AsthmaNet

ACUTE ASTHMA ASSESSMENT QUESTIONNAIRE

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

(Participant Completed)

Please check only one box for each question.

1. <u>In the past 3 days</u>, how much of the time did your asthma keep you from doing your usual activities at work, school, or at home?

(1000)
- ❑0 None of the time
- ❑1 A little of the time
- ❑2 Some of the time
- ❑3 Most of the time
- ❑4 All of the time

2. <u>During the past 3 days</u>, how often have you had asthma symptoms? Asthma symptoms include wheezing, coughing, shortness of breath, chest tightness or pain, phlegm or mucus.

(1010)
- ❑0 Not at all
- ❑1 Once per day
- ❑2 2-3 times per day
- ❑3 4-5 times per day
- ❑4 6 or more times per day

3. <u>During the past 3 days</u>, how often have you used your rescue inhaler or nebulizer medication (such as albuterol)?

(1020)
- ❑0 Not at all
- ❑1 Once per day
- ❑2 2-3 times per day
- ❑3 4-5 times per day
- ❑4 6 or more times per day

4. <u>During the past 3 days</u>, how many total times did your asthma symptoms wake you up from sleep? Asthma symptoms include wheezing, coughing, shortness of breath, chest tightness or pain, phlegm or mucus.

(1030)
- ❑0 Not at all
- ❑1 1 time in the last 3 days
- ❑2 2-3 times in the last 3 days
- ❑3 4-5 times in the last 3 days
- ❑4 ≥6 times in the last 3 days

5. How would you rate the amount of impairment you have experienced due to your asthma <u>in the past 3 days</u>?

(1040)
- ❑0 No impairment
- ❑1 Mild impairment
- ❑2 Moderate impairment
- ❑3 Severe impairment
- ❑4 Very severe impairment

6. How stressed or frightened were you by your asthma symptoms <u>in the past 3 days</u>?

(1050)
- ❑0 Not at all
- ❑1 Mildly
- ❑2 Moderately
- ❑3 Severely
- ❑4 Very severely

7. Why do you think your asthma was worse <u>in the past 3 days</u> compared to what is normal for you? Pick the main reason. There is no right or wrong answer. We want your opinion.

(1060)

- ❑$_0$ I have not been worse over the past 3 days. My asthma symptoms have been usual.
- ❑$_1$ Common cold
- ❑$_2$ Allergies
- ❑$_3$ Pollution or chemical irritant
- ❑$_4$ Too little asthma maintenance medication
- ❑$_5$ Exercise
- ❑$_6$ Other (specify)

(1060D) _____

Participant Source Documentation

Participant Initials: __ __ __ **(1070)**

Date: __ __ / __ __ / 20 __ __ **(1080)**
MM DD YYYY

Time: __ __ __ __ *(based on a 24-hour clock)* **(1090)**

AsthmaNet	ASTHMA BOTHER PROFILE	Part. ID: __ __ - __ __ __ - __ __ __ Part. Initials: __ __ __ Visit: __ __ __ Visit Date: __ __ / __ __ / 20 __ __ Coordinator ID: __ __ __ __

(Coordinator Completed by Interview)

- Asthma affects people in many different ways
- For some people asthma causes very little bother
- For others, asthma is very troublesome
- The purpose of this questionnaire is to find out **how much your asthma bothers you overall**

Part One

Please answer the following questions by putting a check mark in the box next to the reply which **most closely applies to you**.

Please don't spend too long thinking about each question. It is your **general impression** which is important.

1. Are you currently retired? **(1000)** ❑$_1$ Yes ❑$_0$ No
   ➔ If ***NO***, skip to Q2.

   1a. Are you retired because of asthma? **(1010)** ❑$_1$ Yes ❑$_0$ No
   ➔ Skip to Q5.

2. Are you currently unemployed? **(1020)** ❑$_1$ Yes ❑$_0$ No
   ➔ If ***NO***, skip to Q3.

   2a. Are you unemployed because of asthma? **(1030)** ❑$_1$ Yes ❑$_0$ No
   ➔ Skip to Q5.

3. Do you get paid to do work? **(1040)** ❑$_1$ Yes ❑$_0$ No
   ➔ If ***NO***, skip to Q5.

4. How much does your asthma bother you at your **paid work?** *(Please check only one box.)* **(1050)**
   ❑$_0$ No bother at all
   ❑$_1$ Minor irritation
   ❑$_2$ Slight bother
   ❑$_3$ Moderate bother
   ❑$_4$ A lot of bother
   ❑$_5$ Makes my life a misery

5. Overall, how much does your asthma bother you when you do **jobs around the house?** For example: housework, shopping, home maintenance, gardening, and child care. *(Please check only one box.)* **(1060)**
   ❑$_0$ No bother at all
   ❑$_1$ Minor irritation
   ❑$_2$ Slight bother
   ❑$_3$ Moderate bother
   ❑$_4$ A lot of bother
   ❑$_5$ Makes my life a misery
   ❑$_0$ None of these really apply to me

6. Overall, how much does your asthma bother your **social life?** For example: visiting friends, walking with friends, talking with friends, going to bars/restaurants, and parties. *(Please check only one box.)*

(1070)
- ❑0 No bother at all
- ❑1 Minor irritation
- ❑2 Slight bother
- ❑3 Moderate bother
- ❑4 A lot of bother
- ❑5 Makes my life a misery

7. Overall, how much does your asthma bother your **personal life?** For example: love life, personal relationships, and family life. *(Please check only one box.)*

(1080)
- ❑0 No bother at all
- ❑1 Minor irritation
- ❑2 Slight bother
- ❑3 Moderate bother
- ❑4 A lot of bother
- ❑5 Makes my life a misery
- ❑0 None of these really apply to me

8. Are you involved in **leisure activities**, such as: walking for pleasure, sports, exercise, travelling, taking vacations?
   ➔ If ***NO***, skip to Q8b.

(1090) ❑1 Yes ❑0 No

8a. When involved in leisure activities, how much does your asthma bother you?

(1100)
- ❑0 No bother at all
- ❑1 Minor irritation
- ❑2 Slight bother
- ❑3 Moderate bother
- ❑4 A lot of bother
- ❑5 Makes my life a misery

8b. Would you say that you can't do some of these sorts of things because of asthma?

(1110) ❑1 Yes ❑0 No

Part Two

Here are some things which often happen to people when they have asthma.

How much is each a bother to you?

9. How much does your asthma bother you when you **sleep?** For example: coughing at night, waking at night, and waking early. *(Please check only one box.)*

(1120)
- ❑0 No bother at all
- ❑1 Minor irritation
- ❑2 Slight bother
- ❑3 Moderate bother
- ❑4 A lot of bother
- ❑5 Makes my life a misery

10. How much does the **cost** of your **asthma medicines** bother you? *(Please check only one box.)*

(1130)
- ❑0 No bother at all
- ❑1 Minor irritation
- ❑2 Slight bother
- ❑3 Moderate bother
- ❑4 A lot of bother
- ❑5 Makes my life a misery

10a. Do you get free prescriptions?

(1140) ❑1 Yes ❑0 No

11. How much does the **inconvenience** or **embarrassment** of **taking your asthma medicines** bother you? *(Please check only one box.)*

(1150)
- ❑0 No bother at all
- ❑1 Minor irritation
- ❑2 Slight bother
- ❑3 Moderate bother
- ❑4 A lot of bother
- ❑5 Makes my life a misery

12. How much do **coughs and colds** bother you? *(Please check only one box.)*

(1160)
- ❑0 No bother at all
- ❑1 Minor irritation
- ❑2 Slight bother
- ❑3 Moderate bother
- ❑4 A lot of bother
- ❑5 Makes my life a misery
- ❑0 Never get coughs or colds

13. **Feeling upset** is also a bother. Does your asthma make you feel **anxious, depressed, tired,** or **helpless**?
➔ If ***NO***, skip to Q14.

(1170) ❑1 Yes ❑0 No

13a. How much does this bother you?

(1180)
- ❑0 No bother at all
- ❑1 Minor irritation
- ❑2 Slight bother
- ❑3 Moderate bother
- ❑4 A lot of bother
- ❑5 Makes my life a misery

Part Three

Worries can also be a bother, particularly if you spend a lot of time worrying.

14. How much bother is the worry that you will have an **asthma attack** when visiting a **new place?** *(Please check only one box.)*

(1190)
- ❑0 I never have this worry
- ❑1 Minor irritation
- ❑2 Slight bother
- ❑3 Moderate bother
- ❑4 A lot of bother
- ❑5 Makes my life a misery

15. How much bother is the worry that you will catch a **cold?** *(Please check only one box.)*

(1200)
- ❑0 I never have this worry
- ❑1 Minor irritation
- ❑2 Slight bother
- ❑3 Moderate bother
- ❑4 A lot of bother
- ❑5 Makes my life a misery

16. How much bother is the worry that you will **let others down?** For example: missed appointments, being off work, and change of plans. *(Please check only one box.)*

(1210)
- ❑0 I never have this worry
- ❑1 Minor irritation
- ❑2 Slight bother
- ❑3 Moderate bother
- ❑4 A lot of bother
- ❑5 Makes my life a misery

17. How much bother is the worry that **your health may get worse in the future?** For example: increasing breathlessness, effects of medicines, and being able to do less. *(Please check only one box.)*

(1220)
- ❑0 I never have this worry
- ❑1 Minor irritation
- ❑2 Slight bother
- ❑3 Moderate bother
- ❑4 A lot of bother
- ❑5 Makes my life a misery

18. How much bother is the worry that you won't be able to cope with an **asthma attack?** *(Please check only one box.)*

(1230)

- ❑0 I never have this worry
- ❑1 Minor irritation
- ❑2 Slight bother
- ❑3 Moderate bother
- ❑4 A lot of bother
- ❑5 Makes my life a misery

Participant Source Documentation

Participant Initials: __ __ __ **(1240)**

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

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

Part. ID: - -

Part. Initials:

Visit:

Asthma Control Test™

Visit Date: / / 2 0

Coordinator ID:

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 past 4 weeks, how much of the time did your asthma 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 past 4 weeks, 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 past 4 weeks, how often did your asthma 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 past 4 weeks, 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 asthma control during the past 4 weeks?

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

AECLIN

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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 cigarettes or other tobacco products? **(1740)** ❑1 Yes ❑0 No
    ➔ If ***NO***, skip to Q13.

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

    ➔ **SKIP TO Q15.**

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

13. Were you ever a smoker of cigarettes or other tobacco products? **(1760)** ❑1 Yes ❑0 No
    ➔ If ***NO***, skip to Q14.

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

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

14. Do you currently live in a household where you are exposed to tobacco smoke? **(1780)** ❑1 Yes ❑0 No

VAPING AND HOOKAH HISTORY

15. Do you currently vape (i.e., use nicotine or any other substances in an e-cigarette device) or use a hookah (waterpipe)? **(1790)** ❑1 Yes ❑0 No
    ➔ If ***NO***, skip to Q16.

    15a. How frequently do you vape or use a hookah? **(1800)**
    ➔ If ***INFREQUENTLY*** or ***OCCASIONALLY***, skip to Q17.
    - ❑1 Infrequently (less than one day a month)
    - ❑2 Occasionally (at least one day a month but less than one day a week)
    - ❑3 Weekly (at least one day a week but not daily)
    - ❑4 Daily

    15ai. How many days a week do you vape or use a hookah? **(1810)** __ days

    15aii. How many times a day do you vape or use a hookah? **(1820)** __ __ times

15aiii. How many years have you vaped or used a hookah? **(1830)** __ __ years

➔ **SKIP TO Q17.**

16. Have you ever vaped or used a hookah in the past? **(1840)** ❑$_1$ Yes ❑$_0$ No
➔ If ***NO***, skip to Q17.

16a. Approximately how many years did you vape or use a hookah? **(1850)** __ __ years

16b. When was the last time that you vaped or used a hookah? __ __ **(1860)** / __ __ **(1870)** / __ __ __ __ **(1880)**

17. Do you currently live in a household where you are exposed to others vaping or using a hookah? **(1890)** ❑$_1$ Yes ❑$_0$ No

18. Do you spend time in social settings (e.g., parties, clubs, study groups, etc.) where you are exposed to others vaping or using a hookah? **(1900)** ❑$_1$ Yes ❑$_0$ No

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

ASTHMA SYMPTOM UTILITY INDEX

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

(Coordinator Completed by Interview)

I would like to ask you some questions about different symptoms of asthma and how often you were bothered by these symptoms in the past 2 weeks.

