Part. ID: _ _
Part. Initials:
Visit:
Visit Date: / / 2 0
Coordinator ID:

Asthma Control Test™

This survey was designed to help you describe your asthma and how your asthma affects how you feel and what you are able to do. To complete it, please mark an ☒ in the one box that best describes your answer.

1. In the <u>past 4 weeks</u>, how much of the time did your <u>asthma</u> keep you from getting as much done at work, school or at home?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐1	☐2	☐3	☐4	☐5

2. During the <u>past 4 weeks</u>, how often have you had shortness of breath?

More than once a day	Once a day	3 to 6 times a week	Once or twice a week	Not at all
☐1	☐2	☐3	☐4	☐5

3. During the <u>past 4 weeks</u>, how often did your <u>asthma</u> symptoms (wheezing, coughing, shortness of breath, chest tightness or pain) wake you up at night or earlier than usual in the morning?

4 or more nights a week	2 to 3 nights a week	Once a week	Once or Twice	Not at all
☐1	☐2	☐3	☐4	☐5

4. During the <u>past 4 weeks,</u> how often have you used your rescue inhaler or nebulizer medication (such as Albuterol, Ventolin®, Proventil®, Maxair® or Primatene Mist®)?

3 or more times per day	1 or 2 times per day	2 or 3 times per week	Once a week or less	Not at all
☐1	☐2	☐3	☐4	☐5

5. How would you rate your <u>asthma</u> control during the <u>past 4 weeks</u>?

Not Controlled at all	Poorly Controlled	Somewhat Controlled	Well Controlled	Completely Controlled
☐1	☐2	☐3	☐4	☐5

To score the ACT

Each response to the 5 ACT questions has a point value from a 1 to 5 as shown on the form. To score the ACT, add up the point values for each response to all five questions.

If your total point value is 19 or below, your asthma may not be well-controlled. Be sure to talk to your healthcare professional about your asthma score.

Take this survey to your healthcare professional and talk about your asthma treatment plan.

* A C T *

AsthmaNet

CLINICAL ADVERSE EVENTS

(Coordinator completed)

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __

Complete this log if the participant experienced any clinical adverse events (including intercurrent events) since the last visit. Check the "None" box if the participant has not experienced any clinical adverse events since the last visit.

❑0 None

* Please complete a Serious Adverse Event Reporting (SERIOUS) form. ** Please complete the appropriate Change in Medications form. *** Please complete the Concomitant Medications (CMED) form.		2. DATE STARTED (Top Line) **(1020)** / 3. DATE STOPPED (Bottom Line) **(1030)**	4. ONGOING at current visit **(1040)**	5. TYPE **(1050)**	6. SEVERITY **(1060)**	7. SERIOUS **(1070)**	8. LIKELIHOOD OF RELATIONSHIP TO STUDY DRUG(S) **(1080)**	9. CHANGE IN STUDY DRUG(S) **(1090)**	10. OUTCOME (Skip if #3 is missing.) **(1100)**	11. TREATMENT REQUIRED **(1110)**	12. ONGOING at final visit **(1120)**
DESCRIPTION OF ADVERSE EVENT **(1000)**	1. ICD9 CODE **(1010)**	MONTH / DAY / YEAR		1 – INTERMITTENT 2 – CONTINUOUS	1 – MILD 2 – MODERATE 3 – SEVERE	1 – YES* 0 – NO	1 – NONE 2 – UNLIKELY (REMOTE) 3 – POSSIBLE 4 – PROBABLE	1 – UNCHANGED 2 – ALTERED**	1 – COMPLETELY RECOVERED 2 – RECOVERED, BUT WITH LASTING EFFECTS 3 – DEATH*	1 – NONE 2 – MEDICATION*** 3 – HOSPITALIZATION* 4 – OTHER	
__ __	_ _ _ . _ _	_ _ / _ _ / 20 _ _ _ _ / _ _ / 20 _ _	❑1								❑1
__ __	_ _ _ . _ _	_ _ / _ _ / 20 _ _ _ _ / _ _ / 20 _ _	❑1								❑1
__ __	_ _ _ . _ _	_ _ / _ _ / 20 _ _ _ _ / _ _ / 20 _ _	❑1								❑1
__ __	_ _ _ . _ _	_ _ / _ _ / 20 _ _ _ _ / _ _ / 20 _ _	❑1								❑1
__ __	_ _ _ . _ _	_ _ / _ _ / 20 _ _ _ _ / _ _ / 20 _ _	❑1								❑1

AsthmaNet

ADULT ASTHMA AND ALLERGY HISTORY

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed by Interview)

ASTHMA HISTORY

1. Approximately how old were you when chest symptoms suggesting asthma first appeared? *(Enter '00' if participant was under 1 year.)* **(1000)** __ __ years

   Did these symptoms appear immediately after or as a result of:

   1a. a respiratory infection such as a cold or pneumonia? **(1020)** ❑1 Yes ❑0 No ❑8 Don't Know

   1b. an occupational or job change? **(1030)** ❑1 Yes ❑0 No ❑8 Don't Know

   1c. a household move? **(1040)** ❑1 Yes ❑0 No ❑8 Don't Know

   ➔ If participant is male, skip to Q2.

   1d. a pregnancy? **(1050)** ❑1 Yes ❑0 No ❑8 Don't Know

   1e. a hormonal change (e.g., menopause)? **(1060)** ❑1 Yes ❑0 No ❑8 Don't Know

2. How old were you when a doctor first diagnosed you with asthma? **(1070)** __ __ years

3. Have any of your immediate blood relatives been told by a physician that they have asthma? *(Check the 'N/A' box if the participant does not have biological siblings or children.)*

   3a. Mother **(1090)** ❑1 Yes ❑0 No ❑8 Don't Know

   3b. Father **(1100)** ❑1 Yes ❑0 No ❑8 Don't Know

   3c. Brother(s) or Sister(s) **(1110)**
   ❑1 Yes
   ❑0 No
   ❑8 Don't Know
   ❑9 N/A

   3d. Child(ren) **(1120)**
   ❑1 Yes
   ❑0 No
   ❑8 Don't Know
   ❑9 N/A

ASTHMA SYMPTOMS

4. How do you categorize your asthma symptoms throughout the course of the year? **(1130)** ❑1 Relatively the same all year ❑2 Vary by season(s)
   ➔ If 'Vary by season(s)', do your asthma symptoms worsen during the…

   4a. Winter? **(1140)** ❑1 Yes ❑0 No

   4b. Spring? **(1150)** ❑1 Yes ❑0 No

   4c. Summer? **(1160)** ❑1 Yes ❑0 No

   4d. Fall? **(1170)** ❑1 Yes ❑0 No

5. In the last 12 months, how many... *(Enter '00' if none)*

   5a. Asthma episodes have you had that required emergency care or an unscheduled office visit? **(1180)** __ __ episodes

   5b. Overnight hospitalizations have you had due to asthma? **(1190)** __ __ hospitalizations

   5c. Courses of systemic corticosteroid therapy (e.g., prednisone, IM, IV) for asthma have you taken? **(1200)** __ __ courses

   5d. Days of work, school, or housework have you missed due to asthma? **(1210)** __ __ __ days
   ➔ If Q5d > 0, complete Q5di.

   5di. In the past 3 months, how many days of work, school, or housework have you missed due to asthma? **(1220)** __ __ days

6. Have you ever been admitted to an intensive care unit for asthma? **(1250)** ❑1 Yes ❑0 No
   ➔ If ***NO***, skip to Q7.

   6a. How many times have you been admitted to an intensive care unit for asthma? **(1260)** __ __

   6b. Have you ever had invasive mechanical ventilation? **(1270)** ❑1 Yes ❑0 No ❑8 Don't Know

   6c. Have you ever had non-invasive mechanical ventilation? **(1280)** ❑1 Yes ❑0 No ❑8 Don't Know

ASTHMA TRIGGERS

7. Do any of the following currently provoke your asthma?

7a.	Exercise/Sports/Play	(1290)	❑1 Yes	❑0 No	❑8 Don't Know
7b.	Menstrual cycle *(If participant is male or a postmenopausal female, leave blank.)*	(1300)	❑1 Yes	❑0 No	❑8 Don't Know
7c.	Aspirin or non-steroidal anti-inflammatory drugs (e.g., Aleve, Motrin)	(1310)	❑1 Yes	❑0 No	❑8 Don't Know
7d.	Respiratory infections (e.g., colds)	(1320)	❑1 Yes	❑0 No	❑8 Don't Know
7e.	Irritants (e.g., pollution, odors, perfumes, chemicals, household cleaners)	(1330)	❑1 Yes	❑0 No	❑8 Don't Know
7f.	Weather conditions (e.g., change in weather, humidity)	(1340)	❑1 Yes	❑0 No	❑8 Don't Know
7g.	Exposure to cold air	(1350)	❑1 Yes	❑0 No	❑8 Don't Know
7h.	Emotional factors (e.g., stress, laughing)	(1360)	❑1 Yes	❑0 No	❑8 Don't Know
7i.	Tobacco smoke	(1370)	❑1 Yes	❑0 No	❑8 Don't Know
7j.	Food additives/preservatives (e.g., MSG, sulfites)	(1380)	❑1 Yes	❑0 No	❑8 Don't Know
7k.	Allergies (e.g., dust, animals, pollens)	(1390)	❑1 Yes	❑0 No	❑8 Don't Know
7l.	Other	(1400)	❑1 Yes	❑0 No	
	If ***YES***, please specify	(1400D)	_____		

ALLERGIES

8. To which of the following did a doctor or other health practitioner say you were allergic?

8a.	Medicines	(1410)	❑1 Yes	❑0 No	❑8 Don't Know
	If ***YES***, please list:	(1410D)	_____		
			_____		

8b. Foods (1420) ❑1 Yes ❑0 No ❑8 Don't Know

If ***YES***, please list: (1420D) _____

_____

8c. Things you breathe in or are exposed to (e.g., dust, pollens, molds, animal fur, feathers, dander) (1430) ❑1 Yes ❑0 No ❑8 Don't Know

8d. Stinging insects such as bees or wasps (1440) ❑1 Yes ❑0 No ❑8 Don't Know

8e. Latex (1450) ❑1 Yes ❑0 No ❑8 Don't Know

8f. Other (1460) ❑1 Yes ❑0 No

If ***YES***, describe: (1460D) _____

_____

9. Have you ever had eczema / atopic dermatitis (i.e., prolonged itchy, scaly skin rash)? (1470) ❑1 Yes ❑0 No ❑8 Don't Know

9a. If ***YES***, was your eczema diagnosed by a doctor? (1500) ❑1 Yes ❑0 No

10. Have any of your immediate blood relatives been told by a physician that they have allergies/eczema/hay fever?
(Check the 'N/A' box if the participant does not have biological siblings or children.)

10a. Mother (1570) ❑1 Yes ❑0 No ❑8 Don't Know

10b. Father (1580) ❑1 Yes ❑0 No ❑8 Don't Know

10c. Brother(s) or Sister(s) (1590)
❑1 Yes
❑0 No
❑8 Don't Know
❑9 N/A

10d. Child(ren) (1600)
❑1 Yes
❑0 No
❑8 Don't Know
❑9 N/A

SMOKING HISTORY

11. Did you grow up in a household where you were exposed to tobacco smoke? **(1730)** ❑$_1$ Yes ❑$_0$ No

12. Do you currently smoke? **(1740)** ❑$_1$ Yes ❑$_0$ No
    ➔ If ***NO***, skip to Q13.

    12a. Record smoking history in pack-years*. **(1750)** __ __ . __ pack-years

    ➔ **STOP HERE.**

13. Were you ever a smoker? **(1760)** ❑$_1$ Yes ❑$_0$ No
    ➔ If ***NO***, skip to Q14.

    13a. Record smoking history in pack-years*. **(1770)** __ __ . __ pack-years

14. Do you currently live in a household where you are exposed to tobacco smoke? **(1780)** ❑$_1$ Yes ❑$_0$ No

COMMENTS: **(6000)**

_____

_____

_____

*Pack-years = # packs per day X # years smoked at that quantity (1 pack contains 20 cigarettes)

AsthmaNet

CONCOMITANT MEDICATIONS FOR ASTHMA/ALLERGY AND ADVERSE EVENTS

(Coordinator completed)

Part. ID: __ __ - __ __ __ - __ __ __

Part. Initials: __ __ __

Visit: __ __ __

Instructions: Since signing the informed consent or last study visit, list all prescription and over-the-counter (OTC) concomitant medications used to treat asthma/allergy symptoms and adverse events. Do not list routine use of study drugs or rescue medications. Check the "None" box if the participant has not started taking any medications since signing the informed consent or last study visit. If the medication is not related to an adverse or laboratory event, leave the event number missing and check the "N/A" box. If the participant is still taking the medication at the end of the current visit, check the "ongoing at current visit" check box and leave the stop date missing. All ongoing medications should be reviewed at subsequent visits to document the stop date of a medication. At the last study visit or an early termination visit, review all ongoing medication and indicate a stop date or check the "ongoing at final visit" check box on the data collection forms and update the medication data in the AsthmaNet data entry application.

At the final study visit or early termination visit, forward all concomitant medications for asthma/allergy and adverse event-related medications forms to the DCC.

❑0 None

NAME OF MEDICATION (1000)	CODE (1010)	RELATED EVENT (1020)	DOSE (1030)	UNITS (1040)	FREQUENCY (1050)	ROUTE (1055)	START DATE (MM/DD/YYYY) (1060)	STOP DATE (MM/DD/YYYY) (1070)	ONGOING AT CURRENT VISIT (1080)	ONGOING AT FINAL VISIT (1090)
— —		Event __ __ ❑0 NA					__ / __ / ____	__ / __ / ____	❑1	❑1
— —		Event __ __ ❑0 NA					__ / __ / ____	__ / __ / ____	❑1	❑1
— —		Event __ __ ❑0 NA					__ / __ / ____	__ / __ / ____	❑1	❑1
— —		Event __ __ ❑0 NA					__ / __ / ____	__ / __ / ____	❑1	❑1
— —		Event __ __ ❑0 NA					__ / __ / ____	__ / __ / ____	❑1	❑1
— —		Event __ __ ❑0 NA					__ / __ / ____	__ / __ / ____	❑1	❑1

UNITS, FREQUENCY, AND ROUTE CODES FOR USE ON THE CONCOMITANT MEDICATIONS FOR ASTHMA/ALLERGY AND ADVERSE EVENTS FORM (CMED)

AsthmaNet

Codes for Units (Q1040)	
Code	Units
1	mg
2	mcg (µg)
3	ml
4	mg/ml
5	mEq
6	g
7	U
8	teaspoon
9	tablespoon
10	patch
11	puffs (oral inhalation)
12	nasal spray
13	packet
14	1 drop
15	mm
16	percent
98	no units
99	other

Codes for Frequency (Q1050)		
Code	Frequency	
1	QD	1 time a day
2	BID	2 times a day
3	TID	3 times a day
4	QID	4 times a day
5	q4h	every 4 hours
6	q5h	every 5 hours
7	q6h	every 6 hours
8	q8h	every 8 hours
9	q12h	every 12 hours
10	q24h	every 24 hours
11	hs	every night at bedtime
12	PRN	as required
13	qod	every other day
14	qw	once a week
15	biw	2 times per week
16	tiw	3 times per week
17	5 times per week	
18	every 5 days	
19	once a month	
20	taper dose	
99	other	

Codes for Route (Q1055)	
Route	Route Desc
1	Epidural Injection
2	External/Topical
3	Inhalation
4	Intraarterial Injection
5	Intraarticular/Intracapsular Injection
6	Intramuscular Injection – IM
7	Intrathecal Injection
8	Intravenous Injection – IV
9	Medicated Gums
10	Misc. Injection
11	Nasal
12	Nebulization
13	Ophthalmic
14	Oral
15	Otic
16	Patch
17	Rectal
18	Subcutaneous Injection – SQ
19	Sublingual
20	Swallowed
21	Urological
22	Vaginal

AsthmaNet	EXHALED NITRIC OXIDE Supervisor ID: __ __ __ __	Part. ID: __ __ - __ __ __ - __ __ __ Part. Initials: __ __ __ Visit: __ __ __ Visit Date: __ __ / __ __ / 20 __ __ Technician ID: __ __ __ __

(Technician Completed)

ENO must be performed prior to any pulmonary function testing. Complete this form only if the participant is eligible according to the appropriate Pulmonary Procedure Checklist form.

