description field) • aaq_1070, abp_1080, abp_1090 were omitted (source doc fields)
ACQ7	acq7.sas7bdat	acq	Asthma Control Questionnaire	• Dataset variables are numbered according to question numbers on form
ACT	act.sas7bdat	act	Asthma Control Test	• Dataset variables are numbered according to question numbers on form
AECLIN	aeclin.sas7bdat	aec	Clinical Adverse Events	• 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: - icd9_cat: ICD-9 category - icd9_long_desc: Full description of ICD-9 code - icd9_short_desc: 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.
AQLQ_12	aqlq_12.sas7bdat	aqa	Asthma Quality of Life Questionnaire with Standardised Activities	• • Dataset variables are numbered according to question numbers on form

Form Name Abbreviation	Dataset Name	Prefix	Form Name or Description	Field Changes/ Comments
ASTHMA_HX_ADULT	asthma_hx_adult.sas7bdat	aha	Adult Asthma and Allergy History	• Date intervals for the vape/hookah date in Question 16b (aha_1860, aha_1870, aha_1880) were stored in variable date_q16b. 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). • aha_1400D, aha_1410D, aha_1420D, aha_1460D were omitted (description fields) • Comment field in aha_6000 was deleted
ASTHMA_HX_PED	asthma_hx_ped.sas7bdat	ahp	Pediatric Asthma and Allergy History	• ahp_1400D, ahp_1410D, ahp_1420D, ahp_1460D, ahp_1560D were omitted (description fields) • Comment field in ahp_6000 was deleted
BODYMEAS_ADULT	bodymeas_adult.sas7bdat	bma	Adult Body Measurements	• Comment field in bma_6000 was deleted
CACT	cact.sas7bdat	cac	Childhood Asthma Control Test for children 4 to 11 years old	• Dataset variables are numbered according to question numbers on form
CMED	cmed.sas7bdat	cme	Concomitant Medications for Asthma/Allergy and Adverse Events	• 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: - class_text: drug class text - class_id: class ID number

Form Name Abbreviation	Dataset Name	Prefix	Form Name or Description	Field Changes/ Comments
				- gen_drug_name: generic drug name - route_text (formatted values of cme_1055) - unit_text (formatted values of cme_1040) - freq_text (formatted values of cme_1050) • 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)
CMED_REF			Units, Frequency, and Route Codes for Use on the Concomitant Medications for Asthma/Allergy and Adverse Events Form (CMED)	
COLD_HX	cold_hx.sas7bdat	chx	Cold History	• chx_1000D was omitted (description field) • Comment field in chx_6000 was deleted
	cortisol_creatinine.sas7bdat		Urine cortisol and urine creatinine lab values obtained from ADx Lab	File includes the following variables: • part_id • vnum (any values occurring prior to visit 1 have been assigned vnum=1 for ease of pulling off the baseline (vnum 1) values) • vnum_c • cortisol (mcg/dL) • creatinine (mcg/dL) • cortisol_censor (1=censored, 0=not

Form Name Abbreviation	Dataset Name	Prefix	Form Name or Description	Field Changes/ Comments
				censored) • creatinine_censor (1=censored, 0=not censored) Original cortisol values of '<1.0' have been reset to '1' and have cortisol_censor=1. Original cortisol values of '<2.0' have been reset to '2' and have cortisol_censor=1. Original creatinine values of '<1.0' have been reset to '1' and have creatinine_censor='1'. Per ADx Lab contact: The reason some samples had higher censoring values ('<1' vs '<2') is because some of the samples had to be diluted due to insufficient volume. Per ADx Lab contact: Cortisol values of 0 represent situations in which there was no detectable cortisol in the sample.
	cortisol_creatinine.sas7bdat (continued)		Urine cortisol and urine creatinine lab values obtained from ADx Lab	Any end-of-treatment-period cortisol or creatinine values that occurred after a treatment failure or late-period exacerbation in that treatment period have been removed.
	cotinine.sas7bdat		Serum cotinine lab values obtained from ADx Lab	File includes the following variables: • part_id • vnum (all records have vnum=1) • vnum_c • cotinine (ng/mL) • pos_neg ('POS': cotinine>=5, 'NEG': cotinine <5)