1. How many days were you bothered by coughing during the past 2 weeks? **(1000)**
   - ❑0 Not at all ***(Skip to Question #3)***
   - ❑1 1-3 days
   - ❑2 4-7 days
   - ❑3 8-14 days

2. On average, how severe was your coughing during the past 2 weeks? **(1010)**
   - ❑1 Mild
   - ❑2 Moderate
   - ❑3 Severe

3. How many days were you bothered by wheezing during the past 2 weeks? **(1020)**
   - ❑0 Not at all ***(Skip to Question #5)***
   - ❑1 1-3 days
   - ❑2 4-7 days
   - ❑3 8-14 days

4. On average, how severe was your wheezing during the past 2 weeks? **(1030)**
   - ❑1 Mild
   - ❑2 Moderate
   - ❑3 Severe

5. How many days were you bothered by shortness of breath during the past 2 weeks? **(1040)**
   - ❑0 Not at all ***(Skip to Question #7)***
   - ❑1 1-3 days
   - ❑2 4-7 days
   - ❑3 8-14 days

6. On average, how severe was your shortness of breath during the past 2 weeks? **(1050)**
   - ❑1 Mild
   - ❑2 Moderate
   - ❑3 Severe

7. How many days were you awakened at night during the past 2 weeks? **(1060)**
   - ❑0 Not at all ***(Skip to Question #9)***
   - ❑1 1-3 days
   - ❑2 4-7 days
   - ❑3 8-14 days

8. On average, how much of a problem was being awakened at night during the past 2 weeks? **(1070)**
   - ❑1 Mild
   - ❑2 Moderate
   - ❑3 Severe

9. How many days were you bothered by side effects of your asthma medication during the past 2 weeks? **(1080)**
   - ❑0 Not at all ***(STOP HERE)***
   - ❑1 1-3 days
   - ❑2 4-7 days
   - ❑3 8-14 days

10. If 1 day or more, what side effects did you have? **(1080D)** _____
    _____

11. On average, how severe were the side effects of your asthma medication during the past 2 weeks? **(1090)**
    - ❑1 Mild
    - ❑2 Moderate
    - ❑3 Severe

Participant Source Documentation

Participant Initials: __ __ __ **(1100)**

Date: __ __ / __ __ / 20 __ __ **(1110)**
MM DD YYYY

Time: __ __ __ __ *(based on a 24-hour clock)* **(1120)**

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					__ / __ / ____	__ / __ / ____	❑ $_1$	❑ $_1$

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

PEDIATRIC LONG PHYSICAL EXAM

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

(Coordinator Completed)

PARENTAL HEIGHT – First study visit only or until both are completed

1. Biological mother's height (complete height or check unknown) **(1000-1010)** __ feet __ __ inches
   (1020) ❑9 Don't Know

2. Biological father's height (complete height or check unknown) **(1030-1040)** __ feet __ __ inches
   (1050) ❑9 Don't Know

PARTICIPANT MEASUREMENTS – Complete at all applicable study visits

3. What type of height measurement was obtained? **(1060)** ❑1 Standing height ❑2 Length

   3a. First measurement **(1070)** __ __ __ . __ cm

   3b. Second measurement **(1080)** __ __ __ . __ cm

   3c. Third measurement **(1090)** __ __ __ . __ cm

   3d. Average height or length measurement **(1100)** __ __ __ . __ cm

   ➔ ***Plot average height or length on gender- and age-appropriate growth charts. See study MOP for further details.***

   3e. In your judgment, was the participant's height or length measurement acceptable? **(1110)** ❑1 Yes ❑0 No

   3ei. If **NO**, why was it unacceptable? **(1120D)** _____

   _____

4. Weight (shoes off, light clothing) **(1130)** __ __ __ . __ kg

   ➔ ***Plot weight on gender- and age-appropriate growth charts. See study MOP for further details.***

ORAL CANDIDIASIS

5. Does the participant have evidence of oral candidiasis? **(1140)** ❑1 Yes ❑0 No
   ➔ ***If YES, complete the Clinical Adverse Events (AECLIN) form.***

LEXAM PED

DO NOT DATA ENTER THE INFORMATION ON THE REST OF THE FORM EXCEPT THE COMMENTS (IF APPLICABLE)

(Licensed Medical Practitioner Completed)

Please indicate current physical findings by checking the appropriate boxes below. If ABNORMAL, please describe concisely.

		Not Done	Normal	Abnormal	
6.	Hair and Skin	❑	❑	❑	_____
7.	Lymph nodes	❑	❑	❑	_____
8.	Eyes (excluding corrective lenses)	❑	❑	❑	_____
9.	Ears, Nose, and Throat	❑	❑	❑	_____
10.	Respiratory	❑	❑	❑	_____
	10a. If Abnormal:				❑ Wheeze on inspiration or expiration ❑ Adventitious sounds other than wheezing ❑ Other _____ _____ _____
11.	Cardiovascular	❑	❑	❑	_____
12.	Gastrointestinal	❑	❑	❑	_____
13.	Musculoskeletal	❑	❑	❑	_____
14.	Neurological	❑	❑	❑	_____
15.	Mental Status	❑	❑	❑	_____
16.	Other _____ (check Not Done if non-applicable)	❑	❑	❑	_____

Licensed Medical Practitioner Source Documentation

Licensed Medical Practitioner Signature: _____

Printed Name: _____

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

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

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

METHACHOLINE CHALLENGE 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 Methacholine Challenge Testing Checklist (METHACHK) form.

Clinic Use Only *(Technician Completed)*
Use the FEV_1 value from the appropriate spirometry testing 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

   If participant is continuing with sputum induction, standard reversal = 4 puffs albuterol.
   If participant is not continuing with sputum induction, standard reversal = 2 puffs albuterol.

   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

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

PEDIATRIC 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. During the past 4 weeks, has the participant had any respiratory infections, colds, or bronchitis (see the Methacholine MOP)? **(1030)** ☐1 Yes ☐0 No

   2a. If ***YES***, during the past 2 weeks, has the participant had any respiratory infections, colds, or bronchitis (see the Methacholine MOP)? **(1040)** ☐1 Yes ☐0 No

3. 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

4. Does the participant have a baseline (pre-diluent) FEV_1 less than 70% of predicted? **(1060)** ☐1 Yes ☐0 No

5. Pregnancy test results *(Check N/A if the participant is male, or is female and has not started menses.)* **(1070)** ☐1 Positive ☐0 Negative ☐9 N/A

6. **If participant's age is ≥ 12 years:** Is the participant's systolic blood pressure > 200 mm Hg or diastolic blood pressure > 100 mm Hg? **(1080)** ☐1 Yes ☐0 No

7. **If participant's age is < 12 years:** Is the participant's systolic blood pressure > 180 mm Hg or diastolic blood pressure > 90 mm Hg? **(1090)** ☐1 Yes ☐0 No

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

9.	Is the participant eligible to proceed with the diluent (solution #0) pulmonary function testing for the methacholine challenge? ***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.***	**(1110)** ☐ 1 Yes ☐ 0 No

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

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 participant did not reverse to 90% of baseline (pre) FEV_1 after the first post-challenge treatment of albuterol.

1. Was an additional treatment used in the first hour? **(1000)** ❑1 Yes ❑0 No
   ➔ If ***NO***, skip to Q3.

   1a. Additional albuterol by MDI **(1010)** ❑1 Yes ❑0 No
   ➔ If ***NO***, skip to Q1b.

   Number of additional puffs of albuterol administered **(1020)** ❑1 2 ❑2 4 ❑3 > 4

   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.

METHA ADD TRT

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 __ __ (MM / DD / YYYY) **(1250)**

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

COMMENTS: **(6000)**

_____

_____

_____

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	POST- IPRATROPIUM (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 ipratropium and wait 30 minutes, then perform spirometry.***

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

2. Time post-ipratropium 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)

_____

_____

_____

PIPRA4 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)**

_____

_____

_____

AsthmaNet

PERCEIVED STRESS SCALE

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

(Participant Completed)

The questions in this scale ask you about your feelings and thoughts **during the last month**. In each case, you will be asked to indicate by checking *how often* you felt or thought a certain way. Please check only one box for each question.

		Never	Almost Never	Sometimes	Fairly Often	Very Often
1.	In the last month, how often have you been upset because of something that happened unexpectedly? **(1000)**	❑0	❑1	❑2	❑3	❑4
2.	In the last month, how often have you felt that you were unable to control the important things in your life? **(1010)**	❑0	❑1	❑2	❑3	❑4
3.	In the last month, how often have you felt nervous and "stressed?" **(1020)**	❑0	❑1	❑2	❑3	❑4
4.	In the last month, how often have you felt confident about your ability to handle your personal problems? **(1030)**	❑0	❑1	❑2	❑3	❑4
5.	In the last month, how often have you felt that things were going your way? **(1040)**	❑0	❑1	❑2	❑3	❑4
6.	In the last month, how often have you found that you could not cope with all the things that you had to do? **(1050)**	❑0	❑1	❑2	❑3	❑4
7.	In the last month, how often have you been able to control irritations in your life? **(1060)**	❑0	❑1	❑2	❑3	❑4
8.	In the last month, how often have you felt that you were on top of things? **(1070)**	❑0	❑1	❑2	❑3	❑4
9.	In the last month, how often have you been angered because of things that happened that were outside of your control? **(1080)**	❑0	❑1	❑2	❑3	❑4
10.	In the last month, how often have you felt difficulties were piling up so high that you could not overcome them? **(1090)**	❑0	❑1	❑2	❑3	❑4

Participant Source Documentation

Participant Initials: __ __ __ **(1100)**

Date: __ __ / __ __ / 20 __ __ **(1110)**
MM DD YYYY

Time: __ __ __ __ *(based on a 24-hour clock)* **(1120)**

AsthmaNet

RAND IMPACT OF ASTHMA ON QOL SF-12

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

(Participant Completed)

The following statements are about how asthma affects the quality of your life. For each statement, please check the one answer that comes closest to the way asthma has affected your life.

		Not at all	A little bit	Somewhat	Quite a bit	Very much
1.	In the <u>past 4 weeks</u>, I worried about the long-term effects of asthma on my health **(1000)**	❑1	❑2	❑3	❑4	❑5
2.	In the <u>past 4 weeks</u>, I had to worry about asthma triggers **(1010)**	❑1	❑2	❑3	❑4	❑5
3.	In the <u>past 4 weeks</u>, my asthma was on my mind **(1020)**	❑1	❑2	❑3	❑4	❑5
4.	In the <u>past 4 weeks</u>, it was hard to get a good night's sleep because of my asthma **(1030)**	❑1	❑2	❑3	❑4	❑5
5.	In the <u>past 4 weeks</u>, I felt like I couldn't enjoy life because of my asthma **(1040)**	❑1	❑2	❑3	❑4	❑5
6.	In the <u>past 4 weeks</u>, I felt that asthma was controlling my life **(1050)**	❑1	❑2	❑3	❑4	❑5
7.	In the <u>past 4 weeks</u>, I felt frustrated that I couldn't make plans in advance because of my asthma **(1060)**	❑1	❑2	❑3	❑4	❑5
8.	In the <u>past 4 weeks</u>, *because of my asthma*, everyday activities were a struggle **(1070)**	❑1	❑2	❑3	❑4	❑5
9.	In the <u>past 4 weeks</u>, asthma placed stress on my relationships with family, friends, significant others, or co-workers **(1080)**	❑1	❑2	❑3	❑4	❑5
10.	In the <u>past 4 weeks</u>, *because of my asthma*, I felt frustrated that I have to do things differently than people who don't have asthma **(1090)**	❑1	❑2	❑3	❑4	❑5
11.	In the <u>past 4 weeks</u>, I felt like I missed out on doing things with others because of my asthma **(1100)**	❑1	❑2	❑3	❑4	❑5
12.	In the <u>past 4 weeks</u>, *because of my asthma*, I had to do a lot of planning to make sure I always had an inhaler ready **(1110)**	❑1	❑2	❑3	❑4	❑5

Participant Source Documentation

Participant Initials: __ __ __ **(1120)**

Date: __ __ / __ __ / 20 __ __ **(1130)**
MM DD YYYY

Time: __ __ __ __ *(based on a 24-hour clock)* **(1140)**

"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

PEDIATRIC SHORT PHYSICAL EXAM

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

(Coordinator Completed)

PARTICIPANT MEASUREMENTS – Complete at all applicable study visits

1. What type of height measurement was obtained? **(1060)** ❑$_1$ Standing height ❑$_2$ Length

   1a. First measurement **(1070)** __ __ __ . __ cm

   1b. Second measurement **(1080)** __ __ __ . __ cm

   1c. Third measurement **(1090)** __ __ __ . __ cm

   1d. Average height or length measurement **(1100)** __ __ __ . __ cm

   ➔ ***Plot average height or length on gender- and age-appropriate growth charts. See study MOP for further details.***

   1e. In your judgment, was the participant's height or length measurement acceptable? **(1110)** ❑$_1$ Yes ❑$_0$ No

   1ei. If **NO**, why was it unacceptable? **(1120D)** _____

   _____

2. Weight (shoes off, light clothing) **(1130)** __ __ __ . __ kg

   ➔ ***Plot weight on gender- and age-appropriate growth charts. See study MOP for further details.***

ORAL CANDIDIASIS

3. Does the participant have evidence of oral candidiasis? **(1140)** ❑$_1$ Yes ❑$_0$ No
   ➔ ***If YES, complete the Clinical Adverse Events (AECLIN) form.***

SEXAM PED

DO NOT DATA ENTER THE INFORMATION ON THE REST OF THE FORM EXCEPT THE COMMENTS (IF APPLICABLE)

Please indicate current physical findings by checking the appropriate boxes below. If ABNORMAL, please describe concisely.