1. Has QC procedure been performed on the NIOX MINO® today? **(1000)** ❑$_1$ Yes ❑$_0$ No

   ➔ If ***NO,*** please specify the reason QC was not performed in Q6000.

2. Did the participant eat or drink within the past hour? **(1010)** ❑$_1$ Yes ❑$_0$ No

3. Did the participant take part in strenuous activity/exercise within the past hour? **(1020)** ❑$_1$ Yes ❑$_0$ No

4. Time eNO started *(based on a 24-hour clock)* **(1040)** __ __ __ __

5. ENO Measurement **(1050)** __ __ __ ppb

COMMENTS: **(6000)**

_____

_____

_____

* E N O *

AsthmaNet

HOME ENVIRONMENT QUESTIONNAIRE

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed by Interview)

Note: If you are a parent or guardian responding for a child, "you" is referring to the child who is the study participant.

1. Who is the respondent?

(1000) ❑1 Self/Participant
❑2 Parent/Guardian
❑3 Other (specify)
(1000D) _____

GENERAL HOUSE CHARACTERISTICS

('House' is meant to refer to the place where you live most of the time.)

2. How long have you lived in the current house? *(Estimate if uncertain.)* **(1010-1020)** __ __ years__ __ months

3. Does your house use a wood burning stove as a primary source of heat? **(1030)** ❑1 Yes ❑0 No ❑8 Don't Know

4. Does your house use an air conditioner? **(1040)** ❑1 Yes ❑0 No ❑8 Don't Know

5. Does your house use an evaporative cooler (swamp cooler)? **(1050)** ❑1 Yes ❑0 No ❑8 Don't Know

6. Does your house use a humidifier? *(Include humidifier built into the heating system of your house.)* **(1060)** ❑1 Yes ❑0 No ❑8 Don't Know

7. Does your house use a dehumidifier? *(Include dehumidifier built into the cooling system of your house.)* **(1070)** ❑1 Yes ❑0 No ❑8 Don't Know

8. Has there been water damage to your house, basement, or its contents during the past 12 months? **(1080)** ❑1 Yes ❑0 No ❑8 Don't Know

9. Has there been any mold or mildew, on any surfaces, inside your house in the past 12 months? **(1090)** ❑1 Yes ❑0 No ❑8 Don't Know
➔ If **NO or DON'T KNOW**, skip to Q11.

10. Which rooms have or have had mold or mildew?

10a. Bathroom(s) **(1100)** ❑1 Yes ❑0 No

10b. Basement or attic	**(1110)**	❑$_1$ Yes	❑$_0$ No
10c. Kitchen	**(1120)**	❑$_1$ Yes	❑$_0$ No
10d. Your bedroom	**(1130)**	❑$_1$ Yes	❑$_0$ No
10e. Other bedrooms	**(1140)**	❑$_1$ Yes	❑$_0$ No
10f. Living or family room	**(1150)**	❑$_1$ Yes	❑$_0$ No
10g. Other	**(1160)**	❑$_1$ Yes	❑$_0$ No
If ***YES***, please specify	**(1160D)**	_____	

11. Do you ever see cockroaches in your house? **(1170)** ❑$_1$ Yes ❑$_0$ No
    ➔ If ***NO***, skip to Q13.

12. In which room(s) have you seen cockroaches?

12a. Kitchen	**(1180)**	❑$_1$ Yes	❑$_0$ No
12b. Basement or attic	**(1190)**	❑$_1$ Yes	❑$_0$ No
12c. Bathroom(s)	**(1200)**	❑$_1$ Yes	❑$_0$ No
12d. Living or family room	**(1210)**	❑$_1$ Yes	❑$_0$ No
12e. Your bedroom	**(1220)**	❑$_1$ Yes	❑$_0$ No
12f. Other bedrooms	**(1230)**	❑$_1$ Yes	❑$_0$ No
12g. Garage	**(1240)**	❑$_1$ Yes	❑$_0$ No
12h. Other	**(1250)**	❑$_1$ Yes	❑$_0$ No
If ***YES***, please specify	**(1250D)**	_____	

13. Do you ever see rodents (mice, rats) or rodent droppings in your house? **(1260)** ❑$_1$ Yes ❑$_0$ No
    ➔ If ***NO***, skip to Q15***.***

14. In which room(s) have you seen rodents or rodent droppings?

14a. Kitchen	**(1270)**	❑$_1$ Yes	❑$_0$ No
14b. Basement or attic	**(1280)**	❑$_1$ Yes	❑$_0$ No
14c. Bathroom(s)	**(1290)**	❑$_1$ Yes	❑$_0$ No

14d. Living or family room (1300) ❑1 Yes ❑0 No

14e. Your bedroom (1310) ❑1 Yes ❑0 No

14f. Other bedrooms (1320) ❑1 Yes ❑0 No

14g. Garage (1330) ❑1 Yes ❑0 No

14h. Other (1340) ❑1 Yes ❑0 No

If ***YES***, please specify (1340D) _____

15. Are any of the following located on your property or next to your property?

15a. Barns (1350) ❑1 Yes ❑0 No

15b. Hay (1360) ❑1 Yes ❑0 No

15c. Woodsheds (1370) ❑1 Yes ❑0 No

15d. Firewood (1380) ❑1 Yes ❑0 No

15e. Chicken coops (1390) ❑1 Yes ❑0 No

15f. Corral (1400) ❑1 Yes ❑0 No

CHARACTERISTICS OF THE PARTICIPANT'S BEDROOM

(If the participant does not have a bed or bedroom, answer for the place where the participant sleeps.)

16. What is the floor covering in your bedroom? (1410)
- ❑1 Rug/carpet
- ❑2 Vinyl tile or linoleum
- ❑3 Wood
- ❑4 Ceramic tile
- ❑5 Other (specify)

(1410D) _____

- ❑9 Don't know

17. What type of mattress is on your bed? (1420)
➔ If ***NONE***, skip to Q19.
- ❑1 None
- ❑2 Inner spring mattress
- ❑3 Foam mattress
- ❑4 Waterbed
- ❑5 Air mattress
- ❑6 Other (specify)

(1420D) _____

- ❑9 Don't know

18. Is the mattress completely enclosed in an allergy-proof, encasing cover? **(1430)** ❑1 Yes ❑0 No

19. Does your bed have a box spring? **(1440)** ❑1 Yes ❑0 No
    ➔ If ***NO***, skip to Q21.

20. Is the box spring completely enclosed in an allergy-proof, encasing cover? **(1450)** ❑1 Yes ❑0 No

21. What type of pillow do you usually sleep with? **(1460)**
    ➔ If ***NONE***, skip to Q23.
    ❑1 None
    ❑2 Feather/down
    ❑3 Foam/Dacron/synthetic
    ❑5 Other (specify)
    (1460D) _____
    ❑9 Don't know

22. Is the pillow completely enclosed in an allergy-proof, encasing cover? **(1470)** ❑1 Yes ❑0 No

PETS

23. Does your household have any pets? **(1480)** ❑1 Yes ❑0 No
    ➔ If ***NO***, skip to Q25.

24. Enter the number of pets that the household has. (*Enter '00' if none. If none to Q24a – Q24d, skip to the next question.*)

24a. Cat	**(1490)** __ __	**(1500)**	❑1 Indoor	❑2 Outdoor ❑3 Both
24b. Dog	**(1510)** __ __	**(1520)**	❑1 Indoor	❑2 Outdoor ❑3 Both
24c. Rabbit, guinea pig, hamster, gerbil, or mouse	**(1530)** __ __	**(1540)**	❑1 Indoor	❑2 Outdoor ❑3 Both
24d. Bird	**(1550)** __ __	**(1560)**	❑1 Indoor	❑2 Outdoor ❑3 Both

25. In general, and on a regular basis, are you exposed to any of the following animals?

25a. Cat **(1570)** ❑1 Yes ❑0 No

25b. Dog **(1580)** ❑1 Yes ❑0 No

25c. Rabbit, guinea pig, hamster, gerbil, or mouse **(1590)** ❑1 Yes ❑0 No

25d. Bird **(1600)** ❑1 Yes ❑0 No

25e. Farm animals **(1610)** ❑1 Yes ❑0 No

25f. Other **(1620)** ❑1 Yes ❑0 No

If ***YES***, please specify **(1620D)** _____

➔ ***If participant is 6 years of age or older, STOP HERE and complete the source documentation box.***

DAY CARE

26. Did the participant attend day care during the 1st year of life? **(1630)** ❑1 Yes ❑0 No

26a. If ***YES***, at what age did the day care attendance begin? **(1640)** __ __ months

27. Does the participant currently attend day care? **(1650)** ❑1 Yes ❑0 No
➔ ***If No, STOP HERE and complete the source documentation box.***

27a. Is the day care… **(1660)** ❑1 In home day care
❑2 Nonresidential
❑3 Mixed

27b. How many children are in the participant's day care room? **(1670)** __ __ children

27c. How many hours per day is the participant at day care? **(1680)** __ __ hours

27d. How many days per week is the participant at day care? **(1690)** __ days

27e. How many months per year is the participant at day care? **(1700)** __ __ months

Participant/Guardian Source Documentation
Participant/Guardian Initials: __ __ __ **(1710)**
Date: __ __ / __ __ / 20 __ __ **(1720)**
MM DD YYYY

Coordinator Completed
COMMENTS
(6000):_____

_____

_____

AsthmaNet

HOUSEHOLD SOCIO-ECONOMIC INFORMATION

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Parent/Legal Guardian or Participant Completed)

Please answer the following questions about your primary household. If you're a college student living away from home during the school year, the questions pertain to your parents' household.

1. Who is the respondent? **(1000)**
   - ❑1 Self/Participant
   - ❑2 Parent/Guardian
   - ❑3 Other (specify) **(1000D)** _____

2. Which category best describes the **highest** grade or educational level that **any member of your household** has achieved? (Check one box only.) **(1010)**
   - ❑0 No High School diploma
   - ❑1 GED
   - ❑2 High School diploma
   - ❑3 Technical training
   - ❑4 Some college, no degree
   - ❑5 Associate degree
   - ❑6 Bachelors degree
   - ❑7 Masters degree
   - ❑8 MD/PhD/JD/PharmD
   - ❑9 Decline to answer
   - ❑10 Don't know

3. To help us characterize the economic status of our study participants, please indicate which category best describes the **combined annual income**, before taxes, of **all members of your household** for the last year. (Check one box only.) **(1020)**
   - ❑1 Less than $25,000
   - ❑2 $25,000 - $49,999
   - ❑3 $50,000 - $99,999
   - ❑4 $100,000 or more
   - ❑9 Decline to answer
   - ❑10 Don't know

4. How many people (adults and children) are supported by this income reported in Q3? **(1030)** __ __ people

COMMENTS: **(6000)**

_____

_____

_____

* H O U S E H O L D S E I *

AsthmaNet

ADULT METHACHOLINE CHALLENGE TESTING CHECKLIST

Supervisor ID: __ __ __ __

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Technician ID: __ __ __ __

(Technician Completed)

Complete this form only if the participant is eligible according to the Pulmonary Procedure Checklist form and successfully completed baseline spirometry session(s).

Exclusions and Confounders

1. Has the participant had any severe acute illness in the past 4 weeks? **(1000)** ☐1 Yes ☐0 No

   1a. If ***YES***, has the participant received permission from the supervising physician to proceed with the methacholine challenge testing? **(1010)** ☐1 Yes ☐0 No
   Physician's Signature: **(1020)** _____

2. Has the participant used 4 or more days of systemic corticosteroid (e.g., prednisolone, prednisone, Solumedrol, Decadron) for the treatment of an asthma exacerbation in the past 4 weeks? **(1050)** ☐1 Yes ☐0 No

3. Does the participant have a baseline (pre-diluent) FEV_1 less than 55% of predicted or less than 1.0 L? **(1060)** ☐1 Yes ☐0 No

4. Pregnancy test results **(1070)** ☐1 Positive ☐0 Negative ☐9 N/A
   (Check N/A if the participant is male, or is female and is post-menopausal, had a hysterectomy or tubal ligation.)

5. Is the participant's systolic blood pressure > 200 mm Hg or diastolic blood pressure > 100 mm Hg? **(1080)** ☐1 Yes ☐0 No

6. Is there any other reason the participant should not proceed with the methacholine challenge testing? **(1100)** ☐1 Yes ☐0 No
   If ***YES***, explain: **(1100D)** _____

7. Is the participant eligible to proceed with the diluent (solution #0) pulmonary function testing for the methacholine challenge? **(1110)** ☐1 Yes ☐0 No
   If any of the shaded boxes are completed, the participant is NOT eligible for the methacholine challenge testing.
   ➔ ***If YES, proceed to the Methacholine Challenge Testing (METHA) form.***

COMMENTS: **(6000)**

_____

METHACHK ADULT

AsthmaNet	**POST-Advair® (2 puffs) SPIROMETRY TESTING** Supervisor ID: __ __ __ __	Part. ID: __ __ - __ __ __ - __ __ __ Part. Initials: __ __ __ Visit: __ __ __ Visit Date: __ __ / __ __ / 20 __ __ Technician ID: __ __ __ __

(Technician Completed)

Complete this form only if the participant is eligible according to the appropriate Pulmonary Procedure Checklist form and successfully completed baseline spirometry session(s).

➔ ***Post-Advair® spirometry testing will be performed 1 hour after 2 puffs Advair® 115/21 are administered to participant.***

1. Time Advair® administered *(based on 24-hour clock)* **(1000)** __ __ __ __

2. Time post-Advair® spirometry started *(based on 24-hour clock)* **(1010)** __ __ __ __

The reported FEV_1, FVC and FEF Max are the best measurements of all acceptable maneuvers.

3. Highest FVC **(1020)** __ . __ __ L

4. Highest FEV_1 **(1030)** __ . __ __ L

5. Highest FEV_1 (% predicted) **(1040)** __ __ __ % predicted

6. FEF Max **(1050)** __ __ . __ __ L/S

The reported FEF_{25-75} corresponds to the maneuver where FEV_1 + FVC is maximized.

7. FEF_{25-75} **(1060)** __ . __ __ L/S

8. In your judgment, was the participant's spirometry technique acceptable? **(1070)** ❑$_1$ Yes ❑$_0$ No

COMMENTS: (6000)

_____

_____

_____

* P A D V A I R S P I R O *

AsthmaNet

POST-ALBUTEROL (4 puffs) SPIROMETRY TESTING

Supervisor ID: __ __ __ __

Part. ID: __ __ - __ __ __ - __ __ __

Part. Initials: __ __ __

Visit: __ __ __

Visit Date: __ __ / __ __ / 20 __ __

Technician ID: __ __ __ __

(Technician Completed)

Complete this form only if the participant is eligible according to the appropriate Pulmonary Procedure Checklist form and successfully completed baseline spirometry session(s).

