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? **(1090)** ❑1 Yes ❑0 No
   ➔ If ***NO***, skip to Q8b.

   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)**

Asthma Control Test™

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

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

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

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

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

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

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

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

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

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

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

To score the ACT

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

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

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

AsthmaNet

CLINICAL ADVERSE EVENTS

(Coordinator completed)

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

Part. Initials: __ __ __

Visit: __ __ __

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

❑0 None

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

AsthmaNet

ADULT ASTHMA AND ALLERGY HISTORY

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

(Coordinator Completed by Interview)

ASTHMA HISTORY

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

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

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

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

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

   ➔ If participant is male, skip to Q2.

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

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

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

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

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

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

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

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

ASTHMA HX ADULT

ASTHMA SYMPTOMS

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

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

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

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

   4d. Fall? **(1170)** ❑1 Yes ❑0 No

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

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

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

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

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

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

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

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

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

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

ASTHMA TRIGGERS

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

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

ALLERGIES

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

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

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

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

_____

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

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

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

8f. Other **(1460)** ❑1 Yes ❑0 No

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

_____

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

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

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

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

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

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

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

SMOKING HISTORY

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

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

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

    ➔ **STOP HERE.**

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

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

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

COMMENTS: **(6000)**

_____

_____

_____

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

AsthmaNet

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

COLD HISTORY

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.

Please answer the following questions with respect to your cold history over the past 12 months.

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

2. In the past 12 months, how many respiratory tract infections/colds did you experience? (Enter '00' if none.)
   ➔ If **'00'**, STOP HERE.
   (1010) __ __ colds in past 12 months

3. In the past 12 months, how severe were your colds usually?
   (1020) ❑1 Extremely mild
   ❑2 Mild
   ❑3 Moderate
   ❑4 Severe

4. In the past 12 months, has a cold EVER made your asthma worse?
   ➔ If **NO**, STOP HERE.
   (1030) ❑1 Yes ❑0 No

5. In the past 12 months, when you had a cold, how often did it make your asthma worse?
   (1040) ❑1 Rarely
   ❑2 Sometimes
   ❑3 Usually
   ❑4 Always

6. In the past 12 months, when colds made your asthma worse, how severe did your asthma usually get?
   (1050) ❑1 Extremely mild
   ❑2 Mild
   ❑3 Moderate
   ❑4 Severe

COMMENTS: (6000)

_____

_____

_____

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

MAXIMUM REVERSIBILITY 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 (PULMONARYCHK) 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. Participant's FEV_1 after 4 puffs of albuterol

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

   2b. Highest FEV_1 **(1030)** __ . __ __ L

   2c. Highest FEV_1 (% predicted) **(1040)** __ __ __ % predicted

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

3. Time albuterol administered *(based on 24-hour clock)* **(1050)** __ __ __ __

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

   4a. Time spirometry started *(based on 24-hour clock)* **(1060)** __ __ __ __

   4b. Highest FEV_1 **(1070)** __ . __ __ L

   4c. Highest FEV_1 (% predicted) **(1080)** __ __ __ % predicted

   4d. Percent difference in FEV_1

   $$\frac{(Q4b - Q2b)}{Q2b} \times 100$$ **(1090)** __ __ . __ %

   4e. Is the percent difference from Q4d ≤ 5.0%? **(1100)** ❑$_1$ Yes ❑$_0$ No

   ➔ ***If YES, skip to Q7 and continue with remaining visit procedures.***

   ➔ ***If NO, administer 2 puffs of albuterol and wait 10 to 15 minutes, then perform spirometry.***

5. Time albuterol administered *(based on 24-hour clock)* **(1110)** __ __ __ __

6. Participant's FEV_1 after last 2 puffs of albuterol

   6a. Time spirometry started *(based on 24-hour clock)* **(1120)** __ __ __ __

   6b. Highest FEV_1 **(1130)** __ . __ __ L

   6c. Highest FEV_1 (% predicted) **(1140)** __ __ __ % predicted

7. In your judgment, was the participant's technique acceptable? **(1150)** ❑$_1$ Yes ❑$_0$ No

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

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? ☐ 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

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.