		Not Done	Normal	Abnormal	
4.	Hair and Skin	❑	❑	❑	_____
5.	Eyes, Ears, Nose, and Throat	❑	❑	❑	_____
6.	Respiratory	❑	❑	❑	_____

6a. If Abnormal:

- ❑ Wheeze on inspiration or expiration
- ❑ Adventitious sounds other than wheezing
- ❑ Other _____
  _____
  _____
  _____

Coordinator Source Documentation

Coordinator Signature: _____

Printed Name: _____

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

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

COMMENTS: (6000)

_____

_____

_____

AsthmaNet

SINONASAL QUESTIONNAIRE

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

(Participant Completed)

Over the last 3 months how often, on average, did you have the following symptoms? Please check one box for each symptom.

		Never	1-4 times per month	2-6 times per week	Daily
Runny Nose	**(1000)**	❑$_0$	❑$_1$	❑$_2$	❑$_3$
Post nasal drip	**(1010)**	❑$_0$	❑$_1$	❑$_2$	❑$_3$
Need to blow your nose	**(1020)**	❑$_0$	❑$_1$	❑$_2$	❑$_3$
Facial pain/pressure	**(1030)**	❑$_0$	❑$_1$	❑$_2$	❑$_3$
Nasal obstruction	**(1040)**	❑$_0$	❑$_1$	❑$_2$	❑$_3$

Participant Source Documentation

Participant Initials: __ __ __ **(1050)**

Date: __ __ / __ __ / 20 __ __ **(1060)**
MM DD YYYY

Time: __ __ __ __ *(based on a 24-hour clock)* **(1070)**

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

SPUTUM INDUCTION LAB VALUES

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

(Technician Completed)

Processing Sample

1. Processing Date **(1000)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)
2. Time processing started *(based on 24-hour clock)* **(1010)** __ __ __ __
3. Total Cell Count **(1020)** __ __ __ __. __ x 10^4 cells/ml

4. Was the participant's sputum sample processed within 4 hours after collection? **(1030)** ❑1 Yes ❑0 No

   ➔ ***If YES, send the sputum sample for reading.***
   ➔ ***If NO, STOP HERE and mark the samples as excluded in the Biological Sample Tracking module.***

COMMENTS: **(6000)**

_____

_____

_____

SPUTLAB

AsthmaNet

SPUTUM INDUCTION READ

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

(Technician Completed)

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

2. Rate slide's quality: **(1010)**
   - ❑1 Very good
   - ❑2 Good
   - ❑3 Acceptable
   - ❑4 Poor but readable
   - ❑5 Not readable

   ➔ Comment: **(6000)**
   _____
   _____
   _____
   _____

3. Record the number on the slide(s) that was (were) read **(1020)** __ **(1030)** __
   ➔ ***These are numbers that were assigned to the slides at each site.***

4. Total Cell Count **(1040)** __ __ __ __ . __ x 10^4 cells/ml
   ➔ ***Transcribe Total Cell Count from the Sputum Processing Worksheet.***

Differential Cell Counts

5. Squamous Cells **(1050)** __ __ . __ %

The parameters below are calculated following exclusion of squamous cells.

6. Epithelial Cells **(1060)** __ __ . __ %
7. Macrophages **(1070)** __ __ . __ %
8. Neutrophils **(1080)** __ __ . __ %
9. Eosinophils **(1090)** __ __ . __ %
10. Lymphocytes **(1100)** __ __ . __ %

SPUTREAD

AsthmaNet

SPUTUM INDUCTION

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

(Technician Completed)

Complete this form only if the participant is eligible according to the Sputum Induction Checklist (SPUTUMCHK) form.

(If attempting sputum induction for the first time in this protocol or participant has not had an adequate sample at prior attempts, do not complete Q1.)

1. For this protocol, what was the duration of sputum induction the first time the participant's sample was processed within 4 hours after collection? **(1000)** __ __ . __ minutes

   Duration of sputum induction at current visit should not exceed this.

2. Sputum induction start time *(based on 24-hour clock)* **(1010)** __ __ __ __

3. Sputum induction stop time *(based on 24-hour clock)* **(1020)** __ __ __ __

4. Duration of sputum induction collection phase at this visit **(1030)** __ __ . __ minutes

   4a. Was the duration ≥ 4 minutes? **(1040)** ❑1 Yes ❑0 No

5. Volume of sputum sample at this visit **(1050)** __ __ __ . __ ml

   5a. Is the volume adequate for processing? **(1060)** ❑1 Yes ❑0 No

6. Is the sample adequate for laboratory analysis? **(1070)** ❑1 Yes ❑0 No
   If either shaded box in Q4a or Q5a is completed, the sputum sample is not adequate and should not be sent for processing.

   ➔ ***If YES, the technician processing the sample should complete the Sputum Induction Lab Values (SPUTLAB) form.***

SPUTUM

7. Participant's FEV_1 immediately after completion of sputum induction:

7a.	FEV_1	**(1080)**	__ . __ __ L
7b.	FEV_1 (% predicted)	**(1090)**	__ __ __ % predicted
7c.	Time of FEV_1 in Q7a (based on 24-hour clock)	**(1100)**	__ __ __ __
7d.	Percent difference in FEV_1 $\frac{(\text{Reference} - \text{Q7a})}{\text{Reference}}$ X100	**(1110)**	__ __ . __ %

Reference = FEV_1 used for assessment of eligibility for SI.

7e. Did the participant's FEV_1 drop > 10% from reference FEV_1 as indicated in Q7d? **(1120)** ❑$_1$ Yes ❑$_0$ No

➔ ***If NO, STOP HERE and continue with remaining visit procedures.***

➔ ***If YES, proceed to the Additional Treatment for Sputum Induction (SPUTUM_ADD_TRT) form.***

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

ADDITIONAL TREATMENT POST SPUTUM INDUCTION

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

(Technician Completed)

Complete this form only if the participant has experienced > 10% fall in FEV_1 immediately after completion of sputum induction.

Clinic Use Only

Sputum Induction Reversal Reference Value: *Reference X 0.90 = __ . __ __ L*

Reference = FEV_1 used for assessment of eligibility for Sputum Induction.

➔ Administer 2 puffs of albuterol and wait 10-15 minutes, then perform spirometry.

1. Participant's FEV_1 after initial 2 puffs of albuterol

   1a. FEV_1 **(1000)** __ . __ __ L

   1b. FEV_1 (% predicted) **(1010)** __ __ __ % predicted

   1c. Time of FEV_1 from Q1a *(based on 24-hour clock)* **(1020)** __ __ __ __

   1d. Was the FEV_1 from Q1a ≥ the sputum induction reversal reference value in the gray box above? **(1030)** ❑$_1$ Yes ❑$_0$ No
   - ➔ If **YES**, stop here and continue with remaining visit procedures.
   - ➔ If **NO**, administer 2 puffs of albuterol and wait 10-15 minutes, then perform spirometry. Proceed to Q2.

2. Participant's FEV_1 after 2 additional puffs of albuterol

   2a. FEV_1 **(1040)** __ . __ __ L

   2b. FEV_1 (% predicted) **(1050)** __ __ __ % predicted

   2c. Time of FEV_1 from Q2a *(based on 24-hour clock)* **(1060)** __ __ __ __

   2d. Was the FEV_1 from Q2a ≥ the sputum induction reversal reference value in the gray box above? **(1070)** ❑$_1$ Yes ❑$_0$ No
   - ➔ If **NO**, complete the source documentation box below.

Physician Source Documentation

Physician Signature: _____ **(1080)**

Date: __ __ / __ __ / 20 __ __ **(1090)**
MM DD YYYY

Time: __ __ __ __ *(based on a 24-hour clock)* **(1100)**

SPUTUM ADD TRT

AsthmaNet	SPUTUM INDUCTION CHECKLIST	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).

(Only complete Q1 for participants who completed a methacholine challenge at this visit.)

1. Was the participant's FEV_1 after reversal from the methacholine challenge ≥ 90% of the baseline FEV_1 (i.e., greater than or equal to the methacholine reversal reference value (B) in the gray box on the Methacholine Challenge Testing (METHA) form)? **(1000)** ❑$_1$ Yes ❑$_0$ No

   1a. If ***NO***, has the participant received permission from the supervising physician to proceed with sputum induction testing? **(1010)** ❑$_1$ Yes ❑$_0$ No

   Physician's Signature: **(1020)** _____

2. Participant's FEV_1 used for assessment of eligibility for sputum induction **(1030)** __ . __ __ L

3. Participant's FEV_1 (% predicted) used for assessment of eligibility for sputum induction **(1040)** __ __ __ % predicted

4. Was the participant's FEV_1 (% predicted) from Q3 ≥ 50% predicted? **(1050)** ❑$_1$ Yes ❑$_0$ No

5. Has the participant used any smokeless tobacco products (e.g., chew, snuff) today? **(1055)** ❑$_1$ Yes ❑$_0$ No

6. Is there any other reason the participant should not proceed with sputum induction? **(1060)** ❑$_1$ Yes ❑$_0$ No

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

   _____

7. Is the participant eligible for sputum induction? **(1070)** ❑$_1$ Yes ❑$_0$ No
   If any of the shaded boxes are completed, the participant is NOT eligible for sputum induction.

   ➔ ***If YES, proceed to the Sputum Induction (SPUTUM) form.***

COMMENTS: (6000)

_____

_____

AsthmaNet

ASTHMA-SPECIFIC WORK PRODUCTIVITY AND ACTIVITY IMPAIRMENT QUESTIONNAIRE

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

(Participant Completed)

The following questions ask about the effect of your asthma on your ability to work, attend classes, and perform regular daily activities. When you think about the past seven days, do not include today. Please check the box or fill in the blank as indicated.

1. Are you currently employed (working for pay)? **(1000)** ❑$_1$ Yes ❑$_0$ No
   ➔ If **NO**, skip to Question 5.

2. In general, how many hours per week do you usually work? **(1010)** __ __ __ . __ hours

3. During the past seven days, how many hours did you miss from work because of problems associated with your asthma? Include hours you missed because you were sick, times you went in late, left early, etc. because you were experiencing problems with your asthma. (Do not include time you missed to participate in this study.) **(1020)** __ __ __ . __ hours

4. During the past seven days, how much did asthma affect your productivity while you were working? Think about days you were limited in the amount or kind of work you could do, days you accomplished less than you would like, or days you could not do your work as carefully as usual. If asthma affected your work only a little, choose a low number. Choose a high number if asthma affected your work a great deal.

Asthma had no effect on my work

0 1 2 3 4 5 6 7 8 9 10

Asthma completely prevented me from working

CIRCLE A NUMBER

Coordinator Completed

(1030) __ __

5. Do you currently attend classes in an academic setting (middle school, high school, college, graduate school, additional course work, etc.)? **(1040)** ❑$_1$ Yes ❑$_0$ No
   ➔ If **NO**, skip to Question 9.

6. In general, how many hours per week do you usually attend classes? **(1050)** __ __ __ . __ hours

7. During the past seven days, how many hours did you miss from class or school because of problems associated with your asthma? (Do not include time you missed to participate in this study.) **(1060)** __ __ __ . __ hours

WPAI ASTHMA

8. During the past seven days, how much did asthma affect your productivity while in school or attending classes in an academic setting? Think about days your attention span was limited, you had trouble with comprehension or days in which you could not take tests as effectively as usual. If asthma affected your productivity at school or in class only a little, choose a low number. Choose a high number if asthma affected your productivity a great deal.

Asthma had no effect on my class work

0 1 2 3 4 5 6 7 8 9 10

CIRCLE A NUMBER

Asthma completely prevented me from doing my class work

Coordinator Completed

(1070) __ __

9. During the past seven days, how much did your asthma affect your ability to do your regular daily activities, other than work at a job or attend classes? By regular activities, we mean the usual activities you do, such as work around the house, shopping, childcare, exercising, studying, etc. Think about times you were limited in the amount or kind of activities you could do and times you accomplished less than you would like. If asthma affected your activities only a little, choose a low number. Choose a high number if asthma affected your activities a great deal.