➔ ***Administer 4 puffs of albuterol and wait 10 to 15 minutes, then perform spirometry.***

1. Time albuterol administered *(based on 24-hour clock)* **(1000)** __ __ __ __

2. Time post-albuterol spirometry started *(based on 24-hour clock)* **(1010)** __ __ __ __

The reported FEV_1, FVC and FEF Max are the best measurements of all acceptable maneuvers.

3. Highest FVC **(1020)** __ . __ __ L

4. Highest FEV_1 **(1030)** __ . __ __ L

5. Highest FEV_1 (% predicted) **(1040)** __ __ __ % predicted

6. FEF Max **(1050)** __ __ . __ __ L/S

The reported FEF_{25-75} corresponds to the maneuver where FEV_1 + FVC is maximized.

7. FEF_{25-75} **(1060)** __ . __ __ L/S

8. In your judgment, was the participant's spirometry technique acceptable? **(1070)** ❑$_1$ Yes ❑$_0$ No

COMMENTS: (6000)

_____

_____

_____

PALB4 SPIRO

AsthmaNet

URINE PREGNANCY TEST

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed)

Complete this form for female participants ages 6 and older. All female participants ages 6 and older or her parent/guardian must review the completed form and provide source documentation below.

1. Is the participant unable to bear children due to any of the following reasons?

1a. Pre-menarche **(1000)** ☐1 Yes ☐0 No
➔ If **YES**, stop here and have the parent/guardian complete the source documentation box below.

1b. Post-menopausal (at least one year since last menses) **(1010)** ☐1 Yes ☐0 No

1c. Hysterectomy **(1020)** ☐1 Yes ☐0 No

1d. Tubal ligation **(1030)** ☐1 Yes ☐0 No

➔ ***If any of the shaded boxes are filled in, a pregnancy test is not required. Proceed to the source documentation box below.***

2. Pregnancy test results **(1040)** ☐1 Positive ☐0 Negative
➔ ***If pregnancy test results are positive, the participant must be terminated from study participation. Complete the appropriate Termination of Study Participation form and follow study termination procedures.***

Participant/Guardian Source Documentation
Participant/Guardian Initials: __ __ __ **(1050)**
Date: __ __ / __ __ / 20 __ __ **(1060)**
MM DD YYYY

COMMENTS: **(6000)**

_____

_____

_____

* P R E G T E S T *

AsthmaNet

PRIOR CONDITIONS FOR ADULT PARTICIPANTS

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed by Interview)

PRIOR DISEASES, ILLNESSES, AND SURGERIES

Have you had any diseases, illnesses, conditions, or surgeries related to the following areas?

						If Yes, Comment
1.	Blood, Lymph, or Immune Systems	**(1000)**	❑1 Yes	❑0 No	**(1000D)**	_____
2.	Eyes	**(1010)**	❑1 Yes	❑0 No	**(1010D)**	_____
3.	Breasts	**(1020)**	❑1 Yes	❑0 No	**(1020D)**	_____
4.	Endocrine Systems	**(1030)**	❑1 Yes	❑0 No	**(1030D)**	_____
5.	Heart and Blood Vessels	**(1040)**	❑1 Yes	❑0 No	**(1040D)**	_____
6.	Liver or Pancreas	**(1050)**	❑1 Yes	❑0 No	**(1050D)**	_____
7.	Kidneys or Urinary Tract System	**(1060)**	❑1 Yes	❑0 No	**(1060D)**	_____
8.	Reproductive System	**(1070)**	❑1 Yes	❑0 No	**(1070D)**	_____
9.	Muscles or Bones	**(1080)**	❑1 Yes	❑0 No	**(1080D)**	_____
10.	Nervous System	**(1090)**	❑1 Yes	❑0 No	**(1090D)**	_____
11.	Psychiatric	**(1100)**	❑1 Yes	❑0 No	**(1100D)**	_____
12.	Drug Allergies	**(1110)**	❑1 Yes	❑0 No	**(1110D)**	_____
13.	Other	**(1120)**	❑1 Yes	❑0 No	**(1120D)**	_____

COMMENTS: (6000)

_____

_____

_____

AsthmaNet

PRIOR CONDITIONS FOR ALL PARTICIPANTS

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed by Interview)

Note: If you are a parent or guardian responding for a child, "you" is referring to the child who is the study participant.

1. Who is the respondent? **(1000)**
   - ❑1 Self/Participant
   - ❑2 Parent/Guardian
   - ❑3 Other (specify) **(1000D)** _____

PRIOR DISEASES, ILLNESSES, AND SURGERIES

Have you had any diseases, illnesses, conditions, or surgeries related to the following areas?

						If Yes, Comment
2.	Skin	**(1010)**	❑1 Yes	❑0 No	**(1010D)**	_____
3.	Ears, Nose, or Throat					
3a.	Have you ever had allergic rhinitis (hay fever)?	**(1020)**	❑1 Yes	❑0 No	❑9 Don't know	
3b.	Have you ever had nasal polyps?	**(1030)**	❑1 Yes	❑0 No	❑9 Don't know	
3c.	Do you have chronic or recurrent sinusitis (treated with antibiotics and/or surgery)?	**(1040)**	❑1 Yes	❑0 No	❑9 Don't know	
3d.	Have you ever been diagnosed with vocal cord dysfunction?	**(1050)**	❑1 Yes	❑0 No	❑9 Don't know	
3e.	Have you ever had other conditions related to the ear, nose, or throat?	**(1060)**	❑1 Yes	❑0 No	**(1060D)**	_____
4.	Lung - other than asthma					
4a.	Have you ever had pneumonia?	**(1070)**	❑1 Yes	❑0 No	❑9 Don't know	

PRIOR COND ALL

If Yes, Comment

4ai. If **YES**, were you diagnosed by chest x-ray? **(1080)** ❑1 Yes ❑0 No ❑9 Don't know

4aii. If **YES**, were you treated with antibiotics? **(1090)** ❑1 Yes ❑0 No ❑9 Don't know

4b. Have you ever had bronchitis? **(1100)** ❑1 Yes ❑0 No ❑9 Don't know

4c. Have you ever had other conditions related to the lungs (besides asthma)? **(1110)** ❑1 Yes ❑0 No **(1110D)** _____

5. Stomach or Intestines

5a. Do you have gastroesophageal reflux disease (GERD)? **(1120)** ❑1 Yes ❑0 No ❑9 Don't know

5b. Have you ever had other conditions related to the stomach or intestines? **(1130)** ❑1 Yes ❑0 No **(1130D)** _____

6. Sleep Disorder

6a. Have you been diagnosed with sleep disordered breathing (sleep apnea)? **(1150)** ❑1 Yes ❑0 No **(1150D)** _____

6ai. If **YES**, are you being treated with CPAP or BiPAP? **(1160)** ❑1 Yes ❑0 No

6b. Have you ever had other sleep disorders? **(1170)** ❑1 Yes ❑0 No **(1170D)** _____

7. Have you ever had other conditions that have not been mentioned on this form? **(1180)** ❑1 Yes ❑0 No **(1180D)** _____

COMMENTS: (6000)

_____

_____

_____

AsthmaNet

PRIOR ASTHMA/ALLERGY TREATMENT

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed by Interview)

Note: If you are a parent or guardian responding for a child, "you" is referring to the child who is the study participant.

1. Who is the respondent?

(1000) ❑1 Self/Participant
❑2 Parent/Guardian
❑3 Other (specify)
(1000D) _____

Next I will read a list of medications that are used to treat asthma and allergies. Please indicate if you have used each medication ***during the past 12 months FOR ASTHMA OR ALLERGIES***. If you have used a particular medication, please indicate to the best of your knowledge the date it was last taken.

During the past 12 months were the following medications used FOR ASTHMA OR ALLERGIES?		**If Yes, indicate date medication was last taken Month / Day / Year**
2. Short-acting Inhaled Beta-Agonists by Inhaler (**e.g., albuterol, Primatene Mist, Maxair, ProAir, Proventil, Ventolin, Xopenex)**	**(1010)** ❑1 Yes ❑0 No ❑9 Don't Know	__ __ / __ __ / 20 __ __ **(1020) (1030) (1040)**
2a. If **YES**, indicate average weekly puffs in the past month (Enter '000' if none used)	**(1050)** __ __ __ weekly puffs	
3. Rescue treatment via a Nebulizer Machine **(e.g., albuterol, ipratropium, Combivent, Xopenex, levalbuterol)**	**(1060)** ❑1 Yes ❑0 No ❑9 Don't Know	__ __ / __ __ / 20 __ __ **(1070) (1080) (1090)**
4. Long-acting Inhaled Beta-Agonists **(e.g., Serevent, Foradil, salmeterol, formoterol)** ➔ ***Do not consider combination medications.***	**(1100)** ❑1 Yes ❑0 No ❑9 Don't Know	__ __ / __ __ / 20 __ __ **(1110) (1120) (1130)**
5. Oral Beta-Agonists **(e.g., albuterol, Brethine, Bricanyl, metaproterenol, Proventil, Ventolin, Repetabs, Volmax)**	**(1140)** ❑1 Yes ❑0 No ❑9 Don't Know	__ __ / __ __ / 20 __ __ **(1150) (1160) (1170)**

PRIOR TRT

6.	Oral Theophylline (short-acting or sustained release) **(e.g., Aminophylline, Slo-Phyllin, Slo-bid, Theo-Dur, Uniphyl)**	(1180)	❑1 Yes ❑0 No ❑9 Don't Know	__ __ / __ __ / 20 __ __ (1190) (1200) (1210)

If Yes, indicate date medication was last taken Month / Day / Year

7.	Inhaled Anticholinergic by Inhaler (**e.g., Atrovent, Combivent, Spiriva**)	(1220)	❑1 Yes ❑0 No ❑9 Don't Know	__ __ / __ __ / 20 __ __ (1230) (1240) (1250)
8.	Leukotriene Antagonist / 5LO Inhibitors (**e.g., Accolate, Zyflo, Singulair**)	(1260)	❑1 Yes ❑0 No ❑9 Don't Know	__ __ / __ __ / 20 __ __ (1270) (1280) (1290)
9.	IgE Blocker (**e.g., Xolair**)	(1300)	❑1 Yes ❑0 No ❑9 Don't Know	__ __ / __ __ / 20 __ __ (1310) (1320) (1330)
10.	Oral Steroids FOR ASTHMA (**e.g., Prednisone, Prelone, Pediapred, Medrol, Orapred, Decadron, dexamethasone**)	(1340)	❑1 Yes ❑0 No ❑9 Don't Know	__ __ / __ __ / 20 __ __ (1350) (1360) (1370)

10a. If **YES**, in the past 12 months, how many courses of steroids by mouth have you taken FOR ASTHMA? (1380)

- ❑1 1 course
- ❑2 2 courses
- ❑3 3 courses
- ❑4 4 courses
- ❑5 5 courses
- ❑6 More than 5 courses

11.	Injectable Steroids FOR ASTHMA (**e.g., Medrol, Solumedrol, Decadron, dexamethasone, triamcinolone, Kenalog, hydrocortisone IV**)	(1390)	❑1 Yes ❑0 No ❑9 Don't Know	__ __ / __ __ / 20 __ __ (1400) (1410) (1420)

12. Steroids by Inhaler **(1430)** ❑1 Yes ❑0 No ❑9 Don't Know — __ __ / __ __ / 20 __ __ **(1440) (1450) (1460)**
(e.g., Asmanex Twisthaler, QVAR, Flovent, Pulmicort Flexhaler)
➔ ***Do not consider combination medications.***
➔ If **YES**, complete Q12a – Q12c

12a. Indicate most recent type of inhaled steroid taken (refer to PRIOR_TRT_CARD reference card) **(1470)** __ __ __ code

12ai. If **Other**, specify the name of the medication **(1470D)** _____

12b. Indicate number of daily puffs used **(1480)** __ __ daily puffs

12c. Indicate the total number of months that you used the inhaled steroid out of the past 12 months **(1490)** __ __ months

If Yes, indicate date medication was last taken Month / Day / Year

13. Steroids by Nebulizer **(1500)** ❑1 Yes ❑0 No ❑9 Don't Know — __ __ / __ __ / 20 __ __ **(1510) (1520) (1530)**
(e.g., Pulmicort Respules, budesonide)
➔ If **YES**, complete Q13a – Q13c

13a. Indicate most recent type of nebulized steroid taken (refer to PRIOR_TRT_CARD reference card) **(1535)** __ __ code

13ai. If **Other**, specify the name of the medication **(1500D)** _____

13b. Indicate number of daily treatments used **(1540)** __ __ daily treatments

13c. Indicate the total number of months that you used the nebulized steroid out of the past 12 months **(1550)** __ __ months

14. Long-Acting Beta-Agonist and Inhaled Steroid Combination Medications **(1560)** ❑1 Yes ❑0 No ❑9 Don't Know — __ __ / __ __ / 20 __ __ **(1570) (1580) (1590)**
(e.g., Advair Diskus, Symbicort MDI, Dulera MDI)
➔ If **YES**, complete Q14a – Q14c

14a. Indicate most recent type of combination medication taken (refer to PRIOR_TRT_CARD reference card) **(1600)** __ __ __ __ code

14ai. If **Other**, specify the name of the medication **(1600D)** _____

14b. Indicate number of daily puffs used **(1610)** __ __ daily puffs

14c. Indicate the total number of months that you used the combination medication out of the past 12 months **(1620)** __ __ months

During the past 12 months were the following nasal treatments used FOR ALLERGIES?

15. Nasal Steroids (**e.g., Beconase, Vancenase, Flonase, Nasacort, Nasalide, Nasarel, Omnaris, Rhinocort, Nasonex)** **(1630)** ❑1 Yes ❑0 No ❑9 Don't Know — __ __ / __ __ / 20 __ __ **(1640) (1650) (1660)**

16. Non-steroidal Anti-allergic Nasal Medications (**e.g., Nasalcrom, Astelin, Astepro, ipratropium**) **(1670)** ❑1 Yes ❑0 No ❑9 Don't Know — __ __ / __ __ / 20 __ __ **(1680) (1690) (1700)**

During the past 12 months were the following general allergy treatments used?

If Yes, indicate date medication was last taken Month / Day / Year

17. Anti-allergic Oral Medications (**e.g., fexofenadine, loratadine, cetirizine, chlorpheniramine**) **(1710)** ❑1 Yes ❑0 No ❑9 Don't Know — __ __ / __ __ / 20 __ __ **(1720) (1730) (1740)**

During the past 12 months were the following skin treatments used FOR ECZEMA OR ALLERGIES?

18. Topical Steroids – Prescription (**e.g., Synalar, Lidex, Dermacin, Fluocinonide**) **(1750)** ❑1 Yes ❑0 No ❑9 Don't Know — __ __ / __ __ / 20 __ __ **(1760) (1770) (1780)**

19. Topical Steroids – OTC (**e.g., Hydrocortisone - multiple strengths and products)** **(1790)** ❑1 Yes ❑0 No ❑9 Don't Know — __ __ / __ __ / 20 __ __ **(1800) (1810) (1820)**

During the past 12 months were there any OTHER medications used FOR ASTHMA OR ALLERGIES?

20. Other Medication FOR ASTHMA OR ALLERGIES **(1830)** ❑1 Yes ❑0 No ❑9 Don't Know __ __ / __ __ / 20 __ __ **(1840) (1850) (1860)**

20a. If **YES**, specify the name of the medication **(1830D)** _____

During the past 12 months were the following treatments used for conditions OTHER THAN ASTHMA?