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 **(1180)** ❑1 Yes ❑0 No
➔ If ***YES***, please complete the Serious Adverse Event (SERIOUS) form.

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? **(1230)** ❑1 Yes ❑0 No
➔ If ***NO***, complete the source documentation box below.

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

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)**
➔ ***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.***
☐1 Positive
☐0 Negative

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	

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)**

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
(e.g., Asmanex Twisthaler, QVAR, Flovent, Pulmicort Flexhaler)
➔ ***Do not consider combination medications.***
➔ If **YES**, complete Q12a – Q12c
(1440) __ __ / **(1450)** __ __ / 20 **(1460)** __ __

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
(e.g., Pulmicort Respules, budesonide)
➔ If **YES**, complete Q13a – Q13c
(1510) __ __ / **(1520)** __ __ / 20 **(1530)** __ __

13a. 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
(e.g., Advair Diskus, Symbicort MDI, Dulera MDI)
➔ If **YES**, complete Q14a – Q14c
(1570) __ __ / **(1580)** __ __ / 20 **(1590)** __ __

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)**

"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

SERIOUS

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

ALLERGY SKIN TEST RESULTS

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

(Coordinator Completed)

1. Has the participant had a previous skin test using AsthmaNet procedures within the approved time limit? **(1000)** ❑1 Yes ❑0 No

   ➔ ***(Protocol-specific time limits for reusing the SKIN_TEST form can be found in the Manual of Operations for each protocol.)***
   ➔ ***If NO, proceed to Q2.***

   1a. Date of previous skin test **(1010)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

   1b. ID of coordinator who performed the skin test **(1020)** __ __ __ __

   ➔ ***STOP HERE, do not complete the rest of the form. Please refer to the protocol-specific MOP for details on how to enter the form.***

2. Has the participant used any of the medications, listed in the skin test section of the AsthmaNet MOP within the exclusionary periods? **(1030)** ❑1 Yes ❑0 No

3. Was the participant's most recent FEV_1 below 60% predicted? **(1040)** ❑1 Yes ❑0 No ❑9 N/A
   ➔ ***If NO or N/A, proceed to Q4.***

   3a. Has the participant received permission from the supervising physician to proceed with the skin testing procedure? **(1050)** ❑1 Yes ❑0 No
   ➔ ***If YES, obtain physician's signature:*** **(1055)** _____

4. Is the participant eligible for allergy skin testing? **(1060)** ❑1 Yes ❑0 No
   If any of the shaded boxes are completed, the participant is ineligible for allergy skin testing. STOP HERE.
   ➔ ***Allergy skin testing may be rescheduled for the next visit if the participant is ineligible due to Q2 or Q3a.***

5. Has the participant ever had a severe systemic reaction to allergy skin testing? **(1070)** ❑1 Yes ❑0 No
   ➔ ***If YES, STOP HERE. Please refer to the protocol-specific MOP for details on how to proceed.***

SKIN TEST

6. Has the participant ever had an anaphylactic reaction to egg? **(1080)** ❑1 Yes ❑0 No

7. Has the participant ever had an anaphylactic reaction to peanut? **(1090)** ❑1 Yes ❑0 No

8. Has the participant ever had an anaphylactic reaction to milk? **(1100)** ❑1 Yes ❑0 No

➔ ***If Q6, Q7, or Q8 is answered YES, do not administer that particular allergen. Please refer to the protocol-specific MOP for details on how to proceed.***

9. Time test sites **pricked** *(based on a 24-hour clock)* **(1110)** __ __ __ __

10. Time test sites **evaluated** *(based on a 24-hour clock)* **(1120)** __ __ __ __
    ➔ ***Test sites must be evaluated 20 minutes after pricking test sites.***

If there was a positive result, transfer the tracing of each wheal and record the longest diameter and the diameter at the perpendicular midpoint in mm.