Asthma had no effect on my daily activities

0 1 2 3 4 5 6 7 8 9 10

CIRCLE A NUMBER

Asthma completely prevented me from doing my daily activities

Coordinator Completed

(1080) __ __

Participant Source Documentation

Participant Initials: __ __ __ **(1090)**

Date: __ __ / __ __ / 20 __ __ **(1100)**
MM DD YYYY

Time: __ __ __ __ *(based on a 24-hour clock)* **(1110)**

Visit: Visit Date: / / 2 0 Coordinator ID:

Wisconsin Upper Respiratory Symptom Survey – 21 --- *Daily Symptom Report*

Day:	*Date:*	*Time:*	*ID*: - -

Please fill in one circle for each of the following items: Part. Initials:

	Not sick	Very mildly		Mildly		Moderately		Severely
	0	**1**	**2**	**3**	**4**	**5**	**6**	**7**
How sick do you feel **today**?	O	O	O	O	O	O	O	O

Please rate the **average severity of your cold symptoms over the last 24 hours** for each symptom:

	Do not have this symptom	Very mild		Mild		Moderate		Severe
	0	**1**	**2**	**3**	**4**	**5**	**6**	**7**
Runny nose	O	O	O	O	O	O	O	O
Plugged nose	O	O	O	O	O	O	O	O
Sneezing	O	O	O	O	O	O	O	O
Sore throat	O	O	O	O	O	O	O	O
Scratchy throat	O	O	O	O	O	O	O	O
Cough	O	O	O	O	O	O	O	O
Hoarseness	O	O	O	O	O	O	O	O
Head congestion	O	O	O	O	O	O	O	O
Chest congestion	O	O	O	O	O	O	O	O
Feeling tired	O	O	O	O	O	O	O	O

Over the last 24 hours, how much has your cold interfered with your ability to:

	Not at all	Very mildly		Mildly		Moderately		Severely
	0	**1**	**2**	**3**	**4**	**5**	**6**	**7**
Think clearly	O	O	O	O	O	O	O	O
Sleep well	O	O	O	O	O	O	O	O
Breathe easily	O	O	O	O	O	O	O	O
Walk, climb stairs, exercise	O	O	O	O	O	O	O	O
Accomplish daily activities	O	O	O	O	O	O	O	O
Work outside the home	O	O	O	O	O	O	O	O
Work inside the home	O	O	O	O	O	O	O	O
Interact with others	O	O	O	O	O	O	O	O
Live your personal life	O	O	O	O	O	O	O	O

Compared to yesterday, I feel that my cold is…

Very much better	Somewhat better	A little better	The same	A little worse	Somewhat worse	Very much worse
O	O	O	O	O	O	O

Created by Bruce Barrett MD PhD et al., UW Department of Family Medicine, 777 S. Mills St. Madison, WI 53715, USA

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

(Coordinator Completed)

Complete this form to document the participant's baseline peak flow and rescue use values at Visit 0A for participants in the Supervised Washout and at Visit 1 for participants beginning SIENA at Visit 1. If participant completes Continuation Visit (or Split Visit 1), baseline PEF should be calculated using FEF Max value from baseline Spirometry testing at the initial Visit 1 (visit when reversibility testing was performed).

At subsequent visits (Visits 0B and 1 for Supervised Washout participants, and Visit 2 for those who began SIENA at Visit 1), the P6_BASELINE form will be generated directly from the MedGraphics laptop.

The baseline peak flow and rescue use values on the P6_BASELINE form should match those entered into the participant's spirotel® device at these visits.

1. Participant's baseline peak flow (PEF) value **(1000)** __ __ __ L/M

   ➔ First visit (Visit 0A, or initial Visit 1):
   PEF (FEF Max) from prebronchodilator (baseline) spirometry at first visit (multiply FEF Max by 60 to convert to L/M)

   ➔ If participant completes Visit 1 Continuation Visit (or split Visit 1), baseline PEF should be calculated using FEF Max value from baseline Spirometry testing at the initial Visit 1 (visit when reversibility testing was performed).

2. Participant's baseline rescue use value **(1010)** __ __ puffs/day

   ➔ First visit (Visit 0A, or Visit 1):
   Self-reported average daily use of albuterol during the 14 days prior to first visit.

COMMENTS: (6000)

_____

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AsthmaNet

SIENA
CHANGE IN SCHEDULED STUDY MEDICATIONS

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

(Coordinator Completed)

Complete this form if the participant experiences an adverse event (e.g., asthma exacerbation) that results in altering the status of his/her scheduled study medications (white Twisthaler®/MDI and blue Respimat®). A new form should be submitted each time dosing from the scheduled study medications is discontinued or resumed.

1. Reason for change in scheduled medications status **(1000)**
   - ❑1 Adverse Event
   - ❑2 Other (specify)

   ➔ If ***Other***, please specify and skip to Q2. **(1000D)** _____

   1a. Related adverse event number **(1010)** __ __

2. Current status of participant's scheduled medications **(1020)**
   - ❑1 Discontinued
   - ❑2 Resumed

3. Date change took effect **(1030)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

COMMENTS: (6000)

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AsthmaNet

SIENA COMPLIANCE CHECKLIST

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

(Coordinator Completed)

1. Diary and Peak Flow Compliance

   1a. Number of full days since the last visit **(1000)** __ __ __ days

   1b. Number of days where AM and PM scheduled sessions are complete (AM and PM PEF and all diary questions for AM and PM answered) **(1010)** __ __ __ days

   1c. Percent compliance **(1020)** __ __ __ . __ %

   ➔ ***If the compliance value in Q1c is less than 75%, re-emphasize the importance of completing scheduled diary assessments and peak flows.***

2. Scheduled Respimat® Compliance (Visits 2-9 only)

   2a. Number of scheduled puffs since the last visit **(1030)** __ __ __ puffs

   2b. Number of remaining puffs on scheduled Respimat® **(1040)** __ __ __ puffs

   ➔ ***Reference all returned Respimats®.***

   2c. Number of puffs taken **(1050)** __ __ __ puffs

   ➔ ***[60 x (# used Respimats®)] – Q2b***

   2d. Percent compliance = Q2c/Q2a x 100 **(1060)** __ __ __ . __ %

   ➔ ***If the participant took less than 75% of the scheduled Respimat® puffs, re-emphasize the importance of maintaining the daily dosing schedule.***

3. Scheduled Twisthaler®/MDI Compliance (Visits 4-9 only)

   3a. Number of scheduled puffs since the last visit **(1070)** __ __ __ puffs

   3b. Number of remaining puffs reflected on scheduled Twisthaler®/MDI counters **(1080)** __ __ __ puffs

   ➔ ***Total the values reflected on all counters for all returned Twisthalers® (i.e., out of their pouches) or MDI inhalers.***

3c. Number of puffs taken **(1090)** __ __ __ puffs

- ➔ **Twisthalers:** ***[60 x (# used Twisthalers®)] – Q3b***
- ➔ **MDI:** ***[120 x (# used MDIs)] – Q3b***

3d. Percent compliance = Q3c/Q3a x 100 **(1100)** __ __ __ . __ %

- ➔ ***If the participant took less than 75% of the scheduled Twisthaler®/MDI puffs, re-emphasize the importance of maintaining the daily dosing schedule.***

COMMENTS: **(6000)**

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AsthmaNet

SIENA COORDINATOR STUDY TREATMENT QUESTIONNAIRE

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

(Coordinator Completed)

This questionnaire is to be completed at Visits 5, 7, and 9 by the AsthmaNet coordinator who was primarily responsible for the participant's SIENA visits during the preceding 12 weeks. If a randomized participant terminates prior to the end of a given treatment period, this form should be completed at the time of the termination visit.

Blinded Scheduled Twisthaler®/MDI Contents

1. Participants in the SIENA study are randomized to receive a blinded Twisthaler®/MDI, the contents of which change during the course of the study. You are blinded to the actual contents of the Twisthaler®/MDI at any given time. The Twisthaler®/MDI contains either mometasone or placebo. Please check the box next to the treatment that you believe the participant received **over the past 12 weeks.** **(1000)**
   - ❑1 mometasone
   - ❑2 placebo

2. How sure are you about your answer in Q1? **(1010)**
   - ❑1 Absolutely sure – I know what the Twisthaler®/MDI contains
   - ❑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)**

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AsthmaNet

SIENA COORDINATOR STUDY TREATMENT QUESTIONNAIRE

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

Blinded Scheduled Respimat® Contents

4. Participants in the SIENA study are randomized to receive a blinded Respimat®, the contents of which change during the course of the study. You are blinded to the actual contents of the Respimat® at any given time. The Respimat® contains either tiotropium or placebo. Please check the box next to the treatment that you believe the participant received **over the past 12 weeks.** **(1030)**

   - ❑1 tiotropium
   - ❑2 placebo

5. How sure are you about your answer in Q4? **(1040)**

   - ❑1 Absolutely sure – I know what the Respimat® capsules contain
   - ❑2 Moderately sure
   - ❑3 Somewhat sure
   - ❑4 Not sure at all – purely a guess

6. Please comment with respect to any observations you made that helped you make your choice in Q4. **(1050D)**

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Coordinator Source Documentation
Coordinator's Initials: __ __ __ **(1060)**
Date: __ __ / __ __ / 20 __ __ **(1070)**
MM DD YYYY

AsthmaNet	SIENA ELIGIBILITY CHECKLIST 0A	Part. ID: __ __ - __ __ __ - __ __ __ Part. Initials: __ __ __ Visit: __ __ Visit Date: __ __ / __ __ / 20 __ __ Coordinator ID: __ __ __ __

(Coordinator Completed)

Section 1

1. Has the participant or parent/legal guardian signed the SIENA 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. ***Ages 12-17 Only:*** Has the participant signed and dated the assent form or, if the participant is less than the local age of assent, has the participant given verbal assent? **(1020)** ❑1 Yes ❑0 No

Complete Q3 only if IRB approval for protocol version 4.1 <u>has NOT yet been obtained</u>.

3. Has the participant used an inhaled corticosteroid in the past 6 weeks? **(1030)** ❑1 Yes ❑0 No

   ➔ If ***NO***, the participant is eligible for the Run-In. Please proceed with SIENA Visit Packet 1 (P6_VISIT1). ***Do NOT submit this form to the DCC.***

4. Will the participant be 12 years of age, or older, as of Visit 1? **(1040)** ❑1 Yes ❑0 No

Complete Q5 only if IRB approval for protocol version 4.1 <u>has been obtained</u>.

5. Has the participant used an inhaled corticosteroid or combination inhaled corticosteroid/LABA in the past 3 weeks? **(1043)** ❑1 Yes ❑0 No

   5a. If ***NO***, has the participant used a leukotriene modifier in the past 3 weeks? **(1045)** ❑1 Yes ❑0 No

   ➔ If ***YES***, skip to Q8.

   ➔ If ***NO***, the participant is eligible for the Run-In. Please proceed with SIENA Visit Packet 1 (P6_VISIT1). ***Do NOT submit this form to the DCC.***

6. Over the past 3 months, on average, how many days per week has the participant used inhaled corticosteroid (not combination inhaled corticosteroid/LABA) therapy? **(1050)** __ days per week

   ➔ If ***0***, skip to Q7.

6a. Is Q6 < 5? (1060) ❑1 Yes ❑0 No

6ai. If ***NO***, has the participant used greater than the equivalent of 80-240 mcg of inhaled beclomethasone daily? (1070) ❑1 Yes ❑0 No

➔ Refer to the SIENA ICS Equivalency Reference Card (P6_ICS_EQUIV).

Complete Q7 only if IRB approval for protocol version 4.1 has been obtained.

7. Over the past 3 months, on average, how many days per week has the participant used combination inhaled corticosteroid/LABA therapy? (1073) __ days per week

➔ If ***0***, skip to Q8.

7a. Is Q7 < 5? (1075) ❑1 Yes ❑0 No

8. Over the past 3 months, on average, how many days per week has the participant had daytime asthma symptoms? (1080) __ days per week

8a. Is Q8 ≤ 2? (1090) ❑1 Yes ❑0 No

9. Over the past 3 months, on average, how many nighttime awakenings per month has the participant had due to asthma symptoms? (1100) __ __ awakenings per month

9a. Is Q9 ≤ 2? (1110) ❑1 Yes ❑0 No

10. Over the past 3 months, on average, how many days per week has the participant used his/her short acting beta-agonist (e.g., albuterol, levalbuterol) for relief of symptoms? (1120) __ days per week

10a. Is Q10 < 2? (1130) ❑1 Yes ❑0 No

Section 2

Complete Q11 only if IRB approval for protocol version 4.1 has NOT yet been obtained.