21. Oral Steroids **for Conditions Other Than Asthma** (**e.g., Prednisone, Prelone, Pediapred, Medrol, Orapred, Decadron, dexamethasone**) **(1870)** ❑1 Yes ❑0 No ❑9 Don't Know __ __ / __ __ / 20 __ __ **(1880) (1890) (1900)**

21a. If **YES**, specify indication **(1870D)** _____

If Yes, indicate date medication was last taken Month / Day / Year

22. Injectable Steroids **for Conditions Other Than Asthma** (**e.g., Medrol, Solumedrol, Decadron, dexamethasone, triamcinolone, Kenalog, hydrocortisone IV**) **(1910)** ❑1 Yes ❑0 No ❑9 Don't Know __ __ / __ __ / 20 __ __ **(1920) (1930) (1940)**

22a. If **YES**, specify indication **(1910D)** _____

COMMENTS: **(6000)**

_____

_____

_____

"Attach Registry Form Label Here"	**AsthmaNet REGISTRY FORM**	Participant's Last Name: _____ Participant's First Name: _____ Participant's Initials: __ __ __ Coordinator ID: __ __ __ __

(Coordinator Completed by Interview)

Search the AsthmaNet Registry. If the participant has incomplete status or is not found in the registry, complete the Registry form and enter/update the participant's information appropriately.

ADMINISTRATIVE

1. Three-digit ID for site registering participant and maintaining source documentation: **(SITE_REG)** __ __ __

2. Is the participant ≥ 18 years old? **(1000)** ❑1 Yes ❑0 No
   ➔ If **NO**, skip to Q3.

   2a. IF **YES**: Did the participant sign and date an AsthmaNet Protocol Informed Consent and a HIPAA Authorization Form? **(1010)** ❑1 Yes ❑0 No
   ➔ If **NO**, STOP HERE. Data cannot be entered into the AsthmaNet Registry.

   2ai. IF **YES**: Record the date the consent form was signed. **(1020)** __ __ / __ __ / __ __ __ __
   ➔ Skip to Q5.

3. If the participant is < 18 years old, did the parent/legal guardian sign and date an AsthmaNet Protocol Informed Consent and a HIPAA Authorization Form? **(1030)** ❑1 Yes ❑0 No
   ➔ If **NO**, STOP HERE. Data cannot be entered into the AsthmaNet Registry.

   3a. If **YES**: Record the date the consent form was signed. **(1040)** __ __ / __ __ / __ __ __ __

4. Did the participant sign and date an AsthmaNet Protocol Informed Assent and HIPAA Authorization form according to local IRB rules and regulations? **(1050)** ❑1 Yes ❑0 No ❑2 Not required by IRB
   ➔ If **NO**, STOP HERE. Data cannot be entered into the AsthmaNet Registry.
   ➔ If **NOT REQUIRED**, skip to Q5.

   4a. If **YES**: Record the date assent was given. **(1060)** __ __ / __ __ / __ __ __ __

DEMOGRAPHICS

5. Participant's date of birth **(1070)** __ __ / __ __ / __ __ __ __
   (Ask the participant his/her date of birth.)

6. Participant's gender **(1080)** ❑1 Male ❑2 Female

7. Participant's ethnic background
(Ask the participant to identify his/her ethnic background.)

(1090) ❑1 Hispanic or Latino
❑2 Not Hispanic or Latino

8. Participant's racial background
(Ask the participant to identify all that apply. Check at least one Yes.)

8a. American Indian or Alaskan Native	**(1100)**	❑1 Yes	❑0 No
8b. Asian	**(1110)**	❑1 Yes	❑0 No
8c. Black or African American	**(1120)**	❑1 Yes	❑0 No
8d. White	**(1130)**	❑1 Yes	❑0 No
8e. Native Hawaiian or Other Pacific Islander	**(1140)**	❑1 Yes	❑0 No

9. Participant's primary racial identification (Ask the parent/guardian or participant which category best describes the participant, and check only one box.)

(1150) ❑1 American Indian or Alaskan Native
❑2 Asian or Pacific Islander
❑3 Black or African American
❑4 White
❑5 Hispanic or Latino
❑6 Other

(1160) _____

Registry Form Storage Instructions:

Print the participant's Registry Report with his/her name on the report. Registry Reports and completed Registry forms should be stored alphabetically by participant's last name in the AsthmaNet *Registry binder.*

REGISTRY FORMS AND REPORTS SHOULD <u>NOT</u> BE SENT TO THE DCC.

Participant/Guardian Source Documentation
Participant/Guardian Initials: __ __ __
Date: __ __ / __ __ / 20 __ __
MM DD YYYY

REGISTRY

AsthmaNet

SERIOUS ADVERSE EVENT REPORTING FORM

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed)

This form and a final resolution report (including relevant documents) written by the Principal Investigator should be faxed to the DCC at (717) 531-4359 within 72 hours of notification of a serious event. Also fax the Clinical Adverse Events form (AECLIN), the Concomitant Medications for Asthma and Allergies (CMED) form, and any relevant source documents.

1. Date of Adverse Event **(1000)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

2. Description of Adverse Event (ICD9 Code) **(1010)** __ __ __ . __ __

   Describe: **(1010D)** _____

3. Is the participant currently taking study drug? **(1020)** ❑1 Yes ❑0 No
   ➔ If ***NO***, skip to Q6.

4. Time interval between the last administration of the study drug and the Adverse Event **(1030)** __ __ __

5. What was the unit of time for the interval in Question #4? **(1040)**
   ❑1 Second(s)
   ❑2 Minute(s)
   ❑3 Hour(s)
   ❑4 Day(s)

6. Why was the event serious?

   6a. Fatal event **(1050)** ❑1 Yes ❑0 No

   6b. Life-threatening event **(1060)** ❑1 Yes ❑0 No

   6c. Inpatient hospitalization required **(1070)** ❑1 Yes ❑0 No
   ➔ If ***NO***, skip to Q6d.

   6ai. Admission date **(1080)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

   6aii. Discharge date **(1090)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

   6d. Hospitalization prolonged **(1100)** ❑1 Yes ❑0 No

   6e. Disabling or incapacitating **(1110)** ❑1 Yes ❑0 No

   6f. Overdose **(1120)** ❑1 Yes ❑0 No

6g. Cancer **(1130)** ❑1 Yes ❑0 No

6h. Congenital anomaly **(1140)** ❑1 Yes ❑0 No

6i. Serious laboratory abnormality with clinical symptoms **(1150)** ❑1 Yes ❑0 No

6j. Height failure (per protocol MOP) **(1160)** ❑1 Yes ❑0 No

6k. Pregnancy **(1170)** ❑1 Yes ❑0 No ❑9 N/A

6l. Other **(1180)** ❑1 Yes ❑0 No

If ***YES***, describe: **(1180D)** _____

7. What in your opinion caused the event?

7a. Toxicity of study drug(s) **(1190)** ❑1 Yes ❑0 No

7b. Withdrawal of study drug(s) **(1200)** ❑1 Yes ❑0 No

7c. Concurrent medication **(1210)** ❑1 Yes ❑0 No

If ***YES***, describe: **(1210D)** _____

7d. Other condition or event **(1220)** ❑1 Yes ❑0 No

If ***YES***, describe: **(1220D)** _____

(Investigator Completed)

8. Was the event expected or unexpected? **(1240)** ❑1 Expected ❑2 Unexpected

9. Was the event possibly, probably, or definitely related to study participation? **(1250)** ❑1 Yes ❑0 No

DO NOT ENTER THE FOLLOWING QUESTIONS: FOR REPORTING PURPOSES ONLY.

10. If participant died, cause of death: _____

_____

11. Was an autopsy performed? ❑ Yes ❑ No

If YES, attach report or send as soon as possible.

REPORTING INVESTIGATOR:

Please provide a typed summary of the event including: the participant's status in the study, whether study drugs will be continued, follow-up treatment plans, and communication with the treating physicians and participant or participant's parent/guardian.

COMMENTS: (6000)

_____

_____

_____

Name: _____

Signature:_____

Date: __ __ / __ __ / 20 __ __
MM DD YYYY

AsthmaNet

SPIROMETRY TESTING

Supervisor ID: __ __ __ __

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Technician ID: __ __ __ __

(Technician Completed)

Complete this form only if the participant is eligible according to the appropriate Pulmonary Procedure Checklist form.

1. Time spirometry started *(based on 24-hour clock)* **(1010)** __ __ __ __

The reported FEV_1, FVC and FEF Max are the best measurements of all acceptable maneuvers.

2. Highest FVC **(1020)** __ . __ __ L

3. Highest FEV_1 **(1030)** __ . __ __ L

4. Highest FEV_1 (% predicted) **(1040)** __ __ __ % predicted

5. FEF Max **(1050)** __ __ . __ __ L/S

The reported FEF_{25-75} corresponds to the maneuver where FEV_1 + FVC is maximized.

6. FEF_{25-75} **(1060)** __ . __ __ L/S

7. In your judgment, was the participant's spirometry technique acceptable? **(1070)** ❑$_1$ Yes ❑$_0$ No

COMMENTS: (6000)

_____

_____

_____

* S P I R O *

AsthmaNet

ALfA
ASTHMA
MONITORING LOG

Part. ID: __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Return Visit: __ __
Return Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

To the Participant: Please record your daily RESCUE puffs on this log at the end of each day. Do not include preventive puffs. ***Enter '0' in the column(s) if the specified rescue inhaler was not used on a given day*.** Also, check 'Yes' box in "Morning Flovent® Taken?" column if took AM Flovent® dose as instructed (on the Daily Activities handout); check 'Yes' box in "Evening Flovent® Taken?" column if took PM Flovent® dose as instructed.

Use your RESCUE inhalers as instructed in the handout "If Your Asthma Gets Worse." Contact study personnel if symptoms do not improve after 1 hour of green RESCUE1 use, or if you are experiencing extreme symptoms.

If you have taken at least __ __ puffs per 24 hours for the past 48 hours or 16 or more puffs per 24 hours from your green RESCUE1 and blue RESCUE2 inhalers (combined total puffs), contact study personnel.

Please record any non-study medications you have taken and details of any medical problems you have experienced since your last study visit on the last page of this log.

Date (ddate)	**Total green RESCUE1 Puffs Used** (1000)	**Total blue RESCUE2 Puffs Used** (1010)	**Morning Flovent® Taken?** (1020)	**Evening Flovent® Taken?** (1030)	**Comments**
----------	*Enter '0' if Not Used*	*Enter '0' if Not Used*	----------	----------	----------
			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	

P9 ASTHMA LOG

Date (ddate)	Total green RESCUE1 Puffs Used (1000)	Total blue RESCUE2 Puffs Used (1010)	Morning Flovent® Taken? (1020)	Evening Flovent® Taken? (1030)	Comments
---	*Enter '0' if Not Used*	*Enter '0' if Not Used*	---	---	---
			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	
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			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	
			❑1 Yes	❑1 Yes	

Participant Notes

Non-Study Medications

Please indicate any non-study medications (both prescription and over-the-counter) taken for any reason.

Medication Name	Dosage/Frequency	Dates Taken	Reason

Medical Problems

Please indicate any medical problems you experience, as well as the severity of each (mild, moderate, severe). If you experience an asthma attack (refer to the "If Your Asthma Gets Worse" handout) or significant illness, contact study personnel within 72 hours.

Problem Description	Dates/Times	Severity (mild, moderate, severe)	Comments

Coordinator Completed

COMMENTS

_____

_____

_____

AsthmaNet	ALfA BASELINE PEF AND RESCUE USE VALUES	Part. ID: __ __ - __ __ __ - __ __ __ Part. Initials: __ __ __ Visit: __ __ Visit Date: __ __ / __ __ / 20 __ __ Coordinator ID: __ __ __ __

(Coordinator Completed)

Complete this form at Visits 1 and 2 to document the participant's baseline peak flow and rescue use values.

Clinic Use Only

Participant's baseline peak flow (PEF) value __ __ __ L/M

➔ PEF (FEF Max) from prebronchodilator (baseline) spirometry at Visits 1 and 2 (multiply FEF Max by 60 to convert to L/M)

1. Participant's baseline rescue use value **(1000)** __ __ puffs/day

   ➔ Visit 1: Self-reported average daily use of home rescue inhaler during the 7 days prior to Visit 1.

   ➔ Visit 2: Average daily use of ipratropium (RESCUE1) during the 7 days prior to Visit 2 as recorded on Asthma Monitoring Log.

COMMENTS: (6000)

_____

_____

_____

P9 BASELINE

AsthmaNet	**ALfA COMPLIANCE CHECKLIST**	Part. ID: __ __ - __ __ __ - __ __ __ Part. Initials: __ __ __ Visit: __ __ Visit Date: __ __ / __ __ / 20__ __ Coordinator ID: __ __ __ __

(Coordinator Completed)

1. Scheduled Diskus® Compliance

   1a. Number of scheduled puffs since the last visit **(1000)** __ __ __ puffs

   ➔ ***At Visit 3: Do not count puffs withheld the morning of visit.***

   1b. Number of remaining puffs reflected on scheduled Diskus® counter(s) **(1010)** __ __ __ puffs

   ➔ ***If two or more used Diskuses® are returned (i.e., out of their pouches), then total the values reflected on all counters.***

   1c. Number of puffs taken **(1020)** __ __ __ puffs

   ➔ ***60 x (# used Diskuses®) – Q1b***

   1d. Percent compliance = Q1c/Q1a x 100 **(1030)** __ __ __ . __ %

   ➔ ***At Visit 2: If the participant took less than 80% of the scheduled Diskus® puffs, re-emphasize the importance of maintaining the daily dosing schedule and reschedule visit in 2 weeks. If the participant still took less than 80% of the scheduled Diskus® puffs at the rescheduled Visit 2, the participant is ineligible for the study.***

Complete Q2 at Visit 3 and early post-randomization terminations only.

2. MEMS®6 Monitor Compliance for Scheduled Daily Capsules

   Information for Q2a – Q2d is obtained from the MEMS®6 Monitor Report.

   2a. Number of monitored days **(1040)** __ __ __ days

   2b. Number of correct days **(1050)** __ __ __ days

   2c. % correct days **(1060)** __ __ __ . __ %

   2d. % doses in time-window **(1070)** __ __ __ . __ %

COMMENTS: (6000)

_____

_____

_____

P9 COMPLY

AsthmaNet

ALfA COORDINATOR STUDY TREATMENT QUESTIONNAIRE

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed)

This questionnaire is to be completed at Visit 3 by the AsthmaNet coordinator who was primarily responsible for the participant's ALfA visits during the preceding 10 weeks. If a randomized participant terminates prior to Visit 3, this form should be completed at the time of the termination visit.

Blinded Scheduled Capsule Contents

1. Participants in the ALfA study are randomized to receive either alendronate capsules or placebo capsules. You are blinded to the actual treatment assignment. Please check the box next to the treatment that you believe the participant received **over the past 8 weeks.** **(1000)**
   - ❑$_1$ alendronate
   - ❑$_2$ placebo

2. How sure are you about your answer in Q1? **(1010)**
   - ❑$_1$ Absolutely sure – I know what the capsules contained
   - ❑$_2$ Moderately sure
   - ❑$_3$ Somewhat sure
   - ❑$_4$ Not sure at all – purely a guess

3. Please comment with respect to any observations you made that helped you make your choice in Q1. **(1020D)**

_____

_____

_____

Coordinator Source Documentation
Coordinator's Initials: __ __ __ **(1030)**
Date: __ __ / __ __ / 20 __ __ **(1040)**
MM DD YYYY

AsthmaNet

ALfA ELIGIBILITY CHECKLIST 1

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed)

1. Did the participant sign the ALfA Informed Consent document? **(1000)** ☐1 Yes ☐0 No

   1a. If ***YES***, record the date the consent form was signed. **(1010)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

2. Is the participant 18 years of age, or older? **(1020)** ☐1 Yes ☐0 No

3. Does the participant plan to move away from the clinical site in the upcoming 3 months such that his/her ability to complete the study will be jeopardized? **(1030)** ☐1 Yes ☐0 No

4. Has the participant used investigative drugs and/or enrolled in an intervention trial in the past 30 days, or have plans to enroll in such a trial during the ALfA study? **(1040)** ☐1 Yes ☐0 No

5. Has the participant taken the equivalent of >100 mcg and ≤1000 mcg of fluticasone daily for at least the past 4 weeks? **(1050)** ☐1 Yes ☐0 No

   ➔ Refer to the ALfA ICS Equivalency Reference Card (P9_ICS_EQUIV).