11. *(Positive Control: Largest Wheal) + (Positive Control: Perpendicular Wheal)* =
    2 **(1130)** __ __ __ . __ mm

    11a. Is Q11 < 3mm? **(1140)** ❑1 Yes ❑0 No
    ➔ ***If YES, the test is not valid. STOP HERE. Please refer to the protocol-specific MOP for details on how to proceed.***

12. *(Negative Control: Largest Wheal) + (Negative Control: Perpendicular Wheal)* =
    2 **(1150)** __ __ __ . __ mm

    12a. Q11 – Q12 = **(1160)** __ __ __ . __ mm

    12b. Is Q12a < 3mm? **(1170)** ❑1 Yes ❑0 No
    ➔ ***If YES, the test is not valid. STOP HERE. Please refer to the protocol-specific MOP for details on how to proceed.***

13. Q12 + 3mm = **(1180)** __ __ __ . __ mm

For each allergen, calculate the wheal size:

Wheal Size = (Largest Wheal + Perpendicular Wheal) / 2

Indicate whether there was a positive reaction. A positive reaction is defined as a wheal ≥ Q13.

1. Positive Control (A8)	Was there a reaction? **(1190)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1200)** __ __ __ mm Perpendicular Wheal Diameter: **(1210)** __ __ __ mm	2. Negative Control (A1)	Was there a reaction? **(1220)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1230)** __ __ __ mm Perpendicular Wheal Diameter: **(1240)** __ __ __ mm
3. Cockroach (A7)	Was there a reaction? **(1250)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1260)** __ __ __ mm Perpendicular Wheal Diameter: **(1270)** __ __ __ mm	4. Cat (A2)	Was there a reaction? **(1280)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1290)** __ __ __ mm Perpendicular Wheal Diameter: **(1300)** __ __ __ mm
5. Mold Mix (A6)	Was there a reaction? **(1310)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1320)** __ __ __ mm Perpendicular Wheal Diameter: **(1330)** __ __ __ mm	6. Dog (A3)	Was there a reaction? **(1340)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1350)** __ __ __ mm Perpendicular Wheal Diameter: **(1360)** __ __ __ mm
7. Rat (A5)	Was there a reaction? **(1370)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1380)** __ __ __ mm Perpendicular Wheal Diameter: **(1390)** __ __ __ mm	8. Mouse (A4)	Was there a reaction? **(1400)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1410)** __ __ __ mm Perpendicular Wheal Diameter: **(1420)** __ __ __ mm

9. Peanut (B8)	Was there a reaction? **(1430)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1440)** __ __ __ mm Perpendicular Wheal Diameter: **(1450)** __ __ __ mm	10. Grass Mix (B1)	Was there a reaction? **(1460)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1470)** __ __ __ mm Perpendicular Wheal Diameter: **(1480)** __ __ __ mm
11. Egg, whole (B7)	Was there a reaction? **(1490)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1500)** __ __ __ mm Perpendicular Wheal Diameter: **(1510)** __ __ __ mm	12. Tree Mix (B2)	Was there a reaction? **(1520)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1530)** __ __ __ mm Perpendicular Wheal Diameter: **(1540)** __ __ __ mm
13. Cow Milk (B6)	Was there a reaction? **(1550)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1560)** __ __ __ mm Perpendicular Wheal Diameter: **(1570)** __ __ __ mm	14. Cedar (B3)	Was there a reaction? **(1580)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1590)** __ __ __ mm Perpendicular Wheal Diameter: **(1600)** __ __ __ mm
15. Mite Mix (B5)	Was there a reaction? **(1610)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1620)** __ __ __ mm Perpendicular Wheal Diameter: **(1630)** __ __ __ mm	16. Weed Mix (B4)	Was there a reaction? **(1640)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1650)** __ __ __ mm Perpendicular Wheal Diameter: **(1660)** __ __ __ mm

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)**

* S N Q *

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.***

* S P U T U M *

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 $\frac{(\text{Reference} - \text{Q7a})}{\text{Reference}} \times 100$ **(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