11. Was the participant's FEV_1 % predicted > 80%? (1140) ❑1 Yes ❑0 No

Complete Q12 only if IRB approval for protocol version 4.1 has been obtained.

12. Was the participant's FEV_1 % predicted > 70%? (1145) ❑1 Yes ❑0 No

13. Does the participant have current evidence of any of the conditions listed on the Exclusionary Medical Conditions for SIENA (P6_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? (1150) ❑1 Yes ❑0 No

14. Is the participant currently taking any medications listed on the Exclusionary Drugs for SIENA (P6_EXCLDRUG) reference card? **(1160)** ❑1 Yes ❑0 No

14a. If ***YES***, list: **(1160D)** _____

14b. If ***YES***, is the participant able to go off these medications for the required washout period prior to Visit 1 and for the duration of the study? **(1170)** ❑1 Yes ❑0 No

Section 3

15. Is the participant able to use the spirotel® e-diary/PEF meter correctly, as evidenced by achieving a score of 13 on the spirotel® Performance Checklist (SPIROTEL_PERF)? **(1180)** ❑1 Yes ❑0 No

Eligibility Screening Questions for Visit 1

10 months prior to today's date is: __ __ / __ __ / 20__ __*

a. Does the participant plan to move away from the clinical site in the upcoming 13 months such that his/her ability to complete the study will be jeopardized? ❑ Yes ❑ No

b. Does the participant have plans to use investigative drugs and/or enroll in an intervention trial in the month prior to Visit 1, or during the SIENA study? ❑ Yes ❑ No

c. Does the participant have a history of bladder-neck obstruction, urinary retention, benign prostatic hyperplasia (BPH), or a clinically relevant urologic disorder that precludes study participation? ❑ Yes ❑ No

d. Does the participant have a history of narrow angle glaucoma? ❑ Yes ❑ No

e. Does the participant have a history of significant cardiovascular disorders or arrhythmias? ❑ Yes ❑ No

f. 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 as of Visit 1? ❑ Yes ❑ No

g. Has the participant taken omalizumab within the past month? ❑ Yes ❑ No

h. Has the participant used any smokeless tobacco products (e.g., chew, snuff) in the past 10 months*? ❑ Yes ❑ No

i. Has the participant smoked cigarettes, a pipe, cigar, marijuana, electronic cigarettes, or any other substance in the past 10 months*? ❑ Yes ❑ No

j. Does the participant have a smoking history of more than 10 pack-years if 18 or older, or more than 5 pack-years if 12-17 years old? ❑ Yes ❑ No

k. Has the participant received a physician diagnosis of asthma at least 10 months* ago? ❑ Yes ❑ No

➔ ***If IRB approval for protocol version 4.1 has been obtained, a history consistent with asthma during the past 10 months is acceptable.***

l. Has the participant experienced a life-threatening asthma exacerbation requiring treatment with intubation or mechanical ventilation in the past 4 years and 10 months*? ❑ Yes ❑ No

m. If potentially able to bear children, is the participant pregnant or lactating or unwilling to use an approved birth control method for the duration of the study beginning at Visit 1? ❑ Yes ❑ No

If any of the shaded boxes are completed, the participant will be ineligible at Visit 1 and should not continue with the Supervised Washout.

16. Is the participant eligible to proceed? **(1190)** ❑$_1$ Yes ❑$_0$ No

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

➔ ***If YES*, proceed with remaining Visit 0A procedures.**

Participant Source Documentation

Participant Initials: __ __ __ **(1200)**

Date: __ __ / __ __ / 20 __ __ **(1210)**
MM DD YYYY

COMMENTS: (6000)

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P6 ELIGOA

AsthmaNet	SIENA ELIGIBILITY CHECKLIST 0B	Part. ID: __ __ - __ __ __ - __ __ __ Part. Initials: __ __ __ Visit: __ __ Visit Date: __ __ / __ __ / 20 __ __ Coordinator ID: __ __ __ __

(Coordinator Completed)

Section 1

1.	In the past month, on average, how many days per week has the participant had daytime symptoms?	**(1000)**	__ . __ days per week
	1a. Is Q1 ≤ 2?	**(1010)**	❑$_1$ Yes ❑$_0$ No
2.	In the past month, on average, how many nighttime awakenings per month has the participant had due to asthma symptoms?	**(1020)**	__ __ . __ nighttime awakenings
	2a. Is Q2 ≤ 2?	**(1030)**	❑$_1$ Yes ❑$_0$ No
3.	In the past month, on average, how many days per week has the participant used his/her short acting beta-agonist (e.g., albuterol, levalbuterol) for relief of symptoms?	**(1040)**	__ . __ days per week
	3a. Is Q3 < 2?	**(1050)**	❑$_1$ Yes ❑$_0$ No

Section 2

Complete Q4 only if IRB approval for protocol version 4.1 <u>has NOT yet been obtained</u>.

4.	Was the participant's FEV_1 % predicted > 80%?	**(1060)**	❑$_1$ Yes ❑$_0$ No

Complete Q5 only if IRB approval for protocol version 4.1 <u>has been obtained</u>.

5.	Was the participant's FEV_1 % predicted > 70%?	**(1065)**	❑$_1$ Yes ❑$_0$ No
6.	Is there any new information that makes the participant ineligible according to the eligibility criteria?	**(1070)**	❑$_1$ Yes ❑$_0$ No

7.	Is the participant eligible to proceed?	**(1080)**	❑$_1$ Yes ❑$_0$ No

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

➔ ***If YES*, proceed with remaining Visit 0B procedures.**

COMMENTS: (6000)

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P6 ELIGOB

AsthmaNet	SIENA ELIGIBILITY CHECKLIST 1	Part. ID: __ __ - __ __ __ - __ __ __ Part. Initials: __ __ __ Visit: __ __ Visit Date: __ __ / __ __ / 20 __ __ Coordinator ID: __ __ __ __

(Coordinator Completed)

Do not complete Q1 and Q2 if the participant completed Supervised Washout (at least Visit 0A).

1. Did the participant or parent/legal guardian sign the SIENA 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. ***Ages 12-17 Only:*** Has the participant signed and dated the assent form or, if the participant is less than the local age of assent, has the participant given verbal assent? **(1020)** ❑1 Yes ❑0 No

3. Is the participant 12 years of age, or older? **(1030)** ❑1 Yes ❑0 No

4. Does the participant plan to move away from the clinical site in the upcoming 11 months such that his/her ability to complete the study will be jeopardized? **(1040)** ❑1 Yes ❑0 No

5. 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 SIENA study? **(1050)** ❑1 Yes ❑0 No

Complete Q6 only if IRB approval for protocol version 4.1 <u>has NOT yet been obtained</u>.

6. Has the participant had a respiratory infection within the past 6 weeks? **(1060)** ❑1 Yes ❑0 No

Complete Q7 only if IRB approval for protocol version 4.1 <u>has been obtained</u>.

7. Has the participant had a respiratory infection within the past 4 weeks? **(1065)** ❑1 Yes ❑0 No

Refer to SIENA spirotel® Eligibility Report (P6_ELIG_RPT) to complete Q8, Q9, and Q10 if the participant completed Supervised Washout (at least Visit 0A).

8. During the past 4 weeks, on average, how many days per week has the participant had daytime asthma symptoms? **(1070)** __ . __ days per week

   8a. Is Q8 > 2? **(1080)** ❑1 Yes ❑0 No

9. During the past 4 weeks, how many nighttime awakenings due to asthma symptoms has the participant had? **(1090)** __ __ . __ nighttime awakenings

   9a. Is Q9 > 2? **(1100)** ❑1 Yes ❑0 No

10. During the past 4 weeks, on average, how many days per week has the participant used his/her short-acting beta-agonist (e.g., albuterol, levalbuterol) for relief of symptoms? **(1110)** __ . __ days per week

10a. Is Q10 > 2? **(1120)** ❑1 Yes ❑0 No

11. Is Q8a, Q9a, or Q10a checked ***YES***? **(1130)** ❑1 Yes ❑0 No

12. Is the participant eligible to proceed? **(1140)** ❑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: __ __ __ **(1150)**

Date: __ __ / __ __ / 20 __ __ **(1160)**
MM DD YYYY

COMMENTS: **(6000)**

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AsthmaNet	SIENA 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 SIENA (P6_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 bladder-neck obstruction, urinary retention, benign prostatic hyperplasia (BPH), or a clinically relevant urologic disorder that precludes study participation? **(1010)** ☐1 Yes ☐0 No

3. Does the participant have a history of narrow angle glaucoma? **(1020)** ☐1 Yes ☐0 No

4. Does the participant have a history of significant cardiovascular disorders or arrhythmias? **(1030)** ☐1 Yes ☐0 No

5. Has the participant taken any medications listed on the Exclusionary Drugs for SIENA (P6_EXCLDRUG) reference card within the specified time periods? **(1040)** ☐1 Yes ☐0 No

6. Is the participant currently taking prescription or OTC medication(s) other than those listed on the Allowed Medications (P6_MEDALLOW) reference card? **(1050)** ☐1 Yes ☐0 No

7. Based on input from the participant and the study physician, will the participant need to use intranasal steroids at any time during the study? **(1060)** ☐1 Yes ☐0 No

   7a. 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? **(1070)** ☐1 Yes ☐0 No

8. 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? **(1080)** ☐1 Yes ☐0 No

9. Has the participant taken omalizumab within the past 3 months? **(1090)** ☐1 Yes ☐0 No

10. Has the participant used any smokeless tobacco products (e.g., chew, snuff) in the past year? **(1100)** ☐1 Yes ☐0 No

11. Has the participant smoked cigarettes, a pipe, cigar, marijuana, electronic cigarettes, or any other substance in the past year? **(1110)** ❑1 Yes ❑0 No

12. ***Ages 18+ Only:*** Does the participant have a smoking history of greater than 10 pack-years? **(1120)** ❑1 Yes ❑0 No

13. ***Ages 12-17 Only:*** Does the participant have a smoking history of greater than 5 pack-years? **(1130)** ❑1 Yes ❑0 No

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

Complete Q14 only if IRB approval for protocol version 4.1 <u>has NOT yet been obtained</u>.

14. Has the participant received a physician diagnosis of asthma at least 12 months ago? **(1140)** ❑1 Yes ❑0 No

Complete Q15 only if IRB approval for protocol version 4.1 <u>has been obtained</u>.

15. Has the participant received a physician diagnosis of asthma at least 12 months ago or had a history consistent with asthma for the previous 12 months? **(1145)** ❑1 Yes ❑0 No

16. Has the participant experienced a life-threatening asthma exacerbation requiring treatment with intubation or mechanical ventilation in the past 5 years? **(1150)** ❑1 Yes ❑0 No

17. Has the participant had an asthma exacerbation requiring systemic corticosteroid treatment in the past 6 weeks? **(1160)** ❑1 Yes ❑0 No

Complete Q18 only if IRB approval for protocol version 4.1 <u>has NOT yet been obtained</u>.

18. Has the participant used an oral or inhaled corticosteroid, or leukotriene modifier in the past 6 weeks? **(1170)** ❑1 Yes ❑0 No

Complete Q19 and Q20 only if IRB approval for protocol version 4.1 <u>has been obtained</u>.

19. Has the participant used an oral corticosteroid in the past 6 weeks? **(1173)** ❑1 Yes ❑0 No

20. Has the participant used an inhaled corticosteroid or leukotriene modifier in the past 3 weeks? **(1175)** ❑1 Yes ❑0 No

21. Is the participant potentially able to bear children? (*If participant is male, check N/A and go to Q22.)* **(1180)** ❑1 Yes ❑0 No ❑9 N/A

    21a. If ***YES***, is the participant currently pregnant or lactating? **(1190)** ❑1 Yes ❑0 No

    21b. 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? **(1200)** ❑1 Yes ❑0 No

22. Is the participant eligible to proceed? **(1210)** ❑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: __ __ __ **(1220)**

Date: __ __ / __ __ / 20 __ __ **(1230)**
MM DD YYYY

COMMENTS: (6000)

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

(Coordinator Completed)

Section 1

1. Was the participant's prebronchodilator $FEV_1 \geq 70\%$ predicted? **(1000)** ❑1 Yes ❑0 No

2. Did the participant's FEV_1 improve $\geq 12\%$ and ≥ 200 ml in response to four puffs of albuterol? **(1010)** ❑1 Yes ❑0 No

   ➔ If ***YES***, skip to Q3.

   2a. If ***NO***, does the participant have valid source documentation within the past 6 months for an overread AsthmaNet methacholine challenge (AsthmaNet systems, methacholine, and procedures only) with a $PC_{20} \leq 16$ mg/ml? **(1020)** ❑1 Yes ❑0 No

   ➔ If ***NO***, skip to Q2b.