   5a. If ***YES***, is the participant taking the equivalent of >500 mcg fluticasone daily? **(1060)** ☐1 Yes ☐0 No

      ➔ If ***NO***, skip to Q6.

      5ai. If ***YES***, is the participant's ACT score ≥ 18? **(1070)** ☐1 Yes ☐0 No

6. Does the participant have a medical contraindication to LABA (salmeterol) or a history of adverse reactions to ICS (fluticasone) or LABA preparations or any of their ingredients? **(1080)** ☐1 Yes ☐0 No

7. Does the participant have a history of adverse reactions to anticholinergic inhalers (e.g., Atrovent, Oxivent, Spiriva)? **(1090)** ☐1 Yes ☐0 No

8. Does the participant have a history of adverse reactions or allergic reactions to bisphosphonates (e.g., Actonel, Actonel+Ca, Aredia, Boniva, Didronel, Fosamax, Fosamax+D, Reclast, Skelid, and Zometa)? **(1100)** ☐1 Yes ☐0 No

9. Has the participant had a respiratory infection within the past 4 weeks? **(1110)** ☐1 Yes ☐0 No

10. Has the participant had a dental extraction or root canal in the past 8 weeks, or anticipate having one in the next 3 months? **(1120)** ☐1 Yes ☐0 No

11. Is the participant able to stay upright (sit or stand) for 30 minutes after taking oral medication in the morning? **(1130)** ☐1 Yes ☐0 No

12. Is the participant able to swallow capsules like those used in the ALfA study? **(1140)** ☐1 Yes ☐0 No

13. Is the participant eligible to proceed? **(1150)** ☐1 Yes ☐0 No

If any of the shaded boxes are completed, the participant is ineligible.

➔ ***If YES*, proceed with remaining Visit 1 procedures.**

Participant Source Documentation

Participant Initials: __ __ __ **(1160)**

Date: __ __ / __ __ / 20 __ __ **(1170)**
MM DD YYYY

COMMENTS: (6000)

_____

_____

_____

AsthmaNet	ALfA ELIGIBILITY CHECKLIST 2	Part. ID: __ __ - __ __ __ - __ __ __ Part. Initials: __ __ __ Visit: __ Visit Date: __ __ / __ __ / 20 __ __ Coordinator ID: __ __ __ __

(Coordinator Completed)

1. Does the participant have current evidence of any of the conditions listed on the Exclusionary Medical Conditions for ALfA (P9_EXCLMED) reference card, or any chronic diseases (other than asthma) that would prevent participation in the trial or put the participant at risk by participation? **(1000)** ☐1 Yes ☐0 No

   1a. If ***YES***, describe: **(1000D)** _____

2. Does the participant have a history of…

   2a. bladder-neck obstruction? **(1010)** ☐1 Yes ☐0 No

   2b. urinary retention? **(1020)** ☐1 Yes ☐0 No

   2c. benign prostatic hyperplasia (BPH)? **(1030)** ☐1 Yes ☐0 No

   2d. clinically relevant urologic disorder that precludes study participation? **(1040)** ☐1 Yes ☐0 No

   2e. narrow angle glaucoma? **(1050)** ☐1 Yes ☐0 No

   2f. significant cardiovascular disorders or arrhythmias? **(1060)** ☐1 Yes ☐0 No

   2g. esophageal ulcers? **(1070)** ☐1 Yes ☐0 No

   2h. hematemesis? **(1080)** ☐1 Yes ☐0 No

   2i. uncontrolled gastro-esophageal reflux disease? **(1090)** ☐1 Yes ☐0 No

   2j. delayed esophageal emptying caused by abnormality such as stricture or achalasia? **(1100)** ☐1 Yes ☐0 No

   2k. osteonecrosis of the jaw? **(1110)** ☐1 Yes ☐0 No

3. Has the participant taken any medications listed on the Exclusionary Drugs for ALfA (P9_EXCLDRUG) reference card within the specified time periods? **(1120)** ☐1 Yes ☐0 No

4. Has the participant taken omalizumab (Xolair®) within the past 3 months? **(1130)** ☐1 Yes ☐0 No

5. Has the participant used a LABA in the past 4 weeks? **(1140)** ☐1 Yes ☐0 No

6. Has the participant taken bisphosphonates within the past 6 months? **(1150)** ☐1 Yes ☐0 No

7. Does the participant use aspirin or non-steroidal anti-inflammatory medications (NSAIDs) regularly? **(1153)** ☐1 Yes ☐0 No

   7a. If ***YES***, is the participant able to discontinue use of aspirin and/or NSAIDs during the course of the study? **(1157)** ☐1 Yes ☐0 No

8. Is the participant currently taking prescription or OTC medication(s) other than those listed on the Allowed Medications (P9_MEDALLOW) reference card? **(1160)** ☐1 Yes ☐0 No

9. Based on input from the participant and the study physician, will the participant need to use intranasal steroids at any time during the study? **(1170)** ☐1 Yes ☐0 No

   9a. If ***YES***, is the participant willing to use a single intranasal steroid at a stable dose continuously for the duration of the study, starting at Visit 1? **(1180)** ☐1 Yes ☐0 No

10. Is the participant currently receiving allergen immunotherapy (e.g., allergy shots) other than an established maintenance regimen implemented continuously for a minimum of 3 months? **(1190)** ☐1 Yes ☐0 No

11. Has the participant used any smokeless tobacco products (e.g., chew, snuff) in the past year? **(1200)** ☐1 Yes ☐0 No

12. Has the participant smoked cigarettes, a pipe, cigar, marijuana, electronic cigarettes, or any other substance in the past year? **(1210)** ☐1 Yes ☐0 No

13. Does the participant have a smoking history of greater than 10 pack-years? **(1220)** ☐1 Yes ☐0 No

    ➔ Note: Pack-year history will be recorded on the Adult Asthma and Allergy History (ASTHMA_HX_ADULT) form.

14. Has the participant received a physician diagnosis of asthma at least 12 months ago? **(1230)** ☐1 Yes ☐0 No

15. Has the participant experienced a life-threatening asthma exacerbation requiring treatment with intubation, mechanical ventilation or resulting in hypoxic seizure in the past 2 years? **(1240)** ☐1 Yes ☐0 No

16. Has the participant had an asthma exacerbation or other condition requiring systemic corticosteroid treatment in the past 4 weeks? **(1250)** ☐1 Yes ☐0 No

17. Has the participant taken more than five courses of systemic corticosteroids in the past year for asthma exacerbation conditions? **(1260)** ❑1 Yes ❑0 No

18. Is the participant potentially able to bear children? **(1270)** ❑1 Yes ❑0 No ❑9 N/A
(*If participant is male, check N/A and go to Q19.)*

18a. If ***YES***, is the participant currently pregnant? **(1280)** ❑1 Yes ❑0 No

18b. If ***YES***, is the participant currently lactating? **(1290)** ❑1 Yes ❑0 No

18bi. If ***YES***, is participant willing to not nurse during study and for 6 months following study completion? **(1300)** ❑1 Yes ❑0 No

18c. If ***YES***, does the participant agree to use one of the approved methods indicated on the Birth Control Methods (BIRTH_CTRL) reference card for the duration of the study? **(1310)** ❑1 Yes ❑0 No

18d. If ***YES***, does the participant agree to use one of the approved birth control methods for 6 months following study completion? **(1320)** ❑1 Yes ❑0 No

19. Is the participant eligible to proceed? **(1330)** ❑1 Yes ❑0 No

If any of the shaded boxes are completed, the participant is ineligible.

➔ ***If YES*, proceed with remaining Visit 1 procedures.**

Participant Source Documentation

Participant Initials: __ __ __ **(1340)**

Date: __ __ / __ __ / 20 __ __ **(1350)**
MM DD YYYY

COMMENTS: (6000)

_____

_____

_____

AsthmaNet	ALfA ELIGIBILITY CHECKLIST 3	Part. ID: __ __ - __ __ __ - __ __ __ Part. Initials: __ __ __ Visit: __ Visit Date: __ __ / __ __ / 20 __ __ Coordinator ID: __ __ __ __

(Coordinator Completed)

Section 1

1. Was the participant's prebronchodilator $FEV_1 \geq 50\%$ predicted and ≥ 1L? **(1000)** ❑1 Yes ❑0 No

2. Was the participant's $FEV_1 \geq 80\%$ predicted? **(1010)** ❑1 Yes ❑0 No

   ➔ If ***YES***, skip to Q3.

Complete Q2a only if IRB approval for protocol version 2.2 <u>has NOT yet been obtained</u>.

2a. If ***NO***, did the participant's FEV_1 improve ≥ 12% in response to four puffs of albuterol? **(1020)** ❑1 Yes ❑0 No

   ➔ Skip to Q4.

Complete Q2b only if IRB approval for protocol version 2.2 <u>has been obtained</u>.

2b. If ***NO***, did the participant's FEV_1 improve ≥ 12% in response to four puffs of albuterol? **(1025)** ❑1 Yes ❑0 No ❑9 N/A

   ➔ If ***YES***, skip to Q4.

3. Was the participant's methacholine $PC_{20} \leq 8$ mg/mL? **(1030)** ❑1 Yes ❑0 No

Section 2

4. Is the participant able to use a Diskus® properly, as evidenced by achieving a score of 10 on the Diskus® Inhalation Technique Checklist (TECH_DISKUS)? **(1040)** ❑1 Yes ❑0 No

5. Does the participant have any condition or issue which, in the opinion of the investigator, might interfere with study participation? **(1050)** ❑1 Yes ❑0 No

   6a. If ***YES***, describe: **(1050D)** _____

6. Is the participant eligible to proceed? **(1060)** ❑1 Yes ❑0 No

   If any of the shaded boxes are completed, the participant is ineligible.

   ➔ ***If YES,*** **proceed with remaining Visit 1 procedures.**

COMMENTS: **(6000)**

_____

_____

P9 ELIG3

AsthmaNet

ALfA ELIGIBILITY CHECKLIST 4

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed)

Section 1

For Q1-Q3, refer to P9_LAB in Visit 1 packet.

1. Is the participant's serum total calcium < 8.5 mg/dL? **(1000)** ❑1 Yes ❑0 No

   1a. If ***YES***, is the participant's ionized calcium < 4.4 mg/dL? **(1010)** ❑1 Yes ❑0 No

2. Is the sum of the participant's absolute lymphocyte and monocyte counts < 900 cells/µL? **(1020)** ❑1 Yes ❑0 No

3. Is the participant's estimated Glomerular Filtration Rate (eGFR) < 35 mL/min? **(1030)** ❑1 Yes ❑0 No

4. Since Visit 1, has the participant experienced one or more asthma exacerbations as defined in the protocol? **(1040)** ❑1 Yes ❑0 No

5. Since Visit 1, has the participant taken any medications listed on the Exclusionary Drugs for ALfA (P9_EXCLDRUG) reference card? **(1050)** ❑1 Yes ❑0 No

6. Did the participant take at least 80% of the required puffs from his or her Diskus® during the run-in? **(1060)** ❑1 Yes ❑0 No

Section 2

➔ ***If Visit 2 FEV_1 < 80% of baseline (Visit 1) or < 45% predicted AND participant is experiencing an increase in asthma symptoms (cough, phlegm/mucus, chest tightness, wheezing, or shortness of breath), the participant is experiencing an asthma exacerbation as defined in the protocol and is ineligible. Update Q4 above accordingly, and complete the ALfA Significant Asthma Exacerbation (P9_SIGEX) form.***

Complete Q7 only if IRB approval for protocol version 2.3 <u>has NOT yet been obtained</u>.

7. Was the participant able to provide 40 mL of blood for biochemical assays? **(1070)** ❑1 Yes ❑0 No

Complete Q8 only if IRB approval for protocol version 2.3 <u>has been obtained</u>.

8. Was the participant able to provide 80 mL of blood for biochemical assays? **(1075)** ❑1 Yes ❑0 No

9. Was the participant's salmeterol-protected PC_{20} ≥ 0.25 mg/mL and ≤ 16 mg/mL? **(1080)** ❑1 Yes ❑0 No

P9 ELIG4

10. Does the participant wish to withdraw consent from the study? **(1090)** ☐1 Yes ☐0 No

11. Is there any new information that makes the participant ineligible according to the eligibility criteria? **(1100)** ☐1 Yes ☐0 No

12. Does the participant have any condition or issue which, in the opinion of the investigator, might interfere with study participation? **(1110)** ☐1 Yes ☐0 No

    12a. If ***YES***, describe: **(1110D)** _____

13. Is the participant eligible to proceed? **(1120)** ☐1 Yes ☐0 No

If any of the shaded boxes are completed, the participant is ineligible.

➔ ***If YES,*** **proceed with remaining Visit 2 procedures*.***

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet	ALfA LABORATORY RESULTS	Part. ID: __ __ - __ __ __ - __ __ __ Part. Initials: __ __ __ Visit: __ __ Visit Date: __ __ / __ __ / 20 __ __ Coordinator ID: __ __ __ __

(Coordinator Completed)

1. CBC with differential cell count

1a. WBC	**(1000)**	__ __ __ . __ K/µL
1b. HCT	**(1010)**	__ __ . __ %
1c. HGB	**(1020)**	__ __ . __ g/dL
1d. Platelet count	**(1030)**	__ __ __ K/µL
1e. Differential (absolute count)		
1ei. Lymphocytes	**(1040)**	__ __ __ __ cells/µL
1eii. Monocytes	**(1050)**	__ __ __ __ cells/µL

Clinic Use Only

Lymphocytes + Monocytes *(1ei + 1eii)* __ __ __ __ cells/µL

➔ ***Sum for completion of P9_ELIG4 Q1020.***

1eiii. Basophils	**(1060)**	__ __ __ __ cells/µL
1eiv. Neutrophils	**(1070)**	__ __ __ __ cells/µL
1ev. Eosinophils	**(1080)**	__ __ __ __ cells/µL
2. Serum Calcium (total)	**(1090)**	__ __ . __ mg/dL
2a. Ionized Calcium *(if serum Calcium < 8.5 mg/dL)*	**(1100)**	__ __ . __ mg/dL
3. Serum Creatinine	**(1110)**	__ __ . __ mg/dL
4. Estimated GFR (eGFR)	**(1120)**	__ __ __ . __ mL/min

➔ ***To calculate, see following page for instructions.***
➔ ***If eGFR <35 mL/min, the participant is ineligible to continue in ALfA.***

Clinic Use Only: Use on-line calculator at www.mdcalc.com/creatinine-clearance-cockcroft-gault-equation to compute the Cockcroft-Gault estimate. The following values are required to compute eGFR.

Gender ❑ Male ❑ Female Age __ __ years

Weight (lbs) __ __ __ . __ lbs Height (in) __ __ in

➔ ***Following completion of the above fields on the website, value given for "Creatinine Clearance Modified for Underweight/Normal weight/Overweight patient" should be entered in Q1120.***

COMMENTS: (6000)

_____

_____

_____

AsthmaNet

ALfA METHACHOLINE CHALLENGE TESTING

Supervisor ID: __ __ __ __

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Technician ID: __ __ __ __

(Technician Completed)

Complete this form only if the ALfA study participant is eligible according to the Methacholine Challenge Testing Checklist (METHACHK) form.