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

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

   _____

6. 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)**

_____

_____

* S P U T U M C H K *

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

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 — Asthma completely prevented me from working

0 1 2 3 4 5 6 7 8 9 10

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 — Asthma completely prevented me from doing my class work

CIRCLE A NUMBER

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 — Asthma completely prevented me from doing my daily activities

CIRCLE A NUMBER

Coordinator Completed

(1080) __ __

Participant Source Documentation

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

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

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

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

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

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

	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

VIDA BASELINE PEF AND RESCUE USE VALUES

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

(Coordinator Completed)

Complete this form at Visits 2 and 3 with the participant's baseline peak flow and rescue use values. These values should match those entered into the participant's spirotel® device at these visits.

1. Participant's baseline peak flow (PEF) value **(1000)** __ __ __ L/M
   - ➔ Visit 2:
     - If methacholine challenge completed at visit: PEF (FEF Max) from prebronchodilator (baseline) spirometry at Visit 2 (convert to L/M).
     - If no methacholine challenge completed at visit: PEF (FEF Max) from prebronchodilator (baseline) spirometry at Visit 1 (convert to L/M).
   - ➔ Visit 3: Average of the AM PEFs collected the 14 days prior to the visit. Refer to Spirotel® VIDA Eligibility and Baseline Report.

2. Participant's baseline rescue use value **(1010)** __ __ puffs/day
   - ➔ Visit 2: Self-reported average daily use of albuterol/levalbuterol during the 14 days prior to Visit 2.
   - ➔ Visit 3: Average daily use of levalbuterol/Xopenex® during the 14 days prior to Visit 3. Refer to Spirotel® VIDA Eligibility and Baseline Report.

COMMENTS: (6000)

_____

_____

_____

P1 BASELINE

AsthmaNet

VIDA
CHANGE IN STUDY MEDICATIONS
(Visits 4-9 and 90-92)

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

(Coordinator Completed)

Complete this form if the participant experienced an adverse event (e.g. treatment failure) that resulted in altering the dose of his/her Alvesco® inhaler or scheduled study capsules. Any changes in dosing related to a given adverse event, including increases in treatment and subsequent reductions in dosing when an event has been resolved, should be documented on this form. A new form should be filed each time a dosing change is made; multiple forms may be necessary to document treatment for a given event.

This form must also be completed if the participant's Alvesco® dose was altered due to a study-defined taper.

1. Reason for change in study medications **(1000)** ❑1 Adverse Event ❑2 Study-defined Taper
   ➔ If **Study-defined Taper**, skip to Q2.

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

2. Was the dose of the Alvesco® MDI changed? **(1020)** ❑1 Yes ❑0 No
   ➔ If ***NO***, skip to Q3.

   2a. Dose changed from **(1030)** __ puffs per day

   2b. Dose changed to **(1040)** __ puffs per day

   2c. Date participant started new dose **(1050)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

3. Was the status of the participant's scheduled study capsules changed? **(1060)** ❑1 Yes ❑0 No
   ➔ If ***NO***, **STOP HERE**.

   3a. Current status of participant's study capsules **(1070)** ❑1 Discontinued ❑2 Resumed

   3b. Date change took effect **(1080)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

COMMENTS: (6000)

_____

_____

_____

P1 CHANGE MEDS

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

(Coordinator Completed)

Check the following compliance criteria for all scheduled Visits 3-10 and at post randomization early termination visits (88).

(Visit 3-10 and 88)

1. DOSER™ Compliance for Alvesco® MDI

If the interval between visits exceeds 30 days, complete Q1a – Q1f using data for the 30 days prior to the visit.