   2ai. PC_{20} **(1030)** __ __ . __ __ mg/ml

   2aii. Source documentation date **(1040)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

   2aiii. Technician ID **(1050)** __ __ __ __

   2aiv. Supervisor ID, if applicable **(1060)** __ __ __ __

   2b. If ***NO*** to Q2a, at Visit 1 continuation visit, was the participant's methacholine $PC_{20} \leq 16$ mg/ml? **(1070)** ❑1 Yes ❑0 No

Section 2

3. Is the participant able to use the spirotel® e-diary/PEF meter correctly, as evidenced by achieving a score of 13 on the Spirotel® Performance Checklist (SPIROTEL_PERF)? **(1080)** ❑1 Yes ❑0 No ❑9 N/A

   ➔ Check ***N/A*** if participant completed Supervised Washout visits.

4. Has the participant used the Respimat® previously? **(1090)** ❑1 Yes ❑0 No

   4a. Is the participant able to use a Respimat® properly, as evidenced by achieving a score of 13 on the Respimat® Inhalation Technique Checklist (P6_TECH_RESP)? **(1100)** ❑1 Yes ❑0 No

5. Is the participant able to use a metered dose inhaler properly, as evidenced by achieving a score of 11 on the MDI Inhalation Technique Checklist (Without Spacer) (P6_TECH_MDI_NOSP)? **(1110)** ☐1 Yes ☐0 No

6. Does the participant have any condition or issue which, in the opinion of the investigator, might interfere with study participation? **(1120)** ☐1 Yes ☐0 No

   6a. If ***YES***, describe: **(1120D)** _____

7. Is the participant eligible to proceed? **(1130)** ☐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)**

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AsthmaNet	SIENA ELIGIBILITY CHECKLIST 4	Part. ID: __ __ - __ __ __ - __ __ __ Part. Initials: __ __ __ Visit: __ __ Visit Date: __ __ / __ __ / 20 __ __ Coordinator ID: __ __ __ __

(Coordinator Completed)

1.	Since Visit 1, has the participant experienced a treatment failure event as defined in the protocol?	**(1000)**	❑$_1$ Yes	❑$_0$ No
1a.	If ***YES***, has the participant experienced two or more treatment failures?	**(1010)**	❑$_1$ Yes	❑$_0$ No
2.	Since Visit 1, has the participant experienced one or more asthma exacerbations as defined in the protocol?	**(1020)**	❑$_1$ Yes	❑$_0$ No
3.	Since Visit 1, has the participant taken any medications listed on the Exclusionary Drugs for SIENA (P6_EXCLDRUG) reference card?	**(1030)**	❑$_1$ Yes	❑$_0$ No
4.	Is there any new information that makes the participant ineligible according to the eligibility criteria?	**(1050)**	❑$_1$ Yes	❑$_0$ No
5.	Does the participant have any condition or issue which, in the opinion of the investigator, might interfere with study participation?	**(1060)**	❑$_1$ Yes	❑$_0$ No

6.	Is the participant eligible to proceed?	**(1070)**	❑$_1$ Yes	❑$_0$ No

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

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

COMMENTS: (6000)

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AsthmaNet	SIENA ELIGIBILITY CHECKLIST 5	Part. ID: __ __ - __ __ __ - __ __ __ Part. Initials: __ __ __ Visit: __ __ Visit Date: __ __ / __ __ / 20 __ __ Coordinator ID: __ __ __ __

(Coordinator Completed)

Section 1

1. Did the participant provide two acceptable sputum induction samples during the run-in? **(1000)** ☐1 Yes ☐0 No

2. Since Visit 1, has the participant experienced a treatment failure event as defined in the protocol? **(1010)** ☐1 Yes ☐0 No

   2a. If ***YES***, has the participant experienced two or more treatment failures? **(1020)** ☐1 Yes ☐0 No

Complete Q2ai only if IRB approval for protocol version 4.1 <u>has NOT yet been obtained.</u>

2ai. If ***NO***, did the participant complete open-label Asmanex® treatment at least 6 weeks ago? **(1030)** ☐1 Yes ☐0 No

➔ If ***NO***, Visit 3 should be rescheduled so that randomization occurs at least 6 weeks after completion of Asmanex® treatment.

Complete Q2aii only if IRB approval for protocol version 4.1 <u>has been obtained.</u>

2aii. If ***NO***, did the participant complete open-label Asmanex® treatment at least 3 weeks ago? **(1035)** ☐1 Yes ☐0 No

➔ If ***NO***, Visit 3 should be rescheduled so that randomization occurs at least 3 weeks after completion of Asmanex® treatment.

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

4. Since Visit 1, has the participant taken any medications listed on the Exclusionary Drugs for SIENA (P6_EXCLDRUG) reference card? **(1050)** ☐1 Yes ☐0 No

Complete Q5 only if IRB approval for protocol version 4.1 <u>has NOT yet been obtained.</u>

5. Has the participant experienced a respiratory tract infection in the past 6 weeks? **(1060)** ☐1 Yes ☐0 No

➔ If ***YES***, Visit 3 should be rescheduled so that randomization occurs at least 6 weeks after resolution of the respiratory infection.

P6 ELIG5

Complete Q6 only if IRB approval for protocol version 4.1 <u>has been obtained.</u>

6. Has the participant experienced a respiratory tract infection in the past 4 weeks? **(1065)** ☐1 Yes ☐0 No

   ➔ If ***YES***, Visit 3 should be rescheduled so that randomization occurs at least 4 weeks after resolution of the respiratory infection.

7. According to the Spirotel® SIENA Eligibility Report:

Complete Q7a and Q7b only if IRB approval for protocol version 4.1 <u>has NOT yet been obtained.</u>

7a. Did the participant report daytime asthma symptoms daily during the run-in? **(1070)** ☐1 Yes ☐0 No

7b. Did the participant report night-time awakenings due to asthma symptoms more than once per week during the run-in? **(1080)** ☐1 Yes ☐0 No

Complete Q7c only if IRB approval for protocol version 4.1 <u>has been obtained.</u>

7c. Did the participant report night-time awakenings due to asthma symptoms more than twice per week during the run-in? **(1085)** ☐1 Yes ☐0 No

7d. Did the participant report daily albuterol use for asthma symptom control during the run-in? **(1090)** ☐1 Yes ☐0 No

7e. Did the participant record at least 75% of AM and PM peak flow measurements and symptoms on his or her spirotel® during the run-in? **(1100)** ☐1 Yes ☐0 No

8. Did the participant take at least 75% of the required puffs from his or her Respimat® during the run-in? **(1110)** ☐1 Yes ☐0 No

Section 2

9. Was the participant's prebronchodilator $FEV_1 \geq 70\%$ predicted? **(1120)** ☐1 Yes ☐0 No

Do NOT complete Q10 and Q10a if participant will be randomized to MDI.

10. Has the participant used the Twisthaler® previously? **(1130)** ☐1 Yes ☐0 No

10a. Is the participant able to use a Twisthaler® inhaler properly, as evidenced by achieving a score of 13 on the Twisthaler® Inhalation Technique Checklist (P6_TECH_TWIST)? **(1140)** ☐1 Yes ☐0 No

11. Does the participant wish to withdraw consent from the study? **(1150)** ☐1 Yes ☐0 No

12. Is there any new information that makes the participant ineligible according to the eligibility criteria? **(1160)** ☐1 Yes ☐0 No

13. Does the participant have any condition or issue which, in the opinion of the investigator, might interfere with study participation? **(1170)** ☐1 Yes ☐0 No

13a. If ***YES***, describe: **(1170D)** _____

14. Is the participant eligible to proceed? **(1180)** ☐1 Yes ☐0 No

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

➔ ***If YES,*** **proceed with remaining Visit 3 procedures.**

COMMENTS: **(6000)**

_____

_____

_____

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

(Coordinator Completed)

1. CBC with differential cell count

1a. Eosinophils (absolute count)	**(1000)**	__ __ __ __ /µL
1b. WBC	**(1010)**	__ __ __ . __ K/µL
1c. Differential		
1fi. Lymphocytes	**(1020)**	__ __ . __ %
1fii. Monocytes	**(1030)**	__ __ . __ %
1fiii. Basophils	**(1040)**	__ __ . __ %
1fiv. Neutrophils	**(1050)**	__ __ . __ %
1fv. Eosinophils	**(1060)**	__ __ . __ %

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

SIENA PARTICIPANT STUDY TREATMENT QUESTIONNAIRE

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

(Parent/Legal Guardian or Participant Completed)

This questionnaire is to be completed by the SIENA participant or parent/guardian at Visits 5, 7, and 9. If a randomized participant terminates prior to the end of a given treatment period, please ask the participant or parent/guardian to complete this form during the termination visit. Coordinators should ensure that participants understand what their choices are for Question #2 and #5 before they begin to complete the form.

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) _____

Blinded Scheduled Twisthaler® Contents

2. As a SIENA study participant, you were randomized to receive either a real (i.e., active) mometasone Twisthaler® or a look-alike placebo (i.e., inactive) Twisthaler®. The contents of the Twisthaler® change at certain points during the study. Please check the box next to the treatment that you believe you received **over the past 12 weeks.**

(1010)
- ❑1 mometasone
- ❑2 placebo

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

(1020)
- ❑1 Absolutely sure – I know what the Twisthaler® contains
- ❑2 Moderately sure
- ❑3 Somewhat sure
- ❑4 Not sure at all – purely a guess

4. Please comment with respect to any observations you made that helped you make your choice in Question 2 (for example: **taste, smell, or physical sensations** related to your scheduled Twisthaler®).

(1030)
- ❑1 I have no comments
- ❑2 I noticed the following: *(Describe below)*

(1030D) _____

_____

_____

_____

AsthmaNet

SIENA PARTICIPANT STUDY TREATMENT QUESTIONNAIRE

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

Blinded Scheduled Respimat® Contents

5. As a SIENA study participant, you were randomized to receive either a real (i.e., active) tiotropium Respimat® or a look-alike placebo (i.e., inactive) Respimat®. The contents of the Respimat® change at certain points during the study. Please check the box next to the treatment that you believe you received **over the past 12 weeks.**

(1040)
- ❑1 tiotropium
- ❑2 placebo

6. How sure are you about your answer to Question 5?

(1050)
- ❑1 Absolutely sure – I know what the Respimat® capsules contain
- ❑2 Moderately sure
- ❑3 Somewhat sure
- ❑4 Not sure at all – purely a guess

7. Please comment with respect to any observations you made that helped you make your choice in Question 5 (for example: **taste, smell, or physical sensations** related to your scheduled Respimat®).

(1060)
- ❑1 I have no comments
- ❑2 I noticed the following: *(Describe below)*

(1060D) _____

_____

_____

_____

Participant/Guardian Source Documentation

Participant/Guardian Initials: __ __ __ **(1070)**

Date: __ __ / __ __ / 20 __ __ **(1080)**
MM DD YYYY

AsthmaNet	SIENA 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 or rescue albuterol were used, record the medication(s) on the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form.

1.	Have you consumed caffeine in the past **4** hours? **Examples:** Pepsi, Coke, Coffee, Mountain Dew, Tea, Rootbeer, Red Bull, 5-hour ENERGY	**(1000)**	❑1 Yes	❑0 No
2.	Have you used medications with caffeine in the past **4** hours? **Examples:** Anacin, Darvon compound, Esgic, Excedrin, Fiorinal, Fioricet, No Doz, Norgesic, Vivarin	**(1010)**	❑1 Yes	❑0 No
3.	Have you used any weight loss medications in the past **4** hours? **Examples:** Belviq, bitter orange, Xenadrine, EFX, Thermorexin, Qsymia	**(1020)**	❑1 Yes	❑0 No
4.	Have you consumed any food containing alcohol or beverages containing alcohol in the past **4** hours?	**(1030)**	❑1 Yes	❑0 No
5.	Have you used a rescue intermediate-acting inhaled beta-agonist in the past **6** hours? **Examples:** albuterol (Proventil), study RESCUE (ProAir®)	**(1040)**	❑1 Yes	❑0 No
6.	***(Visit 1 only)*** Have you used a short-acting anticholinergic in the past **6** hours? **Examples:** ipratropium (Atrovent, Combivent)	**(1050)**	❑1 Yes	❑0 No
7.	Have you used any ophthalmic antihistamines in the past **6** hours? **Examples:** Alaway, Elestat, Emadine, Optivar, Pataday, Patanol, Zaditor	**(1060)**	❑1 Yes	❑0 No
8.	Have you used any nasal antihistamines in the past **6** hours? **Examples:** Astelin, Astepro, Livostin, Patanase	**(1070)**	❑1 Yes	❑0 No
9.	Have you used any nasal decongestants in the past **6** hours? **Examples:** oxymetazoline (Afrin)	**(1080)**	❑1 Yes	❑0 No
10.	Have you used any oral antihistamines in the past **48** hours? **Examples:** Allegra, Benadryl, Chlor-Trimeton, Clarinex, Claritin, Tylenol PM	**(1090)**	❑1 Yes	❑0 No

11. Have you used any oral decongestants or cold remedies in the past **48** hours? (1100) ❑1 Yes ❑0 No
Examples: pseudoephedrine (Sudafed), Tylenol Allergy

12. Have you used any smokeless tobacco products today? (1110) ❑1 Yes ❑0 No
Examples: chewing tobacco, snuff

13. At this time, is your asthma worse because of recent exposure to triggers? (1120) ❑1 Yes ❑0 No
Examples: cold air, smoke, allergens, recent exercise, a recent respiratory tract infection, or other pulmonary infection

14. Is there any other reason you should not proceed with spirometry testing? (1130) ❑1 Yes ❑0 No

If ***YES,*** explain: (1130D) _____

_____

15. Is the participant eligible to proceed with the spirometry testing? (1140) ❑1 Yes ❑0 No

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

Exception: An ineligible participant may proceed with spirometry if this is an FEV_1 re-assessment visit for evaluation of significant asthma exacerbation, or if this is a combined Asthma Exacerbation (V9XA) and crossover (or last) visit.