Clinic Use Only *(Technician Completed)*
Use the FEV_1 value from the PADVAIR_SPIRO form as the baseline reference.

A. Baseline (pre) FEV_1 prior to methacholine challenge __ . __ __ L

B. Methacholine Reversal Reference Value (Question A x 0.90 = __ . __ __ L)

1. Post Diluent FEV_1 **(1000)** __ . __ __ L

2. Did the participant drop ≥ 20% at the diluent stage? **(1010)** ❑$_1$ Yes ❑$_0$ No
   ➔ If ***YES***, proceed to Q5. Record 'Yes' for Q5 and 0 for Q5a.

3. Last concentration of methacholine administered **(1020)** __ __ . __ __ __ __ mg/ml

4. FEV_1 after last concentration of methacholine administered **(1030)** __ . __ __ L

5. Did the participant achieve a PC_{20}? **(1040)** ❑$_1$ Yes ❑$_0$ No
   ➔ If ***NO***, proceed to Q6.

   5a. PC_{20} **(1050)** __ __ . __ __ mg/ml

6. Time methacholine challenge ended *(based on 24-hour clock)* **(1060)** __ __ __ __

7. Participant's FEV_1 after standard reversal from methacholine challenge

   For ALfA study only:
   Standard reversal = 2 puffs ipratropium.

   7a. FEV_1 **(1070)** __ . __ __ L

   7b. Time of FEV_1 in Q7a (*based on 24-hour clock)* **(1080)** __ __ __ __

   7c. Was the FEV_1 from Q7a ≥ the methacholine reversal reference value (B) in the gray box above? **(1090)** ❑$_1$ Yes ❑$_0$ No

➔ ***If YES, STOP HERE and continue with remaining visit procedures.***
➔ ***If NO, proceed to the Additional Treatment for Methacholine Challenge Testing (METHA_ADD_TRT) form.***

COMMENTS: **(6000)**

* M E T H A *

AsthmaNet	**ALfA ADDITIONAL TREATMENT POST METHACHOLINE CHALLENGE TESTING** Supervisor ID: __ __ __ __	Part. ID: __ __ - __ __ __ - __ __ __ Part. Initials: __ __ __ Visit: __ __ __ Visit Date: __ __ / __ __ / 20 __ __ Technician ID: __ __ __ __

(Technician Completed)

Complete this form only if the ALfA participant did not reverse to 90% of baseline (pre) FEV_1 after the first post-challenge treatment of ipratropium.

1. Was an additional treatment used in the first hour? **(1000)** ❑$_1$ Yes ❑$_0$ No
   ➔ If ***NO***, skip to Q3.

   1a. Additional ipratropium **(1010)** ❑$_1$ Yes ❑$_0$ No
   ➔ If ***NO***, skip to Q1b.

   Number of additional puffs of ipratropium administered **(1020)** ❑$_1$ 2

   1b. Nebulized Beta-agonist **(1030)** ❑$_1$ Yes ❑$_0$ No

   1c. Subcutaneous epinephrine **(1040)** ❑$_1$ Yes ❑$_0$ No

   1d. Implementation of clinic emergency protocol or algorithm **(1050)** ❑$_1$ Yes ❑$_0$ No

   1e. Other **(1060)** ❑$_1$ Yes ❑$_0$ No

   If ***YES***, specify: **(1060D)** _____

2. Participant's FEV_1 after additional treatment within first hour.

   2a. FEV_1 **(1070)** __ . __ __ L

   2b. Time of FEV_1 in Q2a *(based on 24-hour clock)* **(1090)** __ __ __ __

   2c. Was the FEV_1 from Q2a ≥ the methacholine reversal reference value (B) in the gray box on the Methacholine Challenge Testing (METHA) form? **(1100)** ❑$_1$ Yes ❑$_0$ No
   ➔ If ***YES, STOP HERE*** and continue with remaining visit procedures.

   ➔ If ***NO***, proceed to Q3.

3. Was additional treatment used after one hour? **(1110)** ❑$_1$ Yes ❑$_0$ No
   ➔ If ***NO***, skip to Q4.

   3a. Additional albuterol by MDI **(1120)** ❑$_1$ Yes ❑$_0$ No
   ➔ If ***NO***, skip to Q3b.

	Number of additional puffs of albuterol administered	(1130)	❑1 2	❑2 4 ❑3 > 4
3b.	Nebulized Beta-agonist	(1140)	❑1 Yes	❑0 No
3c.	Subcutaneous epinephrine	(1150)	❑1 Yes	❑0 No
3d.	Implementation of clinic emergency protocol or algorithm	(1160)	❑1 Yes	❑0 No
3e.	Treatment in the emergency room	(1170)	❑1 Yes	❑0 No
3f.	Overnight hospitalization ➔ If ***YES***, please complete the Serious Adverse Event (SERIOUS) form.	(1180)	❑1 Yes	❑0 No
3g.	Other	(1190)	❑1 Yes	❑0 No
	If ***YES***, specify:	(1190D)	_____	

4. Participant's final FEV_1 after methacholine challenge

4a.	FEV_1	(1200)	__ . __ __ L
4b.	Time of FEV_1 in Q4a *(based on 24-hour clock)*	(1220)	__ __ __ __
4c.	Was the FEV_1 from Q4a ≥ the methacholine reversal reference value (B) in the gray box on the Methacholine Challenge Testing (METHA) form? ➔ If ***NO***, complete the source documentation box below.	(1230)	❑1 Yes ❑0 No

Physician Source Documentation

Physician's Signature: _____ (1240)

Date: __ __ / __ __ / 20 __ __ (1250)
MM DD YYYY

Time: __ __ __ __ *(based on a 24-hour clock)* (1260)

COMMENTS: (6000)

_____

_____

_____

AsthmaNet

ALfA PARTICIPANT STUDY TREATMENT QUESTIONNAIRE

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Participant Completed)

This questionnaire is to be completed by the ALfA participant at Visit 3. If a randomized participant terminates prior to Visit 3, please ask the participant to complete this form during the termination visit. Coordinators should ensure that participants understand what their choices are for Question #1 before they begin to complete the form.

Blinded Scheduled Capsules

1. As an ALfA study participant, you were randomized to receive either real (i.e., active) alendronate capsules or look-alike placebo (i.e., inactive) capsules. Please check the box next to the treatment that you believe you received **over the past 8 weeks.**

(1000)
- ❑$_1$ alendronate
- ❑$_2$ placebo

2. How sure are you about your answer to Question 1?

(1010)
- ❑$_1$ Absolutely sure – I know what the capsules contained
- ❑$_2$ Moderately sure
- ❑$_3$ Somewhat sure
- ❑$_4$ Not sure at all – purely a guess

3. Please comment with respect to any observations you made that helped you make your choice in Question 1 (for example: **taste, smell, or physical sensations** related to your scheduled capsules).

(1020)
- ❑$_1$ I have no comments
- ❑$_2$ I noticed the following: *(Describe below)*

(1020D) _____

_____

_____

_____

Participant Source Documentation
Participant Initials: __ __ __ **(1030)**
Date: __ __ / __ __ / 20 __ __ **(1040)**
MM DD YYYY

AsthmaNet

ALfA PULMONARY PROCEDURE CHECKLIST

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Technician ID: __ __ __ __

(Participant Interview Completed)

Complete this form at all visits where baseline spirometry is required. If any medications other than study Diskus®, rescue ipratropium or albuterol were used, record the medication(s) on the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form.

1. Have you used any weight loss medications in the past **4** hours? **(1000)** ☐1 Yes ☐0 No
   Examples: Belviq, bitter orange, Xenadrine, EFX, Thermorexin, Qsymia
2. Have you consumed any food containing alcohol or beverages containing alcohol in the past **4** hours? **(1010)** ☐1 Yes ☐0 No
3. Have you consumed caffeine in the past **6** hours? **(1020)** ☐1 Yes ☐0 No
   Examples: Pepsi, Coke, Coffee, Mountain Dew, Tea, Rootbeer, Red Bull, 5-hour ENERGY
4. Have you used medications with caffeine in the past **6** hours? **(1030)** ☐1 Yes ☐0 No
   Examples: Anacin, Darvon compound, Esgic, Excedrin, Fiorinal, Fioricet, No Doz, Norgesic, Vivarin
5. Have you used a short-acting anticholinergic in the past **12** hours? **(1040)** ☐1 Yes ☐0 No
   Examples: ipratropium (study green RESCUE1, Atrovent)
6. Have you used an intermediate-acting inhaled beta-agonist in the past **24** hours? **(1050)** ☐1 Yes ☐0 No
   Examples: albuterol (study blue RESCUE2, Combivent, Proventil, ProAir, Ventolin)
7. Have you used any ophthalmic antihistamines in the past 1**2** hours? **(1060)** ☐1 Yes ☐0 No
   Examples: Alaway, Elestat, Emadine, Optivar, Pataday, Patanol, Zaditor
8. Have you used any nasal antihistamines in the past **12** hours? **(1070)** ☐1 Yes ☐0 No
   Examples: Astelin, Astepro, Livostin, Patanase
9. Have you used a tricyclic antidepressant or atypical antipsychotic in the past **24** hours? **(1073)** ☐1 Yes ☐0 No
   Examples: amitriptyline (Elavil), clomipramme (Anafranil), desipramine (Norpramin), doxepin (Sinequan), imipramine (Tofranil), nortriptyline (Pamelor), quetiapine (Seroquel)

P9 PULMONARYCHK

9a. If ***YES***, have you taken your morning dose? **(1075)** ❑1 Yes ❑0 No

➔ ***If YES to Q9 and NO to Q9a, participant's last dose prior to the next visit should be taken at the same time as it was taken prior to this visit.***

10. Have you used any second-generation oral antihistamines in the past **24** hours? **(1080)** ❑1 Yes ❑0 No
Examples: fexofenadine (Allegra), des/loratadine (Clarinex, Claritin), levo/cetirizine (Xyzal, Zyrtec)

11. Have you used any first-generation or other types of oral antihistamines in the past **12** hours? **(1090)** ❑1 Yes ❑0 No
Examples: brompheniramine (Ala-Hist, Dimetapp, etc), diphenhydramine (Benadryl, Tylenol PM, Sominex, etc), carbinoxamine, dex/chlorpheniramine (ChlorTrimeton), cyproheptadine, clemastine (Dayhist, Tavist), doxylamine (NyQuil, Unisom, etc), hydroxyzine (Atarax, Vistaril), ketotifen (Zaditen), meclizine (Dramamine)

➔ ***If participant is taking medication not listed here, refer to AsthmaNet Drug Codes list to determine class or contact Scientific Coordinator at DCC.***

12. Have you used any nasal decongestants in the past **6** hours? **(1100)** ❑1 Yes ❑0 No
Examples: oxymetazoline (Afrin)

13. Have you used any oral decongestants or cold remedies in the past **48** hours? **(1110)** ❑1 Yes ❑0 No
Examples: pseudoephedrine (Sudafed), Tylenol Allergy

14. Have you used any smokeless tobacco products today? **(1120)** ❑1 Yes ❑0 No
Examples: chewing tobacco, snuff

15. ***(Visits 2 and 3 only)*** When did you last take your scheduled Diskus®?

15a. Date **(1130)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

15b. Time *(based on 24 hour clock)* **(1140)** __ __ __ __

15c. ***(Visit 3 only)*** Did the participant last take scheduled Diskus® prior to 1 AM last evening? **(1150)** ❑1 Yes ❑0 No

15d. ***(Visit 3 only)*** Did the participant take scheduled Diskus® between 5 PM and 1 AM last evening? **(1155)** ❑1 Yes ❑0 No

16. ***(Visits 2 and 3 only)*** Has the participant had a respiratory infection within the past 4 weeks? **(1157)** ☐1 Yes ☐0 No

➔ ***If YES at Visit 2, reschedule visit to allow 4 weeks between resolution of lower respiratory symptoms and Visit 2. If respiratory infection was acute, supervising physician should be consulted. If physician feels methacholine challenge results will be adversely affected even after 4 week delay, the date of the rescheduled visit should be based on the physician's discretion.***

➔ ***If YES at Visit 3, reschedule visit to allow 4 weeks between resolution of lower respiratory symptoms and Visit 3. If respiratory infection was acute, supervising physician should be consulted. If physician feels methacholine challenge results will be adversely affected even after 4 week delay, the date of the rescheduled visit should be based on the physician's discretion. If 4+ week delay requires more than 12 weeks on alendronate, participant should be terminated.***

17. At this time, is your asthma worse because of recent exposure to triggers? **(1160)** ☐1 Yes ☐0 No
Examples: cold air, smoke, allergens, recent exercise, a recent respiratory tract infection, or other pulmonary infection

18. Is there any other reason you should not proceed with spirometry testing? **(1170)** ☐1 Yes ☐0 No

If ***YES,*** explain: **(1170D)** _____

19. Is the participant eligible to proceed with the spirometry testing? **(1180)** ☐1 Yes ☐0 No

If any of the shaded boxes are filled in, the participant is ineligible for spirometry.

➔ ***If YES, proceed to Q19 or the next form/procedure listed on the visit procedure checklist.***

➔ ***If NO, reschedule visit.***

If participant is 18 to 20 years old, complete Q19 at Visits 2 and 3.

At Visit 1, refer to height recorded on the Adult Body Measurements (BODYMEAS_ADULT) form; do not record on this form.

20. Height (without shoes) **(1190)** __ __ __ cm

COMMENTS: **(6000)**

_____

AsthmaNet	**ALfA SALIVA COLLECTION CHECKLIST**	Part. ID: __ __ - __ __ __ - __ __ __ Part. Initials: __ __ __ Visit: __ __ __ Visit Date: __ __ / __ __ / 20 __ __ Technician ID: __ __ __ __

(Coordinator Completed)

1.	Has the participant had dental work performed in the past 24 hours?	**(1000)**	❑1 Yes	❑0 No
2.	Has the participant engaged in vigorous physical activity in the past 3 hours?	**(1010)**	❑1 Yes	❑0 No
3.	Has the participant eaten in the past 60 minutes?	**(1020)**	❑1 Yes	❑0 No
4.	Has the participant engaged in repetitive chewing (including but not limited to chewing gum, nicotine gum, paraffin wax, chewing tobacco) or used hard candies, cough drops, lozenges, etc. in the past 60 minutes?	**(1030)**	❑1 Yes	❑0 No
5.	Has the participant brushed or flossed his/her teeth in the past 45 minutes?	**(1040)**	❑1 Yes	❑0 No
6.	Has at least 10 minutes elapsed since the participant rinsed his/her mouth with water?	**(1050)**	❑1 Yes	❑0 No

7.	Is the participant eligible to proceed with saliva collection?	**(1060)**	❑1 Yes	❑0 No

If any of the shaded boxes are completed, the participant is ineligible to provide a saliva sample at this time.

8. Pre-Advair® saliva collection start time (*based on 24 hour clock*) **(1070)** __ __ __ __

***REMINDER**:*

- ➔ ***Proceed with FeNO testing and spirometry prior to administering Advair®.***
- ➔ ***Post-Advair® saliva collection should occur one hour after Advair® administration.***

9. Post-Advair® saliva collection start time (*based on 24 hour clock*) **(1080)** __ __ __ __

COMMENTS: (6000)

_____

_____

_____

P9 SALIVACHK

AsthmaNet	ALfA SIGNIFICANT ASTHMA EXACERBATION	Part. ID: __ __ - __ __ __ - __ __ __ Part. Initials: __ __ __ Visit: __ __ Visit Date: __ __ / __ __ / 20 __ __ Coordinator ID: __ __ __ __

(Coordinator Completed)

Complete this form each time a participant experiences an asthma exacerbation.