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

➔ Value obtained from Q1 on P1_COMPLY_WKS

1b. Total number of puffs in the DOSER™ history **(1010)** __ __ __ puffs

➔ Value obtained from Q2 on P1_COMPLY_WKS

1c. Percent compliance= $\frac{\text{Q1b}}{\text{Q1a}}$ X 100 **(1020)** __ __ __ . __ %

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

1d. Total number of full days since the last visit **(1030)** __ __ days

➔ Value obtained from Q4 on P1_COMPLY_WKS

1e. Total number of compliant days **(1040)** __ __ days

➔ Value obtained from Q5 on P1_COMPLY_WKS

1f. Percent compliance= $\frac{\text{Q1e}}{\text{Q1d}}$ X 100 **(1050)** __ __ __ . __ %

➔ **If the participant took the correct daily dose less than 75% of the days, re-emphasize the importance of maintaining the daily dosing schedule.**

2. MEMS®6 Monitor Compliance for Scheduled Daily Capsules

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

2a. Number of monitored days **(1060)** __ __ __ days

2b. Number of doses taken **(1070)** __ __ __ doses

2c. % prescribed number of doses taken **(1080)** __ __ __ . __ %

2d. Doses in time-window/prescribed doses **(1090)** __ __ __ . __ %

➔ **If the percent compliance in Q2c and Q2d is less than 75%, re-emphasize the importance of maintaining the daily dosing schedule.**

3. Diary and Peak Flow Compliance

Information for Q3a – Q3c is obtained from the Spirotel® Participant Compliance Report.

3a. Number of full days since the last visit **(1100)** __ __ __ days

3b. Number of days where AM and PM scheduled sessions are complete (AM and PM PEF and all diary questions for AM and PM answered) **(1110)** __ __ __ days

3c. Percent compliance= $\frac{\text{Q3b}}{\text{Q3a}}$ X 100 **(1120)** __ __ __ . __ %

➔ **If the percent compliance in Q3c is less than 75%, re-emphasize the importance of completing scheduled diary assessments and peak flows.**

(Visit 4 only)

4. Prednisone Tablet Count

4a. Number of tablets returned in prednisone vial **(1130)** __ __ tablets

4b. Number of tablets taken (14 - Q4a) **(1140)** __ __ tablets

4c. Number of prescribed tablets **(1150)** __ __ tablets

4d. Percent compliance= $\frac{\text{Q4b}}{\text{Q4c}}$ X 100 **(1160)** __ __ __ . __ %

(Visit 5 only)

5. Loading Dose Capsule Count

5a. Number of capsules returned in loading dose vial **(1170)** __ capsules

5b. Number of capsules taken (2 - Q5a) **(1180)** __ capsules

5c. Percent compliance= $\frac{\text{Q5b}}{2}$ X 100 **(1190)** __ __ __ %

COMMENTS: (6000)

_____

_____

_____

AsthmaNet

VIDA COORDINATOR STUDY TREATMENT QUESTIONNAIRE (Visits 5-10, 88 and 90-92)

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

(Coordinator Completed)

This questionnaire is to be completed at Visit 10 by the AsthmaNet coordinator who was primarily responsible for the participant's VIDA visits during the preceding 28 weeks. If a randomized participant terminates prior to Visit 10, this form should be completed at the time of the termination visit.

1. **Blinded Scheduled Capsules**

Participants in the VIDA study were randomized to receive either Vitamin D capsules or placebo capsules. You were blinded to the actual treatment assignment. Please check the box that most closely represents your feelings about the treatment the participant received **during the randomized treatment period (Visit 4 through Visit 10)**.

(1000)

- ❑1 I am certain the capsules contained placebo.
- ❑2 I think the capsules probably contained placebo.
- ❑3 I have no idea which type of capsules the participant received, but my guess would be:

(1010)

- ❑1 Placebo
- ❑2 Vitamin D

- ❑4 I think the capsules probably contained Vitamin D.
- ❑5 I am certain the capsules contained Vitamin D.

2. Please comment with respect to any other observations you made that helped you make your choice in Q1. **(1015D)**

_____

_____

_____

_____

Coordinator Source Documentation

Coordinator's Initials: __ __ __ **(1020)**

Date: __ __ / __ __ / 20 __ __ **(1030)**
MM DD YYYY

AsthmaNet

VIDA ELIGIBILITY CHECKLIST 1

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: 0
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed)

1. Did the participant sign the VIDA 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. Did the participant consent to participate in the Immune Substudy (i.e., Green mechanistic study)? **(1020)** ❑1 Yes ❑0 No ❑9 N/A
   ➔ Check ***N/A*** if the substudy has closed recruitment.