Exception: An ineligible participant may proceed with spirometry if he/she is already known to be a treatment failure at visit 1, 2, 3, 4, 6, or 8.

➔ ***If YES, proceed to Q16 or the next form/procedure listed on the visit procedure checklist.***

If participant is 18 to 20 years old, complete Q16 at Visits 2-8, and 90A-95A. For Supervised Washout participants 18 to 20 years old, Q16 should also be completed at Visits 0B and 1.

At Visits 0A, 1 (for non-Supervised Washout participants only) and 9, refer to height recorded on the Adult Body Measurements (BODYMEAS_ADULT) form; do not record on this form.

16. Height (without shoes) (1150) __ __ __ cm

COMMENTS: (6000)

_____

_____

_____

AsthmaNet

SIENA SIGNIFICANT ASTHMA EXACERBATION

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

(Coordinator Completed)

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

(Do not complete Q1 at Visits 0A and 0B)

1. Did the participant fail to respond within 48 hours to the treatment failure rescue algorithm? **(1000)** ❑1 Yes ❑0 No

2. Did the participant use at least 16 puffs as needed albuterol per 24 hours for a period of 48 hours? **(1010)** ❑1 Yes ❑0 No

(Do not complete Q3 at Visits 0A, 0B, and 1)

3. Did the participant experience prebronchodilator FEV_1 values < 50% of the <u>baseline</u> prebronchodilator value obtained at Visit 1 on two consecutive spirometric determinations made on different days? **(1020)** ❑1 Yes ❑0 No ❑9 Not evaluated

(Do not complete Q4 at Visits 0A, 0B, and 1)

4. Did the participant experience prebronchodilator FEV_1 values < 40% of <u>predicted</u> on two consecutive spirometric determinations made on different days? **(1030)** ❑1 Yes ❑0 No ❑9 Not evaluated

5. Did the study or treating physician prescribe the participant oral/parenteral corticosteroids for the treatment of his/her asthma? **(1040)** ❑1 Yes ❑0 No

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

6. Did the participant experience a significant asthma exacerbation in the opinion of the study investigator or personal physician? **(1050)** ❑1 Yes ❑0 No

7. Did the participant experience a significant asthma exacerbation? **(1060)** ❑1 Yes ❑0 No
   If any of the shaded boxes in Q1-Q6 is filled in, the participant experienced an asthma exacerbation.

   ➔ ***If YES, complete the rest of the form and record the exacerbation on the Clinical Adverse Events (AECLIN) form using ICD-9 code 493.92. The SIENA Treatment Failure Checklist (P6_TXFAIL_CHK) should also be completed.***

   ➔ ***If NO, STOP HERE. Do NOT submit this form to the DCC.***

8. Date exacerbation conditions were met **(1070)** __ __ / __ __ / 20 __ __
   MM DD YYYY

9. Did the participant seek care for significant asthma exacerbation conditions? **(1080)** ❑1 Yes ❑0 No

➔ If ***NO***, skip to Q12.

10. What type of care was sought?

10a. Study Investigator or Coordinator? **(1090)** ❑1 Yes ❑0 No

10ai. If ***YES***, indicate type of contact **(1100)** ❑1 Scheduled clinic visit
❑2 Unscheduled clinic visit
❑3 Phone contact

10b. Primary Care or Other Physician? **(1110)** ❑1 Yes ❑0 No

10bi. If ***YES***, indicate the type of contact **(1120)** ❑1 Scheduled clinic visit
❑2 Unscheduled clinic visit
❑3 Phone contact

10c. Emergency Department visit? **(1130)** ❑1 Yes ❑0 No

10d. Urgent care visit? **(1140)** ❑1 Yes ❑0 No

11. Was the participant hospitalized? **(1150)** ❑1 Yes ❑0 No

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

If ***YES***,

11a. Duration of hospital stay **(1160)** __ __ . __ days

11b. Was intubation or ventilation assistance required? **(1170)** ❑1 Yes ❑0 No

11c. Was the participant admitted to the intensive care unit? **(1180)** ❑1 Yes ❑0 No

12. Has the participant taken any of the following medications (excluding study ICS) since significant asthma exacerbation conditions started?

➔ If ***YES*** to any of Q12a-Q12f, complete the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form.

12a. Inhaled corticosteroids	**(1190)**	❑$_1$ Yes	❑$_0$ No
12b. Nebulized bronchodilator	**(1200)**	❑$_1$ Yes	❑$_0$ No
12c. Oral corticosteroids	**(1210)**	❑$_1$ Yes	❑$_0$ No
12d. IM or IV steroids	**(1220)**	❑$_1$ Yes	❑$_0$ No
12e. Antibiotics	**(1230)**	❑$_1$ Yes	❑$_0$ No
12f. Other	**(1240)**	❑$_1$ Yes	❑$_0$ No

(1240D) _____

13. *(Physician Completed)* Why do you think the participant experienced a significant asthma exacerbation? **(1250)**

- ❑$_1$ Common cold
- ❑$_2$ Allergies
- ❑$_3$ Pollution or chemical irritant
- ❑$_4$ Too little asthma maintenance medication
- ❑$_5$ Exercise
- ❑$_6$ Other (specify)

(1250D) _____

14. Physician Narrative Assessment

_____

_____

_____

Physician Source Documentation

Physician's Signature: _____ **(1260)**

Date: __ __ / __ __ / 20__ __ (MM / DD / YYYY) **(1270)**

Time: __ __ __ __ *(based on a 24-hour clock)* **(1280)**

COMMENTS: **(6000)**

_____

_____

AsthmaNet	SIENA SIGNIFICANT ASTHMA EXACERBATION PHONE FOLLOW-UP	Part. ID: __ __ - __ __ __ - __ __ __ Part. Initials: __ __ __ Visit: __ __ __ Visit Date: __ __ / __ __ / 20 __ __ Coordinator ID: __ __ __ __

(Coordinator Completed)

For participants who met significant asthma exacerbation criteria, complete this form at Asthma Exacerbation phone contacts following Asthma Exacerbation visit. At Phone Contact #1, additional care and medications started since Asthma Exacerbation visit should be recorded. At Phone Contact #2 and #3, additional care and medications started since last Asthma Exacerbation phone contact should be recorded.

1. Which phone contact following Asthma Exacerbation visit is being performed? **(1000)**
   - ❑1 Phone Contact #1 (Day 10: Visit 9___ B)
   - ❑2 Phone Contact #2 (Day 14: Visit 9___ C)
   - ❑3 Phone Contact #3 (Day 21: Visit 9___ D)

2. Since the most recent Asthma Exacerbation contact, has the participant sought additional care for significant asthma exacerbation conditions? **(1010)** ❑1 Yes ❑0 No

   ➔ If ***NO***, skip to Q5.

3. What type of care was sought?

   3a. Study Investigator or Coordinator? **(1020)** ❑1 Yes ❑0 No

   3ai. If ***YES***, indicate type of contact **(1030)**
   - ❑1 Scheduled clinic visit
   - ❑2 Unscheduled clinic visit
   - ❑3 Phone contact

   3b. Primary Care or Other Physician? **(1040)** ❑1 Yes ❑0 No

   3bi. If ***YES***, indicate the type of contact **(1050)**
   - ❑1 Scheduled clinic visit
   - ❑2 Unscheduled clinic visit
   - ❑3 Phone contact

   3c. Emergency Department visit? **(1060)** ❑1 Yes ❑0 No

   3d. Urgent care visit? **(1070)** ❑1 Yes ❑0 No

4. Was the participant hospitalized? **(1080)** ❑1 Yes ❑0 No

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

If ***YES***,

4a. Duration of hospital stay **(1090)** __ __ . __ days

4b. Was intubation or ventilation assistance required? **(1100)** ❑1 Yes ❑0 No

4c. Was the participant admitted to the intensive care unit? **(1110)** ❑1 Yes ❑0 No

5. Due to persistent symptoms, has the participant started taking any of the following medications since the most recent Asthma Exacerbation contact?

➔ If ***YES*** to any of Q5a-Q5f, complete the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form.

5a. Inhaled corticosteroids **(1120)** ❑1 Yes ❑0 No

5b. Nebulized bronchodilator **(1130)** ❑1 Yes ❑0 No

5c. Oral corticosteroids **(1140)** ❑1 Yes ❑0 No

5d. IM or IV steroids **(1150)** ❑1 Yes ❑0 No

5e. Antibiotics **(1160)** ❑1 Yes ❑0 No

5f. Other **(1170)** ❑1 Yes ❑0 No

(1170D) _____

6. Physician Narrative Assessment

_____

_____

_____

Physician Source Documentation

Physician's Signature: _____ **(1180)**

Date: __ __ / __ __ / 20__ __ **(1190)**
MM DD YYYY

Time: __ __ __ __ *(based on a 24-hour clock)* **(1200)**

COMMENTS: **(6000)**

_____

_____

Scheduled AM Assessment (4 AM – 1 PM, inclusive)

Q1. Number of times the participant woke up last night due to asthma symptoms __ (numeric 0 – 9)

Q2 will only be displayed for Visits 2-9

Q2. Number of puffs the participant will take from the BLUE study inhaler this morning __ (numeric 0 – 9)

Q3 will only be displayed for Visits 4-9

Q3. Number of puffs the participant will take from the WHITE study inhaler this morning __ (numeric 0 – 9)

Q4. Has the participant taken any puffs from his/her RED RESCUE albuterol inhaler in the past 4 hours? __ (1 = Yes, 0 = No)

Nighttime Symptoms (symptoms experienced since the PM e-diary assessment was completed)

Q5. Shortness of Breath score __ (0, 1, 2, 3)

Q6. Chest tightness score __ (0, 1, 2, 3)

Q7. Wheezing score __ (0, 1, 2, 3)

Q8. Coughing score __ (0, 1, 2, 3)

Q9. Phlegm/Mucus score __ (0, 1, 2, 3)

AM alerts:

- Take puffs from Study Inhaler(s).
- Peak flow is low. Call clinic ASAP. (If scheduled PEF < 65% of baseline peak flow)
- E-diary data indicates you need YELLOW inhaler. Call clinic ASAP. (Q1 ≥ 1 for 2 consecutive sessions or for 3 or more sessions in 14 calendar days)

Scheduled PM Assessment (5 PM – 3 AM, inclusive)

Q10. Number of puffs the participant will take from the WHITE study inhaler tonight __ (numeric 0 – 9)

Q11. Has the participant taken any puffs from his/her RED RESCUE albuterol inhaler during the past 4 hours? __ (1 = Yes, 0 = No)

Symptoms since waking this morning (symptoms experienced since the AM e-diary assessment was completed)

Q12. Shortness of Breath score __ (0, 1, 2, 3)

Q13. Chest tightness score __ (0, 1, 2, 3)

Q14. Wheezing score __ (0, 1, 2, 3)

Q15. Coughing score __ (0, 1, 2, 3)

Q16. Phlegm/Mucus score __ (0, 1, 2, 3)

Q17. Did your regular exercise cause unusually severe shortness of breath during the past 24 hours? __ (1 = Yes, 0 = No, 9 = N/A)

Q18. Number of RED RESCUE albuterol puffs taken in the past 24 hours to prevent symptoms (for example: before exercise, before smoke exposure, or before exposure to pets) __ __ (numeric 0 – 40)

Rescue puff instructions for Q19 and Q20: Preventive RED RESCUE albuterol puffs (e.g., prior to exercise, smoke exposure, exposure to pets) should not be counted towards total puffs or total times the RED RESCUE inhaler was used.