1. Did the participant experience an increase in cough, phlegm/mucus, chest tightness, wheezing, or shortness of breath in association with any of the following:

   1a. An increase in rescue use (ipratropium (RESCUE1) and albuterol (RESCUE2) combined) of ≥ 8 puffs/day over baseline use for a period of 48 hours? **(1000)** ❑$_1$ Yes ❑$_0$ No

   ➔ Refer to ALfA Baseline PEF and Rescue Use Values (P9_BASELINE) form.

   1b. Use of ≥ 16 puffs of his/her rescue inhaler(s) (ipratropium (RESCUE1) and albuterol (RESCUE2) combined) in a 24 hour period? **(1010)** ❑$_1$ Yes ❑$_0$ No

   1c. A fall in prebronchodilator FEV_1 to < 80% of baseline (Visit 1)? **(1020)** ❑$_1$ Yes ❑$_0$ No ❑$_9$ N/A

   1d. A fall in prebronchodilator FEV_1 to < 45% of predicted? **(1030)** ❑$_1$ Yes ❑$_0$ No ❑$_9$ N/A

   1e. Treatment with systemic corticosteroids for his/her asthma exacerbation? **(1040)** ❑$_1$ Yes ❑$_0$ No

   ➔ If ***YES***, please record on Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form.

2. Did the participant experience a significant asthma exacerbation? **(1050)** ❑$_1$ Yes ❑$_0$ No
   If any of the shaded boxes in Q1a-Q1e are completed, the participant experienced an asthma exacerbation.

   ➔ ***If YES, complete the rest of this form and record the exacerbation on the Clinical Adverse Events (AECLIN) form using ICD-9 code 493.92. If IRB approval for Version 2.2 <u>has been obtained</u> and:***

   - ***First exacerbation of treatment phase, schedule Visit 3 to allow 4 weeks between completion of prednisone and Visit 3. If this requires more than 12 weeks on alendronate, participant should be terminated.***
   - ***Second exacerbation of treatment phase, participant should be terminated.***

   ➔ ***If NO, STOP HERE and continue with remaining visit procedures. Do NOT submit this form to the DCC.***

3. Date exacerbation conditions were met **(1060)** __ __ / __ __ / 20 __ __
MM DD YYYY

4. Did the participant seek care for significant asthma exacerbation conditions? **(1070)** ❑1 Yes ❑0 No
➔ If ***NO***, skip to Q7.

5. What type of care was sought?

5a. Study Investigator or Coordinator? **(1080)** ❑1 Yes ❑0 No

5ai. If ***YES***, indicate type of contact **(1090)** ❑1 Scheduled clinic visit
❑2 Unscheduled clinic visit
❑3 Phone contact

5b. Primary Care or Other Physician? **(1100)** ❑1 Yes ❑0 No

5bi. If ***YES***, indicate the type of contact **(1110)** ❑1 Scheduled clinic visit
❑2 Unscheduled clinic visit
❑3 Phone contact

5c. Emergency Department visit? **(1120)** ❑1 Yes ❑0 No

5d. Urgent Care Visit? **(1130)** ❑1 Yes ❑0 No

6. Was the participant hospitalized? **(1140)** ❑1 Yes ❑0 No

➔ If ***YES***, complete the Serious Adverse Event Reporting Form (SERIOUS).

If ***YES***,

6a. Duration of hospital stay **(1150)** __ __ . __ days

6b. Was intubation or ventilation assistance required? **(1160)** ❑1 Yes ❑0 No

6c. Was the participant admitted to the intensive care unit? **(1170)** ❑1 Yes ❑0 No

7. Did the participant take any of the following medications (excluding study medication) for treatment of the asthma exacerbation?

➔ If ***YES*** to any of Q7a-Q7f, complete the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form.

7a.	Inhaled corticosteroids	**(1180)**	❑1 Yes ❑0 No
7b.	Nebulized bronchodilator	**(1190)**	❑1 Yes ❑0 No
7c.	Oral corticosteroids	**(1200)**	❑1 Yes ❑0 No
7d.	IM or IV steroids	**(1210)**	❑1 Yes ❑0 No
7e.	Antibiotics	**(1220)**	❑1 Yes ❑0 No
7f.	Other	**(1230)**	❑1 Yes ❑0 No
		(1230D)	_____

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

ALfA
TERMINATION OF STUDY PARTICIPATION

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed)

Complete this form only for participants who successfully completed Visit 1.

1. Has the participant completed the study through Visit 3? **(1000)** ❑$_1$ Yes ❑$_0$ No

   ➔ ***If YES, skip to the SIGNATURES section.***

2. Who initiated termination of the participant? **(1010)** ❑$_1$ Participant ❑$_2$ Clinical Staff

   ➔ ***If participant withdrew due to impending clinical staff termination, indicate termination by clinical staff.***

   ➔ ***If Clinical Staff, skip to Q4.***

3. Indicate the **primary** reason the participant has withdrawn from the study.

   ❑$_1$ no longer interested in participating* **(1020)**
   ❑$_2$ no longer willing to follow protocol*
   ❑$_3$ difficult access to clinic (location, transportation, parking)
   ❑$_4$ unable to make visits during clinic hours
   ❑$_5$ moving out of the area
   ❑$_6$ unable to continue due to personal constraints*
   ❑$_7$ unable to continue due to medical condition unrelated to asthma*
   ❑$_8$ side effects of study medications*
   ❑$_9$ dissatisfied with asthma control
   ❑$_{10}$ other*

***Additional explanation required: (1030D)**

_____

_____

➔ ***Skip to SIGNATURES section.***

P9 TERM

4. Did clinical staff terminate the participant due to…

4a.	pregnancy? *(Check N/A if participant is male.)*	(1040)	❑1 Yes	❑0 No ❑9 N/A
4b.	loss to follow-up?*	(1050)	❑1 Yes	❑0 No
	4bi. If ***YES***, date of last contact with participant	(1060)	__ __ / __ __ / 20 __ __ (MM / DD / YYYY)	
	4bii. If ***YES***, type of contact	(1070)	❑1 In-person visit ❑2 Phone call	
4c.	an asthma-related adverse event?*	(1080)	❑1 Yes	❑0 No
4d.	a medication-related adverse event?*	(1090)	❑1 Yes	❑0 No
4e.	an adverse event not related to asthma or medications?*	(1100)	❑1 Yes	❑0 No
4f.	non-compliance with medication dosing?*	(1110)	❑1 Yes	❑0 No
4g.	non-compliance with visit attendance?*	(1120)	❑1 Yes	❑0 No
4h.	significant asthma exacerbation during run-in (Visits 1-2)?*	(1130)	❑1 Yes	❑0 No
4i.	inadequate blood collection at Visit 2?	(1140)	❑1 Yes	❑0 No

➔ ***<40mL if IRB approval for protocol version 2.3 has NOT yet been obtained***

➔ ***<80mL if IRB approval for protocol version 2.3 has been obtained***

4j.	low lymphocytes and monocytes (sum <900 cells/μL)?	(1150)	❑1 Yes	❑0 No
4k.	ineligibility during the run-in period (Visits 1-2) for reasons other than compliance, exacerbation, or inadequate blood samples?*	(1160)	❑1 Yes	❑0 No
4l.	other reason?*	(1170)	❑1 Yes	❑0 No

***Additional explanation required:** (1180D)

_____

_____

_____

4m. Indicate the letter corresponding to the **primary** reason the participant was terminated. (1190) __

SIGNATURES
Please complete the following section regardless of the reason for termination of study participation.

I verify that all information collected on the AsthmaNet ALfA data collection forms for this participant is correct to the best of my knowledge and was collected in accordance with the procedures outlined in the study protocol.

_____ **(1200)** __ __ / __ __ / 20 __ __ **(1210)**
Coordinator Signature MM DD YYYY

_____ **(1220)** __ __ / __ __ / 20 __ __ **(1230)**
Principal Investigator Signature MM DD YYYY

Drugs to be withheld throughout the study.

Excluded Drug	Generic Names (may not be inclusive)	Trade Names (may not be inclusive)	Washout Prior to Visit 1
Steroid Medications			
Oral or intravenous steroids for any reason except as provided in study	dexamethasone, prednisone, prednisolone	Decadron, Medrol, Orapred, Prednisone, Prelone	4 weeks
Inhaled steroids, except as provided in study	beclomethasone, budesonide, ciclesonide, flunisolide, fluticasone, mometasone, triamcinolone acetonide	Aerobid, Alvesco, Asmanex, Azmacort, Flovent, Pulmicort, QVAR	None
Intranasal steroids, except at stable drug and dose throughout study	beclomethasone, budesonide, ciclesonide, flunisolide, fluticasone, mometasone, triamcinolone acetonide	Beconase AQ, Flonase, Nasacort AQ, Nasarel, Nasonex, Omnaris, Rhinocort	None
Nonsteroidal Antiinflammatory Medications			
Leukotriene modifiers	montelukast, zafirlukast, zileuton	Accolate, Singulair, Zyflo	2 weeks
Cromolyn/Nedocromil for asthma	cromolyn, nedocromil	Intal, Tilade	1 week
NSAIDs	aspirin, ibuprofen, naproxen, meloxicam, ketoprofen	Advil, Aleve, Anacin, Ascriptin, Bayer, Bufferin, Ecotrin, Midol, Mobic, Motrin	None
Bronchodilators			
Oral β-agonists	albuterol, metaproterenol, terbutaline	Alupent, Brethine, Bricanyl, Metaprel, Proventil, Repetabs, Ventolin, Volmax	1 week
Short-acting inhaled β-agonists	epinephrine	Bronkaid Mist, Duo-Medihaler, Medihaler-Epi, Primatene Mist	24 hours
Intermediate-acting inhaled β-agonists, except study RESCUE2 drug	albuterol, bitolterol, levalbuterol, metaproterenol, pirbuterol, terbutaline	Alupent, Brethaire, Brethine, Bronkometer, Maxair, Metaprel, Proventil, Tornalate, Ventolin, Xopenex	24 hours
Long-acting inhaled β-agonists, except as provided in study	formoterol, salmeterol	Advair, Dulera, Foradil, Serevent, Symbicort	4 weeks
Short-acting inhaled anticholinergics, except study RESCUE1 drug	atropine, ipratropium bromide, pirenzepine, scopolamine	Atrohist, Atrovent, Bellatal, Combivent, Donnatal, Scopoderm, Transderm-Scop	12 hours
Long-acting inhaled anticholinergics	tiotropium	Spiriva	2 weeks

Drugs to be withheld throughout the study.

Excluded Drug	Generic Names (may not be inclusive)	Trade Names (may not be inclusive)	Washout Prior to Visit 1
Xanthine Derivatives			
Short-acting theophylline	theophylline	Aminophylline, Slo-Phyllin	12 hours
Long-acting theophylline	theophylline	Slo-bid, Theo-Dur	24 hours
Ultra Long-acting theophylline	theophylline	Theo-24, Uniphyl	48 hours
Anti-IgE Therapy			
	omalizumab	Xolair	3 months
Cardiac Drugs			
Alpha-beta blockers	labetalol	Normodyne	2 weeks
Beta blockers	acebutolol, atenolol, betaxolol, bisoprolol, carteolol, metoprolol, nadolol, penbutolol, pindolol, propranolol, timolol	Blocadren, Cartrol, Corgard, Inderal, Kerlone, Levatol, Lopressor, Sectral, Tenormin, Visken, Zebeta	2 weeks
Psych or CNS-Related Drugs			
Monoamine oxidase (MAO) inhibitors	harmaline, iproclozide, iproniazid, isocarboxazid, nialamide, phenelzine, selegiline, toloxatone, tranylcypromine	Nardil, Parnate	4 weeks
Antibiotics			
Macrolide antibiotics, chronic use excluded	azithromycin, clarithromycin, dirithromycin, erythromycin, roxithromycin, troleandomycin	Biaxin, Dynabac, Rulid, Surlid, TAO, Zithromax, Zitromax	2 weeks
Miscellaneous Exclusionary Drugs			
Drugs contraindicated when taking ipratropium	dicyclomine, glycopyrrolate, hyoscyamine, orphenadrine, tolterodine tartrate	Anaspaz, Antiflex, Banflex, Bentyl, Cystospaz, Detrol, Disipal, Donnamar, Flexoject, Levsin, Mio-Rel, Myolin, Myotrol, Orfro, Orphenate, Robinul	None
Drugs for urinary hesitancy	oxybutynin, tolterodine tartrate	Detrol, Ditropan	None
Drugs for narrow angle glaucoma	betaxolol, pilocarpine, timolol maleate	Betoptic S, Ocusert Pilo, Timoptic	None
Bisphosphonates	alendronate, etidronate, ibandronate, pamidronate, risedronate, tiludronate, zoledronic acid	Actonel, Aredia, Boniva, Didronel, Fosamax, Reclast, Skelid, Zometa	6 months

Drugs/substances to be withheld prior to Visits 1-3*.

Drug/Substance	Trade Names (may not be inclusive)	Washout Prior to Visits
ipratropium (study RESCUE1 inhaler)	Atrovent, Combivent	12 hours
albuterol (study RESCUE2 inhaler)	Ventolin, ProAir, Proventil	24 hours
Tricyclic antidepressants and atypical antipsychotics (amitriptyline, clomipramme, desipramine, doxepin, imipramine, nortriptyline, quetiapine)	Anafranil, Elavil, Norpramin, Pamelor, Tofranil, Sinequan, Seroquel	24 hours**
Second-generation oral antihistamines (cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine)	Allegra, Clarinex, Claritin, Xyzal, Zyrtec	24 hours
First-generation and other types of oral antihistamines (brompheniramine, carbinoxamine, chlorpheniramine, clemastine, cyproheptadine, dexchlorpheniramine, dimenhydrinate, diphenhydramine, doxylamine, hydroxyzine, ketotifen, meclizine)	Atarax, Ala-Hist, Benadryl, ChlorTrimeton, Dayhist, Dimetapp, Dramamine, Nyquil, Palgic, Sominex, Tavist, Tylenol PM, Unisom, Vistaril, Zaditen	12 hours
Ophthalmic antihistamines (azelastine ophthalmic, emedastine difumarate, epinastine ophthalmic, ketotifen fumarate, olopatadine ophthalmic)	Alaway, Elestat, Emadine, Opitvar, Pataday, Patanol, Zaditor	12 hours
Nasal antihistamines (azelastine nasal, olopatadine, levocabastine)	Astelin, Astepro, Livostin, Patanase	12 hours
Methylxanthine-containing food or beverages (caffeinated colas, coffee, tea)	Coke, Barq's Rootbeer, Mello-Yellow, Mountain Dew, Pepsi, Red Bull	6 hours
Methylxanthine-containing medications	Anacin, Darvon, Esgic, Excedrin, Fiorinal, Fioricet, No-Doz, Norgesic, Vivarin	6 hours
Weight loss medications	Belviq, bitter orange, Xenadrine, EFX, Thermorexin, Qsymia	4 hours
Alcohol-containing foods or beverages		4 hours

*These drugs/substances are allowed between visits, but not prior to pulmonary function testing.
**If participant must dose evening prior to visit, last dose should be taken at same time prior to each visit.