3. Has this participant previously completed screening for the VIDA study? **(1030)** ❑1 Yes ❑0 No

   3a. If ***YES***, did the participant experience two treatment failure events during the run-in and/or OCS response periods on previous enrollments? **(1040)** ❑1 Yes ❑0 No

4. Is the participant 18 years of age or older? **(1050)** ❑1 Yes ❑0 No

5. Does the participant plan to move away from the clinical site in the upcoming 9 months such that his/her ability to complete the study will be jeopardized? **(1060)** ❑1 Yes ❑0 No

6. Has the participant used investigative drugs and/or enrolled in an intervention trial in the past 30 days, or does the participant have plans to enroll in such a trial during the VIDA study? **(1070)** ❑1 Yes ❑0 No

7. Did the participant receive a physician diagnosis of asthma at least 12 months ago? **(1080)** ❑1 Yes ❑0 No

8. Is the participant receiving chronic oral corticosteroid therapy? **(1090)** ❑1 Yes ❑0 No

9. Has the participant experienced an asthma exacerbation requiring systemic corticosteroids in the past 4 weeks? **(1100)** ❑1 Yes ❑0 No

10. Has the participant experienced a life-threatening asthma exacerbation requiring treatment with intubation and mechanical ventilation in the past 5 years? **(1110)** ❑1 Yes ❑0 No

11. Has the participant been on a stable dose of an asthma controller (i.e., inhaled corticosteroid or leukotriene modifier) for the past 2 weeks? **(1120)** ❑1 Yes ❑0 No

P1 ELIG1

12. Has the participant been using inhaled corticosteroid therapy greater than the equivalent of 1,000 mcg of inhaled fluticasone daily? **(1130)** ☐1 Yes ☐0 No
    ➔ Refer to the VIDA ICS Equivalency Reference Card (P1_ICS_EQUIV).

13. Based on input from the participant and the study physician, will the participant need to use intranasal steroids at any time during the study? **(1140)** ☐1 Yes ☐0 No

    13a. 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 or before Visit 2? **(1150)** ☐1 Yes ☐0 No

14. Is the participant taking, or has the participant taken within the past 6 weeks, supplements containing >1,000 IU/day of vitamin D (including cod liver oil) or >2,500 mg/day of calcium? **(1160)** ☐1 Yes ☐0 No

15. 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? **(1170)** ☐1 Yes ☐0 No

16. Has the participant had a respiratory tract infection in the past 4 weeks? **(1180)** ☐1 Yes ☐0 No

17. Has the participant smoked cigarettes, a pipe, cigar, marijuana, or any other substance in the past year? **(1190)** ☐1 Yes ☐0 No

18. Does the participant have a smoking history greater than 10 pack-years? **(1200)** ☐1 Yes ☐0 No
    ➔ Note: Pack-year history will be recorded on the Adult Asthma and Allergy History (ASTHMA_HX_ADULT) form at Visit 1 if the participant is eligible to continue.

19. Is the participant potentially able to bear children? (*If participant is male, check N/A and go to Q20.)* **(1210)** ☐1 Yes ☐0 No ☐9 N/A

    19a. If ***YES***, is the participant currently pregnant or lactating? **(1220)** ☐1 Yes ☐0 No

    19b. 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? **(1230)** ☐1 Yes ☐0 No

20. Does the participant have current evidence of any of the conditions listed on the Exclusionary Medical Conditions for VIDA (P1_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? **(1240)** ☐1 Yes ☐0 No

    If ***YES***, describe: **(1240D)** _____

    20a. Does the participant report a history of physician-diagnosed nephrolithiasis or ureterolithiasis? **(1250)** ☐1 Yes ☐0 No

21. Is the participant currently taking any medications listed on the Exclusionary Drugs for VIDA (P1_EXCLDRUG) reference card? **(1260)** ☐1 Yes ☐0 No

    If ***YES***, list: **(1260D)** _____

    21a. 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? **(1270)** ☐1 Yes ☐0 No
    ➔ Seek investigator input, as needed.