Form Name Abbreviation	Dataset Name	Prefix	Form Name or Description	Field Changes/ Comments
HEQ	heq.sas7bdat	heq	Home Environment Questionnaire	• 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	household_sei.sas7bdat	sei	Household Socio-Economic Information	• 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.
	immunocapige.sas7bdat		Serum ImmunoCAP allergen and IgE lab values obtained from ADx Lab	File includes the following variables: • part_id • vnum (all records have vnum=1) • vnum_c • test_code (allergen test code) • test_name (allergen test name) • test_result (allergen test result) Units for IgE are IU/mL. Units for ImmunoCAP allergens are kU/L.
LEXAM_PED	lexam_ped.sas7bdat	ple	Pediatric Long Physical Exam	• ple_1120D was deleted (description field) • Comment field in ple_6000 was deleted
METHA	metha.sas7bdat	mth	Methacholine Challenge Testing	• Comment field in mth_6000 was deleted
METHACHK_ADULT	methachk_adult.sas7bdat	mca	Adult Methacholine Challenge Testing Checklist	• mca_1100D was omitted (description field) • Comment field in mca_6000 was deleted

Form Name Abbreviation	Dataset Name	Prefix	Form Name or Description	Field Changes/ Comments
METHACHK_PED	methachk_ped.sas7bdat	mcp	Pediatric Methacholine Challenge Testing Checklist	• mcp_1100D was omitted (description field) • Comment field in mcp_6000 was deleted
METHA_ADD_TRT	metha_add_trt.sas7bdat	mad	Additional Treatment Post Methacholine Challenge Testing	• mad_1240, mad_1250, mad_1260 were omitted (source doc fields) • mad_1060D, mad_1190D were omitted (description fields) • Comment field in mad_6000 was deleted
PALB4_SPIRO	palb4_spiro.sas7bdat	pa4	Post-Albuterol (4 puffs) Spirometry Testing	• Comment field in pa4_6000 was deleted
PAQLQS	paqlqs.sas7bdat	aqp	Paediatric Asthma Quality of Life Questionnaire with Standardised Activities	• Dataset variables are numbered according to question numbers on form under each section
PEDSQL	pedsql.sas7bdat	See Field Changes column	Pediatric Quality of Life Inventory	• Dataset variables are numbered according to question numbers on form under each section (using prefix corresponding to each section): PHYSICAL_1 to PHYSICAL_8 EMOTIONAL_1 to EMOTIONAL_5 SOCIAL_1 to SOCIAL_5 SCHOOL_1 to SCHOOL_5
PREG_TEST	preg_test.sas7bdat	prg	Urine Pregnancy Test	• prg_1050, prg_1060 were omitted (source doc fields) • Comment field in prg_6000 was deleted
PRIOR_COND_ADULT	prior_cond_adult.sas7bdat	pad	Prior Conditions for Adult Participants	• pad_1000D, pad_1010D, pad_1020D, pad_1030D, pad_1040D, pad_1050D,

Form Name Abbreviation	Dataset Name	Prefix	Form Name or Description	Field Changes/ Comments
				pad_1060D, pad_1070D, pad_1080D, pad_1090D, pad_1100D, pad_1110D, pad_1120D were omitted (description fields) • Comment field in pad_6000 was deleted
PRIOR_COND_ALL	prior_cond_all.sas7bdat	pal	Prior Conditions for All Participants	• 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	prior_trt.sas7bdat	ptr	Prior Asthma/Allergy Treatment	• 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).
PRIOR_TRT_CARD			Prior Asthma/Allergy Treatment Form Reference Card	
PSS_10	pss_10.sas7bdat	p10	Perceived Stress Scale	• p10_1100, p10_1110, p10_1120 were omitted (source doc fields)
RAND_IAQL_12	rand_iaql_12.sas7bdat	iaq	RAND Impact of Asthma on QOL SF-12	• iaq_1120, iaq_1130, iaq_1140 were omitted (source doc fields)
	regimen.sas7bdat		Randomized	File contains the following variables:

Form Name Abbreviation	Dataset Name	Prefix	Form Name or Description	Field Changes/ Comments
			treatment assignments	• part_id • age_track • regimen_per1 (unblinded treatment assignment for period 1) • regimen_per2 (unblinded treatment assignment for period 2) • regimen_per3 (unblinded treatment assignment for period 3) • regimen_per4 (unblinded treatment assignment for period 4)
REGISTRY	registry.sas7bdat	reg	AsthmaNet Registry Form	• site_reg variable was omitted • reg_1020, reg_1040, reg_1060 (dates) were altered as described above • reg_1070 (birth date) was omitted; the participant's age at visit 0A was calculated and is stored in variable 'age' (as a whole number) • individual race variables have been omitted (reg_1100, reg_1110, reg_1120, reg_1130, reg_1140) due to sparseness for some of the variables • reg_1150 (primary racial identification) has been re-coded due to sparseness such that those who were in categories 1, 2, 4, 5 and 6 are included in the 'other' category (code 6) • reg_1160 (description for the 'other' race category was omitted

Form Name Abbreviation	Dataset Name	Prefix	Form Name or Description	Field Changes/ Comments
SERIOUS	serious.sas7bdat	ser	Serious Adverse Event Reporting Form	• 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
SEXAM_PED	sexam_ped.sas7bdat	pse	Pediatric Short Physical Exam	• pse_1120D was omitted (description field) • Comment field in pse_6000 was deleted
SPIRO	spiro.sas7bdat	spi	Spirometry Testing	• Comment field in spi_6000 was deleted
SPUTREAD	sputread.sas7bdat	sre	Sputum Induction Read	• sre_1000 (date) was altered as described above • Comment field in sre_6000 was deleted • Cell counts were performed by a central overreader
SPUTUM	sputum.sas7bdat	spu	Sputum Induction	• Comment field in spu_6000 was deleted
SPUTUMCHK	sputumchk.sas7bdat	sch	Sputum Induction Checklist	• sch_1060D was omitted (description field) • Comment field in sch_6000 was deleted
SPUTUM_ADD_TRT	sputum_add_trt.sas7bdat	sad	Additional Treatment Post Sputum Induction	• sad_1080, sad_1090, sad_1100 were omitted (source doc fields)
WPAI_ASTHMA	wpai_asthma.sas7bdat	wpa	Asthma-Specific Work Productivity and Activity Impairment Questionnaire	• wpa_1090, wpa_1100, wpa_1110 were omitted (source doc fields)
P5_COMPLY	p5_comply.sas7bdat	com	BARD Compliance Checklist	• Comment field in com_6000 was deleted
P5_CONTACT	p5_contact.sas7bdat	cnt	BARD Contact Form Visits 1-13	• cnt_1000D, cnt_1020D, cnt_1140D, cnt_1200D, cnt_1210D, cnt_1220D were omitted (description fields)

Form Name Abbreviation	Dataset Name	Prefix	Form Name or Description	Field Changes/ Comments
				• Comment field in com_6000 was deleted
P5_CTXQX	p5_ctxqx.sas7bdat	ctx	BARD Coordinator Study Treatment Questionnaire (Visits 1-13)	• ctx_1030, ctx_1040 were omitted (source doc fields) • Comment field in ctx_1020D was deleted
P5_ELIG1	p5_elig1.sas7bdat	e1	BARD Eligibility Checklist 1	• e1_1010 (date) was altered as described above • e1_1140, e1_1150 were omitted (source doc fields) • Comment field in e1_6000 was deleted
P5_ELIG2	p5_elig2.sas7bdat	e2	BARD Eligibility Checklist 2	• e2_1210, e2_1220 were omitted (source doc fields) • e2_1160D, e2_1180D, e2_1190D were omitted (description fields) • Comment field in e2_6000 was deleted
P5_ELIG3	p5_elig3.sas7bdat	e3	BARD Eligibility Checklist 3	• e3_1130, e3_1180, e3_1220, e3_1270 (dates) were altered as described above • e3_1140, e3_1150, e3_1190, e3_1200, e3_1230, e3_1240, e3_1280, e3_1290 were omitted (tech/supervisor ID fields) • Comment field in e3_6000 was deleted
P5_ELIG4	p5_elig4.sas7bdat	e4	BARD Eligibility Checklist 4	• Comment field in e4_6000 was deleted
P5_ELIG5	p5_elig5.sas7bdat	e5	BARD Eligibility Checklist 5	• e5_1000D, e5_1020D were omitted (description fields) • Comment field in e5_6000 was deleted
P5_LAB	p5_lab.sas7bdat	lab	BARD Laboratory Results	• Comment field in lab_6000 was deleted • lab_1030, lab_1040, lab_1050, lab_1060, lab_1070, lab_1080, lab_1090, lab_1100,