Exclusionary Medical Conditions for ALfA (may not be inclusive)

- Addison's disease
- AIDS
- Benign Prostatic Hyperplasia (BPH)
- Bladder-neck obstruction
- Cardiac arrhythmias or disorders (clinically significant)
- Congenital anomaly, including growth abnormalities (clinically significant)
- Congestive heart failure
- Coronary artery disease (unstable or severe)
- Cushing's disease
- Delayed esophageal emptying (caused by esophageal abnormality)
- Diabetes mellitus (poorly controlled)
- Dyspnea due to cause other than asthma, in judgment of investigator
- Eating disorder (e.g. active anorexia or bulimia)
- Esophageal ulcers (history of)
- Gastro-esophageal reflux disease (GERD; uncontrolled)
- Glaucoma (narrow angle)
- Hematemesis (history of)
- Hematologic disease (unstable, e.g. severe anemia)
- Hepatic disease
- Hypertension (poorly controlled)
- Hyperthyroidism
- Immunologic compromise
- Chronic kidney disease (glomerulonephritis, polycystic kidney disease, etc.)
- Lactation
- Lung disease other than asthma (COPD, emphysema, chronic bronchitis, pulmonary embolism, malignancy, cystic fibrosis, among others)
- Lupus (active disease requiring immunosuppressant)
- Any malignancy other than basal cell skin cancers
- Mental illness (uncontrolled)
- Mental retardation
- Neurologic disease (including epilepsy requiring treatment)
- Obesity treated with bariatric surgery
- Osteonecrosis of jaw (history of)
- Peptic ulcer disease (active)
- Pregnancy
- Schizophrenia
- Skeletal disorders, including osteoporosis and rheumatoid arthritis (excludes degenerative disc disease, scoliosis, and spinal stenosis)
- Sleep apnea (untreated)
- Substance abuse (including active drug or alcohol abuse)
- Tuberculosis (active disease; history of positive skin test with negative chest x-ray allowed)
- Urinary retention (active symptoms within last 6 months)
- Vocal cord dysfunction (diagnosis of)

ALfA Inhaled Corticosteroids Equivalency

AsthmaNet

The following inhaled corticosteroid doses (µg) may be considered equivalent to >100 – 1000µg and >500µg of inhaled fluticasone propionate DPI (Flovent® Diskus®):

	>100 – 1000µg	>500µg
beclomethasone HFA (QVAR®)	>80 – 800	>480
budesonide DPI (Pulmicort Flexhaler®)	>180 – 1800	>1200
ciclesonide HFA (Alvesco®)	>160 – 800	>640
flunisolide HFA (Aerospan™ MDI)	>320 – 1600	>640
fluticasone furoate DPI (Arnuity™ Ellipta®)	100 – 200	200
fluticasone propionate HFA (Flovent®)	>88 – 880	>440
mometasone DPI (Asmanex® Twisthaler®)	>220 – 1100	>400

09/17/2015 version 2.0

P9 ICS EQUIV

ALfA Inhaled Corticosteroids Equivalency

AsthmaNet

The following inhaled corticosteroid doses (µg) may be considered equivalent to >100 – 1000µg and >500µg of inhaled fluticasone DPI (Flovent® Diskus®):

	>100 – 1000µg	>500µg
beclomethasone HFA (QVAR®)	>80 – 800	>480
budesonide DPI (Pulmicort Flexhaler®)	>180 – 1800	>1200
ciclesonide HFA (Alvesco®)	>160 – 800	>640
flunisolide HFA (Aerospan™ MDI)	>320 – 1600	>640
fluticasone HFA (Flovent®)	>88 – 880	>440
mometasone DPI (Asmanex® Twisthaler®)	>220 – 1100	>400

02/18/2015 version1.1

P9 ICS EQUIV

- analgesics for acute/chronic pain management (with MD discretion)
- antianxiety agents/anxiolytics (e.g., diazepam, chlordiazepoxide, alprazolam, clonazepam, lorazepam, gabapentin, buspirone) at a stable dose
- antibiotics (e.g. penicillins, cephalosporins, quinolones, monobactams, sulfonamides, doxycycline, minocycline, nitroimidazoles (Flagyl), macrolides) for intermittent use
- antibiotics for acne (topical/oral) (macrolides allowed for intermittent use only)
- anti-cholesterol medications (e.g., gemfibrozil, statins, fenofibrate, niacin), except cholestipol and cholestyramine
- specific antidepressants at a stable dose
    - Selective Serotonin Reuptake Inhibitors (SSRI) (e.g., citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline)
    - Selective Serotonin Norepinephrine Reuptake Inhibitors (SSNRI) (e.g. desvenlafaxine, duloxetine, venlafaxine)
    - Non-SSRI/SSNRI antidepressants (except MAOI class drugs) (e.g. amitriptyline, amoxapine, bupropion, mirtazapine, nefazodone, trazodone and others)
- antihistamines (e.g. chlorpheniramine (Chlor-Trimeton), desloratadine (Clarinex), diphenhydramine (Benadryl), fexofenadine (Allegra, Allegra-D), loratadine (Claritin), cetirizine (Zyrtec), and others)
- specific antihypertensive medications
    - alpha blockers (e.g. doxazosin, prazosin, terazosin)
    - angiotensin converting enzyme (ACE) inhibitors (e.g. benazepril, captopril, enalapril, fosinopril, lisinopril, quinapril, ramipril)
    - angiotensin receptor blockers (Sartans) (e.g. candesartan, eprosartan, irbesartan, losartan, olmesartan, telmisartan, valsartan)
    - calcium channel blockers (e.g. amlodipine, diltiazem, felodipine, isradipine, nicardipine, nifedipine, verapamil)
    - diuretics (e.g. amiloride, bumetanide, chlorothiazide, chlorthalidone, furosemide, hydrochlorothiazide, indapamide, methyclothiazide, metolazone, spironolactone, triameterene)
    - mineralocorticoid receptor antagonists (e.g. eplerenone)
    - sympathetic nerve inhibitors (e.g. clonidine, guanabenz, guanfacine, methyldopa)
- antitussives (e.g. benzonatate (Tessalon Perles, Zonatuss), dextromethorphan)
- calcium-based antacids used PRN (e.g. TUMS®)
- calcium supplements at a stable dose throughout study (up to 2500 mg/day)
- CNS stimulants/appetite suppressants (e.g. lisdexamfetamine, methylphenidate (Ritalin), amphetamine preps)
- Cox-2 drugs (e.g. celecoxib (Celebrex))
- decongestants (e.g. pseudoephedrine (Sudafed), oxymetazoline (Afrin), and others)
- Depo-Provera®
- oral diabetes medications (for treatment of stable, controlled diabetes)
- erectile dysfunction medications (e.g. sildenafil, tadalafil, vardenafil)
- estrogen/progesterone replacement therapy for postmenopausal women
- expectorants (OTC only) (e.g. guaifenesin)
- eye preparations for allergic eye symptoms (topical) (e.g. antihistamines, NSAIDS, antiallergic compounds)
- H_2 blockers (e.g. ranitidine, cimetidine, famotidine, nizatidine) for GERD
- hair growth preparations (e.g. finasteride (Propecia®))
- hemorrhoid treatments

- herpes medications (e.g. acyclovir (Zovirax), valacyclovir (Valtrex))
- insulin and injectable antidiabetic medications (for treatment of stable, controlled diabetes)
- intranasal steroids (any drug) at a stable dose throughout study
- laxatives
- Librax
- lithium
- migraine analgesics/preventatives (e.g. butalbital, triptans, topiramate)
- nasal antiallergic spray (Cromolyn/Atrovent)
- nasal saline spray
- Norplant®
- oral contraceptives
- proton pump inhibitors (e.g. omeprazole (Prilosec), pantoprazole, lansoprazole (Prevacid), esomeprazole (Nexium)) for GERD
- psyllium
- sleep aids used PRN
- stool softeners
- study medications
- thyroid replacement medication (e.g. Levothroid, Levoxyl, Synthroid)
- tretinoin (Retin-A) for acne
- vitamins, minerals

- Low potency topical corticosteroids (BID)
  alclometasone dipropionate
  desonide
  dexamethasone
  dexamethasone sodium phosphate
  fluocinolone acetonide
  hydrocortisone
  hydrocortisone acetate

- Medium potency topical corticosteroids (BID)

betamethasone benzoate	flurandrenolide
betamethasone dipropionate	fluticasone propionate
betamethasone valerate	hydrocortisone butyrate
clocortolone pivalate	hydrocortisone valerate
desoximetasone	mometasone furoate
fluocinolone acetonide	triamcinolone acetonide

Record the number of the most recent type of inhaled steroid taken in Q12a on the PRIOR_TRT form.

100 beclomethasone MDI (1 puff = 40 mcg) (**e.g., QVAR**)
101 beclomethasone MDI (1 puff = 80 mcg) (**e.g., QVAR**)
102 beclomethasone MDI (1 puff = 100 mcg) (**e.g., QVAR—Canadian**)
200 budesonide DPI (1 puff = 90 mcg) (**e.g., Pulmicort Flexhaler**)
201 budesonide DPI (1 puff = 180 mcg) (**e.g., Pulmicort Flexhaler**)
300 ciclesonide MDI (1 puff = 80 mcg) (**e.g., Alvesco**)
301 ciclesonide MDI (1 puff = 160 mcg) (**e.g., Alvesco**)
400 flunisolide MDI (1 puff = 80 mcg) (**e.g., Aerospan**)
501 fluticasone propionate MDI (1 puff = 44 mcg) (**e.g., Flovent**)
502 fluticasone propionate MDI (1 puff = 110 mcg) (**e.g., Flovent**)
503 fluticasone propionate MDI (1 puff = 220 mcg) (**e.g., Flovent**)
600 fluticasone propionate DPI (1 puff = 50 mcg) (**e.g., Flovent Diskus**)
601 fluticasone propionate DPI (1 puff = 100 mcg) (**e.g., Flovent Diskus**)
602 fluticasone propionate DPI (1 puff = 250 mcg) (**e.g., Flovent Diskus**)
610 fluticasone furoate (1 puff = 100 mcg) (**e.g., Arnuity Ellipta DPI**)
611 fluticasone furoate (1 puff = 200 mcg) (**e.g., Arnuity Ellipta DPI**)
700 mometasone DPI (1 puff = 110 mcg) (**e.g., Asmanex Twisthaler**)
701 mometasone DPI (1 puff = 220 mcg) (**e.g., Asmanex Twisthaler**)
702 mometasone furoate (1 puff = 100 mcg) (**e.g., Asmanex HFA**)
999 Other

Record the number of the most recent type of nebulized steroid taken in Q13a on the PRIOR_TRT form.

10 budesonide (1 neb = 0.25 mg) (**e.g., Pulmicort Respules**)
11 budesonide (1 neb = 0.5 mg) (**e.g., Pulmicort Respules**)
12 budesonide (1 neb = 1.0 mg) (**e.g., Pulmicort Respules**)
99 Other

Record the number of the most recent type of inhaled steroid/long-acting beta-agonist taken in Q14a on the PRIOR_TRT form.

1000 budesonide (1 puff = 80 mcg) / formoterol (1 puff = 4.5 mcg) (**e.g., Symbicort MDI**)
1001 budesonide (1 puff = 160 mcg) / formoterol (1 puff = 4.5 mcg) (**e.g., Symbicort MDI**)
1100 fluticasone propionate (1 puff = 100 mcg) / salmeterol (1 puff = 50 mcg) (**e.g., Advair Diskus**)
1101 fluticasone propionate (1 puff = 250 mcg) / salmeterol (1 puff = 50 mcg) (**e.g., Advair Diskus**)
1102 fluticasone propionate (1 puff = 500 mcg) / salmeterol (1 puff = 50 mcg) (**e.g., Advair Diskus**)
1103 fluticasone propionate (1 puff = 45 mcg) / salmeterol (1 puff = 21 mcg) (**e.g., Advair MDI**)
1104 fluticasone propionate (1 puff = 115 mcg) / salmeterol (1 puff = 21 mcg) (**e.g., Advair MDI**)
1105 fluticasone propionate (1 puff = 230 mcg) / salmeterol (1 puff = 21 mcg) (**e.g., Advair MDI**)
1110 fluticasone furoate (1 puff = 100 mcg) / vilanterol (1 puff = 25 mcg) (**e.g., Breo Ellipta DPI**)
1111 fluticasone furoate (1 puff = 200 mcg) / vilanterol (1 puff = 25 mcg) (**e.g., Breo Ellipta DPI**)
1200 mometasone (1 puff = 100 mcg) / formoterol (1 puff = 5 mcg) (**e.g., Dulera MDI**)
1201 mometasone (1 puff = 200 mcg) / formoterol (1 puff = 5 mcg) (**e.g., Dulera MDI**)
9999 Other

UNITS, FREQUENCY, AND ROUTE CODES FOR USE ON THE CONCOMITANT MEDICATIONS FOR ASTHMA/ALLERGY AND ADVERSE EVENTS FORM (CMED)

AsthmaNet

Codes for Units (Q1040)	
Code	Units
1	mg
2	mcg (µg)
3	ml
4	mg/ml
5	mEq
6	g
7	U
8	teaspoon
9	tablespoon
10	patch
11	puffs (oral inhalation)
12	nasal spray
13	packet
14	1 drop
15	mm
16	percent
98	no units
99	other

Codes for Frequency (Q1050)		
Code	Frequency	
1	QD	1 time a day
2	BID	2 times a day
3	TID	3 times a day
4	QID	4 times a day
5	q4h	every 4 hours
6	q5h	every 5 hours
7	q6h	every 6 hours
8	q8h	every 8 hours
9	q12h	every 12 hours
10	q24h	every 24 hours
11	hs	every night at bedtime
12	PRN	as required
13	qod	every other day
14	qw	once a week
15	biw	2 times per week
16	tiw	3 times per week
17	5 times per week	
18	every 5 days	
19	once a month	
20	taper dose	
99	other	

Codes for Route (Q1055)	
Route	Route Desc
1	Epidural Injection
2	External/Topical
3	Inhalation
4	Intraarterial Injection
5	Intraarticular/Intracapsular Injection
6	Intramuscular Injection – IM
7	Intrathecal Injection
8	Intravenous Injection – IV
9	Medicated Gums
10	Misc. Injection
11	Nasal
12	Nebulization
13	Ophthalmic
14	Oral
15	Otic
16	Patch
17	Rectal
18	Subcutaneous Injection – SQ
19	Sublingual
20	Swallowed
21	Urological
22	Vaginal

FREQUENTLY USED ASTHMA & ALLERGY DRUG CODES

AsthmaNet

Class Name	Generic Drug Name	UN Code
Anticholinergic Agents	Atropine	384024
	Ipratropium	395021
	Tiotropium	304004
Antihistamines	Acrivastine	394040
	Brompheniramine	382545
	Carbinoxamine	382883
	Cetirizine	398026
	Chlorpheniramine	382543
	Cimetidine	382256
	Clemastine	382542
	Cyproheptadine	382541
	Desloratadine	302004
	Dimenhydrinate	382140
	Diphenhydramine	382539
	Doxylamine	382537
	Emedastine	399007
	Famotidine	387011
	Fexofenadine	397035
	Hydroxyzine	382866
	Ketotifen	399018
	Levocetirizine	307015
	Lodoxamide	394014
	Loratadine	397038
	Meclizine	382548
	Nizatidine	394030
	Olopatadine	399006
	Promethazine	382752
	Ranitidine	384046
	Triprolidine	382533
Beta-2 Adrenergic Agonists	Albuterol/Levalbuterol	382145
	Arformoterol	307016
	Formoterol	301023
	Metaproterenol	382084
	Salmeterol	395001
	Terbutaline	382144
Corticosteroids	Beclomethasone	381047
	Budesonide	303008
	Ciclesonide	308032
	Dexamethasone	382869
	Difluprednate	308031
	Flunisolide	381048

Class Name	Generic Drug Name	UN Code
Corticosteroids	Fluocinolone	305019
	Fluorometholone	382870
	Fluticasone	395002
	Hydrocortisone	382871
	Loteprednol	399008
	Mometasone	301021
	Prednisolone	382873
	Prednisone	382796
	Rimexolone	396035
	Triamcinolone	301019
Leukotriene Modifiers	Montelukast	300014
	Zafirlukast	397007
	Zileuton	397013
Xanthine Derivatives	Theophyllines	381006