Q19. Number of RED RESCUE albuterol puffs taken for asthma symptoms or low peak flow during past 24 hours __ __ (numeric 0 – 40)

➔ If **Q19 = 0**, spirotel® will skip the user to Q22.

Q20. Number of times used RED RESCUE albuterol inhaler for asthma symptoms during past 24 hours __ __ (numeric 0 – 20)

Q21. Did RED RESCUE albuterol relieve symptoms for less than 4 hours after treatment during past 24 hours? __ (1 = Yes, 0 = No)

Q22. Was the participant seen by a healthcare provider (doctor's office, ER, urgent care, study site) for an unscheduled visit in the past 24 hours due to asthma symptoms? __ (1 = Yes, 0 = No)

PM alerts:

- Take puffs from Study Inhaler(s)
- Peak flow is low. Call clinic ASAP. (If scheduled PEF < 65% of baseline peak flow)
- Rescue use high. Call clinic ASAP. (Q19 ≥ 16 puffs per 2 consecutive sessions)
- E-diary data indicates you need YELLOW inhaler. Call clinic ASAP.
  - Q20 ≥ 4 for 2 or more consecutive sessions; or
  - Q21 = 1; or
  - Q20 ≥ 1 for 7 or more consecutive sessions AND sum of Q19 over consecutive days > baseline rescue use value x 14; or
  - Q17 = 1 for 2 or more sessions in 7 consecutive days.

Three scheduled AM/PM PEF maneuvers are done following AM/PM questions with the best being saved in The spirotel® device. The 'Highest Peak Flow' will display with an arrow pointing to the corresponding color indicator based on the definitions of the following peak flow zones:

- Green zone: > 80% of PEF reference value
- Yellow zone: >= 65% and <=80% of PEF reference value
- Red Zone: < 65% of PEF reference value

P6 SPIROTEL CREF

AsthmaNet	SIENA 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 0A or Visit 1.

1. Has the participant completed the study through Visit 9? **(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.***

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)
	4bi. 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.	ineligibility during the Supervised Washout (Visits 0A-0B)?*	(1110)	❑1 Yes ❑0 No
4g.	non-compliance with medication dosing?*	(1120)	❑1 Yes ❑0 No
4h.	non-compliance with diary completion?*	(1130)	❑1 Yes ❑0 No
4i.	non-compliance with visit attendance?*	(1140)	❑1 Yes ❑0 No
4j.	non-compliance with peak flow monitoring?*	(1150)	❑1 Yes ❑0 No
4k.	significant asthma exacerbation or two treatment failures during run-in (Visits 1-3)?*	(1160)	❑1 Yes ❑0 No
4l.	ineligibility during the run-in period (Visits 1-3) for reasons other than compliance or exacerbation/treatment failure or high sputum eosinophils (as indicated on Participant Status Report)?*	(1170)	❑1 Yes ❑0 No
4m.	other reason?*	(1180)	❑1 Yes ❑0 No
4n.	ineligibility due to high sputum eosinophils in the run-in (as indicated on Participant Status Report)?	(1185)	❑1 Yes ❑0 No

***Additional explanation required:** **(1190D)**

_____

_____

_____

4o. Indicate the letter corresponding to the **primary** reason the participant was terminated. **(1200)** __

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

I verify that all information collected on the AsthmaNet SIENA 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.

_____ **(1210)** __ __ / __ __ / 20 __ __ **(1220)**
Coordinator Signature MM DD YYYY

_____ **(1230)** __ __ / __ __ / 20 __ __ **(1240)**
Principal Investigator Signature MM DD YYYY

AsthmaNet	SIENA TREATMENT FAILURE CHECKLIST	Part. ID: __ __ - __ __ __ - __ __ __ Part. Initials: __ __ __ Visit: __ __ __ Visit Date: __ __ / __ __ / 20 __ __ Coordinator ID: __ __ __ __

(Coordinator Completed)

Complete this form at all visits from Visit 2 until the end of the study to assess the participant for treatment failure criteria. If a participant experiences treatment failure during the run-in and is seen prior to Visit 2, complete a single form using visit number 1.

For Q1-Q5, refer to the SIENA Spirotel Participant Visit (P6_SPIROTEL_RPT) report.

1.	Did the participant awaken from asthma three or more times in a two-week period or on two consecutive nights?	**(1000)**	❑$_1$ Yes	❑$_0$ No
2.	Did the participant use albuterol for relief of symptoms four or more times/day for two or more consecutive days?	**(1010)**	❑$_1$ Yes	❑$_0$ No
3.	Did albuterol relieve symptoms for less than four hours after treatment?	**(1020)**	❑$_1$ Yes	❑$_0$ No
4.	Did the participant use albuterol for relief of symptoms daily for seven days, and this use exceeded two times the weekly use of albuterol in the baseline period?	**(1030)**	❑$_1$ Yes	❑$_0$ No
5.	Did regular exercise cause unusually severe shortness of breath on two or more days during a seven day period?	**(1040)**	❑$_1$ Yes	❑$_0$ No
6.	Did the participant experience a significant asthma exacerbation? ➔ If ***YES***, complete the SIENA Significant Asthma Exacerbation (P6_SIGEX) form.	**(1050)**	❑$_1$ Yes	❑$_0$ No
7.	Did the participant experience a treatment failure? ***If any of the shaded boxes in Q1-Q6 are filled in, the participant experienced a treatment failure.*** ➔ ***If YES, complete the rest of this form and record the treatment failure on the Clinical Adverse Events (AECLIN) form using ICD-9 code 000.00. Also, if Q6 is answered No, complete a SIENA Treatment Failure Information (P6_TXFAIL) form.*** ➔ ***If NO, STOP HERE and continue with remaining visit procedures.***	**(1060)**	❑$_1$ Yes	❑$_0$ No
8.	Date treatment failure conditions were met	**(1070)**	__ __ / __ __ / 20 __ __ MM DD YYYY	

If treatment failure is result of significant asthma exacerbation, STOP HERE; do not complete page 2.

(Complete Q9 and Q10 at Visits 4-8 only)

9. Has the participant experienced two treatment failures in the current treatment period (between Visits 3 and 5, Visits 5 and 7, or Visits 7 and 9)? **(1080)** ❑1 Yes ❑0 No

10. Does the study physician feel the study treatment contributed directly to the treatment failure, such that it is in the participant's best interest to discontinue the current blinded treatment? **(1090)** ❑1 Yes ❑0 No

If YES to Q9 or Q10, and participant has not experienced significant asthma exacerbation:
- ➔ ***During Period 1 or 2, the participant should be scheduled to begin the next treatment period (Visit 5 or Visit 7) two weeks after finishing treatment for treatment failure.***
- ➔ ***During Period 3, the participant should be scheduled for Visit 9 two weeks after finishing treatment for treatment failure.***

If NO to Q9 and NO to Q10 and participant has not experienced significant asthma exacerbation, a reminder that the last visit of the current treatment period (Visit 5, 7 or 9) should occur:
- ➔ ***Six weeks after finishing treatment for treatment failure if IRB approval for protocol version 4.1 has NOT yet been obtained.***
- ➔ ***Three weeks after finishing treatment for treatment failure if IRB approval for protocol version 4.1 has been obtained.***

Reschedule the last visit of the current treatment period accordingly.

11. Did the participant begin daily treatment with high-dose ICS for 10 days? **(1100)** ❑1 Yes ❑0 No

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

11a. If ***NO***, why did the participant not begin daily treatment with high-dose ICS? **(1110)** ❑1 Did not think symptoms were bad enough

❑2 Other(specify) **(1110D)** _____

COMMENTS: (6000)

_____

_____

_____

AsthmaNet

SIENA TREATMENT FAILURE INFORMATION

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

(Coordinator Completed)

Complete this form for participants who did not meet treatment failure status as a result of a significant asthma exacerbation (P6_TXFAIL_CHK Q6 is answered No).

1. Did the participant seek care for treatment failure conditions? **(1000)** ❑1 Yes ❑0 No

   ➔ If ***NO***, skip to Q3.

2. What type of care was sought?

   2a. Study Investigator or Coordinator? **(1010)** ❑1 Yes ❑0 No

   2ai. If ***YES***, indicate type of contact **(1020)**
   - ❑1 Scheduled clinic visit
   - ❑2 Unscheduled clinic visit
   - ❑3 Phone contact, other than call to notify clinic as instructed in spirotel

   2b. Primary Care or Other Physician? **(1030)** ❑1 Yes ❑0 No

   2bi. If ***YES***, indicate the type of contact **(1040)**
   - ❑1 Scheduled clinic visit
   - ❑2 Unscheduled clinic visit
   - ❑3 Phone contact

   2c. Emergency Department visit? **(1050)** ❑1 Yes ❑0 No

   2d. Urgent care visit? **(1060)** ❑1 Yes ❑0 No

3. Has the participant taken any of the following medications (excluding study medication and high-dose ICS taken as instructed for treatment failure) since treatment failure conditions started?

➔ If ***YES*** to any of Q3a-Q3f, complete the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form.

3a.	Inhaled corticosteroids	**(1070)**	❑1 Yes	❑0 No
3b.	Nebulized bronchodilator	**(1080)**	❑1 Yes	❑0 No
3c.	Oral corticosteroids	**(1090)**	❑1 Yes	❑0 No
	➔ If ***YES***, complete a SIENA Significant Asthma Exacerbation (P6_SIGEX) form.			
3d.	IM or IV steroids	**(1100)**	❑1 Yes	❑0 No
	➔ If ***YES***, complete a SIENA Significant Asthma Exacerbation (P6_SIGEX) form.			
3e.	Antibiotics	**(1110)**	❑1 Yes	❑0 No
3f.	Other	**(1120)**	❑1 Yes	❑0 No
		(1120D)	_____	

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

SIENA
WASHOUT FORM
(Visits 5, 7, 9)

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

(Coordinator Completed)

Complete this form at Visits 5, 7 and 9 to confirm that the participant meets washout requirements prior to proceeding with the visit.

1. During this last treatment period (Visits 3 through 5, Visits 5 through 7, or Visits 7 through 9), has the participant experienced a treatment failure or asthma exacerbation? **(1000)** ❑$_1$ Yes ❑$_0$ No

   ➔ ***If NO, STOP HERE and continue with current visit.***

   ➔ ***If YES, and participant has had an asthma exacerbation, STOP HERE, continue with current visit and complete Asthma Exacerbation forms as prompted on current visit checklist. Asthma Exacerbation forms can be found in Visit 9XA packet.***

2. Has the participant experienced two or more treatment failures in this last treatment period, or does the study physician feel the study treatment contributed directly to the treatment failure such that it is in the participant's best interest to discontinue this period's study treatment? **(1010)** ❑$_1$ Yes ❑$_0$ No

   ➔ ***If NO, proceed to Q3 or Q4 (depending on protocol version currently IRB approved).***

   2a. As of today, have 2 weeks passed since the participant's final dose of open-label Asmanex®? **(1020)** ❑$_1$ Yes ❑$_0$ No

   ➔ ***Refer to Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form for date of final dose.***

   ➔ ***If NO, the current visit must be delayed until the minimum washout period of 2 weeks has been met. Stop the current visit and reschedule accordingly. Do not enter or submit the form to the DCC.***

   ➔ ***If YES, STOP HERE and continue with current visit.***

Complete Q3 only if IRB approval for protocol version 4.1 <u>has NOT yet been obtained</u>.

3. As of today, have 6 weeks passed since the participant's final dose of open-label Asmanex®? **(1040)** ❑$_1$ Yes ❑$_0$ No

   ➔ ***Refer to Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form for date of final dose.***
   ➔ ***If NO, the current visit must be delayed until the minimum washout period of 6 weeks has been met. The maximum washout period is 7 weeks. Stop the current visit and reschedule accordingly. Do not enter or submit the form to the DCC.***
   ➔ ***If YES, STOP HERE and continue with current visit.***

Complete Q4 only if IRB approval for protocol version 4.1 <u>has been obtained</u>.

4. As of today, have 3 weeks passed since the participant's final dose of open-label Asmanex®? **(1050)** ❑$_1$ Yes ❑$_0$ No

   ➔ ***Refer to Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form for date of final dose.***
   ➔ ***If NO, the current visit must be delayed until the minimum washout period of 3 weeks has been met. The maximum washout period is 4 weeks. Stop the current visit and reschedule accordingly. Do not enter or submit the form to the DCC.***
   ➔ ***If YES, STOP HERE and continue with current visit.***

COMMENTS: (6000)

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