Form Name Abbreviation	Dataset Name	Prefix	Form Name or Description	Field Changes/ Comments
				lab_1110, lab_1120, lab_1130, lab_1140, lab_1150, lab_1160 were omitted • ImmunoCAP/IgE measurements are located in the immunocapige.sas7bdat dataset • Cotinine measurements are located in the cotinine.sas7bdat dataset • Urine Cortisol and Creatinine measurements are located in the cortisol_creatinine.sas7bdat dataset
P5_PARTTXQX	p5_parttxqx.sas7bdat	ptx	BARD Participant Study Treatment Questionnaire (Visits 1-13)	• ptx_1040, ptx_1050 were omitted (source doc fields) • ptx_1000D was omitted (description field) • Comment field in ptx_1030D was deleted
	p5_pef_ref.sas7bdat	ref	BARD Spirotel Reference Peak Flow Report	• ref_1000 represents the reference PEF value that was to be programmed into participant's spirotel at current visit and to be used as the PEF_REF value in participant's spirotel until the next visit
P5_PULMONARYCHK	p5_pulmonarychk.sas7bdat	pch	BARD Pulmonary Procedure Checklist	• pch_1140D was omitted (description field) • Comment field in pch_6000 was deleted
P5_RAND_ELIG	p5_rand_elig.sas7bdat	rnd	BARD Randomization Eligibility Checklist	• rnd_1010 (date) was altered as described above • Comment field in rnd_6000 was deleted
P5_SIGEX	p5_sigex.sas7bdat	sig	BARD Significant Asthma Exacerbation	• sig_1030, sig_1260 (dates) were altered as described above • sig_1270, sig_1280, sig_1290 were omitted (source doc fields) • sig_1110D was omitted (description field)

Form Name Abbreviation	Dataset Name	Prefix	Form Name or Description	Field Changes/ Comments
				• Comment field in sig_6000 was deleted
P5_SPIROTEL_REF			BARD spirotel Reference Card	• This reference card shows the symptom score scale associated with the following variables captured by the Spirotel® device and stored in the p5_spirotel.sas7bdat dataset: dry_4 dry_5 dry_6 dry_7 dry_8 dry_11 dry_12 dry_13 dry_14 dry_15 • See also P5_SPIROTEL_CREF form information below
P5_SPIROTEL_CREF	p5_spirotel.sas7bdat	dry	BARD spirotel® Coordinator Reference Card	• This dataset contains the diary and peak flow (PEF) maneuver data collected by the Spirotel device. FEF_{25-75}, FET, FEV_1, 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.

Form Name Abbreviation	Dataset Name	Prefix	Form Name or Description	Field Changes/ Comments
				• 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: - ddate: date on which the diary was completed - vdate: date of the participant's next clinic visit (at which data were typically downloaded)
P5_SPIROTEL_CREF (continued)	p5_spirotel.sas7bdat	dry	BARD spirotel® Coordinator Reference Card	• Variables representing the various maneuvers are as follows (and are not found on the reference card): - am_fef2575: morning session FEF_{25-75} - am_fet: morning session FET - am_fev1: morning session FEV_1 - am_fvc: morning session FVC - am_pef: morning session PEF - pm_fef2575: evening session FEF_{25-75} - pm_fet: evening session FET - pm_fev1: evening session FEV_1 - pm_fvc: evening session FVC - pm_pef: evening session PEF • This dataset has been modified such that

Form Name Abbreviation	Dataset Name	Prefix	Form Name or Description	Field Changes/ Comments
				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.) • Variable PEF_REF represents the participant's reference peak flow value used to determine lack of acceptable asthma control during run-in and to establish green, yellow, and red zones as part of participant's Asthma Action Plan.
P5_STEPDOWN_ASSESS	p5_stepdown_assess.sas7bdat	spd	BARD ICS Step-Down Assessment	• Comment field spd_6000 was deleted
P5_TERM	p5_term.sas7bdat	ter	BARD Termination of Study Participation (Visits 0A-0D and 1-13)	• ter_1050 (date) was altered as described above • ter_1250, ter_1260, ter_1270, ter_1280 were omitted (source doc fields) • ter_1020D, ter_1230D were omitted (description fields)

Table 2. Forms/Procedures Completed at each Study Visit (Visits 0A-0D, 1-13)
(•=regular visit procedure; ❍=completed only as needed)

Form Abbreviation or Procedure Description	Visit Number																	
	0A	0A1	0B	0C	0D	1	2	3	4	5	6	7	8	9	10	11	12	13
AAAQ (12-17, 18+)	•	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍
ACQ7		•																
ACT (12-17, 18+)	•		•			•	•	•	•	•	•	•	•	•	•	•	•	•
AECLIN	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍
AQLQ_12 (12-17, 18+)	•					•			•			•			•			•
ASTHMA_HX_ADULT (12-17, 18+)	•																	
ASTHMA_HX_PED (5-11)	•																	
BODYMEAS_ADULT (18+)	•																	•
CACT (5-11)	•		•			•	•	•	•	•	•	•	•	•	•	•	•	•
CMED	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍
COLD_HX	•																	
HEQ						❍	•		❍									
HOUSEHOLD_SEI						•												
LEXAM_PED (5-11, 12-17)	•																	•
METHA			•	❍	❍	❍												
METHACHK_ADULT (18+)			•	❍	❍	❍												
METHACHK_PED (5-11, 12-17)			•	❍	❍	❍												
METHA_ADD_TRT			❍	❍	❍	❍												
PALB4_SPIRO (5-11)	•								•			•			•			•
PALB4_SPIRO (12-17, 18+)	•					•			•			•			•			•
PAQLQS (5-11)	•					•			•			•			•			•
PEDSQL (5-11)	•					•			•			•			•			•

Form Abbreviation or Procedure Description	Visit Number																	
	0A	0A1	0B	0C	0D	1	2	3	4	5	6	7	8	9	10	11	12	13
PREG_TEST			❍	❍	❍	❍			❍			❍			❍			❍
PRIOR_COND_ADULT (18+)	•																	
PRIOR_COND_ALL	•																	
PRIOR_TRT	•																	
PSS_10 (12-17, 18+)						•												
RAND_IAQL_12 (12-17, 18+)	•					•			•			•			•			•
REGISTRY	•																	
SERIOUS	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍
SEXAM_PED (5-11, 12-17)		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	
SPIRO	•	•	•	❍	❍	•	•	•	•	•	•	•	•	•	•	•	•	•
SPUTREAD (12-17, 18+)						❍												
SPUTUM (12-17, 18+)						•												
SPUTUMCHK (12-17, 18+)						•												
SPUTUM_ADD_TRT (12-17, 18+)						❍												
WPAI_ASTHMA (12-17, 18+)	•	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍
P5_COMPLY		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
P5_CONTACT						•	•	•	•	•	•	•	•	•	•	•	•	•
P5_CTXQX						❍	❍	❍	•	❍	❍	•	❍	❍	•	❍	❍	•
P5_ELIG1	•																	
P5_ELIG2	•																	
P5_ELIG3	•																	
P5_ELIG4			•															
P5_ELIG5						•												
P5_LAB				•	•	•			•			•			•			•

Form Abbreviation or Procedure Description	Visit Number																	
	0A	0A1	0B	0C	0D	1	2	3	4	5	6	7	8	9	10	11	12	13
P5_PARTTXQX						❍	❍	❍	•	❍	❍	•	❍	❍	•	❍	❍	•
P5_PEF_REF (5-11, 12-17)	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	
P5_PEF_REF (18+)	•	•	•	•	•	•	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	
P5_PULMONARYCHK	•	•	•	❍	❍	•	•	•	•	•	•	•	•	•	•	•	•	•
P5_RAND_ELIG			•	•	•	•												
P5_SIGEX	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍
P5_SPIROTEL		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
P5_STEPDOWN_ASSESS		•																
P5_TERM	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	•