22. Is the participant eligible to proceed? **(1280)** ☐1 Yes ☐0 No

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

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

Participant Source Documentation

Participant Initials: __ __ __ **(1290)**

Date: __ __ / __ __ / 20 __ __ **(1300)**
MM DD YYYY

COMMENTS: **(6000)**

_____

_____

AsthmaNet

VIDA ELIGIBILITY CHECKLIST 2

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: 1
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed)

1. Have you been notified that the participant's serum vitamin D level is in the eligible range via the VIDA Participant Status Report? **(1000)** ☐1 Yes ☐0 No

2. Has the participant been on a stable dose of an asthma controller (i.e., inhaled corticosteroid or leukotriene modifier) for the past 2 weeks? **(1010)** ☐1 Yes ☐0 No

3. Has the participant experienced an asthma exacerbation requiring systemic corticosteroids since Visit 0? **(1020)** ☐1 Yes ☐0 No

4. Based on the physical exam and medical history taken at this visit, does the participant have evidence of any of the conditions listed on the Exclusionary Medical Conditions for VIDA (P1_EXCLMED) reference card? **(1030)** ☐1 Yes ☐0 No

   If ***YES***, describe: **(1030D)** _____

5. Does the participant have any condition or compliance issue which, in the opinion of the investigator, might interfere with study participation? **(1040)** ☐1 Yes ☐0 No

6. Has the participant taken any medications listed on the Exclusionary Drugs for VIDA (P1_EXCLDRUG) reference card within the specified time periods? **(1050)** ☐1 Yes ☐0 No

   If ***YES***, list: **(1050D)** _____

7. Is the participant currently taking prescription or OTC medication(s) other than those listed on the Allowed Medications (P1_MEDALLOW) reference card? **(1060)** ☐1 Yes ☐0 No

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

8. Is the participant eligible to proceed? **(1070)** ☐1 Yes ☐0 No

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

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

P1 ELIG2

Participant Source Documentation

Participant Initials: __ __ __ **(1080)**

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

COMMENTS: (6000)

AsthmaNet

VIDA ELIGIBILITY CHECKLIST 3

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: 1
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed)

Complete Q1-Q3 if IRB approval has <u>not yet been obtained</u> to implement the FEV_1 protocol change.

1. Is the participant's prebronchodilator (baseline) 50% ≤ FEV_1 ≤ 90% of predicted? **(1000)** ❑1 Yes ❑0 No
   ➔ If ***NO***, skip to Q8. Participant is ineligible for the study.

2. Did the participant's FEV_1 improve ≥ 12% in response to four puffs of levalbuterol (as part of the maximum reversibility procedure)? **(1010)** ❑1 Yes ❑0 No
   ➔ If ***YES***, the participant has met spirometry eligibility requirements and does not need to undergo a methacholine challenge at Visit 2. Proceed with remainder of the Visit 1 checklist and complete lab results in Q5-Q7 below, when available. Do not answer Q3.

3. Is the participant's prebronchodilator (baseline) FEV_1 ≤ 85% of predicted? **(1020)** ❑1 Yes ❑0 No
   ➔ If ***NO***, skip to Q8. Participant is ineligible for the study.
   ➔ If ***YES***, participant must undergo a methacholine challenge at Visit 2 to meet PC_{20} eligibility requirements. Proceed with remainder of the Visit 1 checklist and complete lab results below, when available.

Complete Q4 if IRB approval <u>has been obtained</u> to implement the FEV_1 protocol change.

4. Is the participant's prebronchodilator (baseline) FEV_1 ≥ 50% of predicted? **(1025)** ❑1 Yes ❑0 No
   ➔ If ***NO***, skip to Q8. Participant is ineligible for the study.

Complete Q5-Q8 after local lab results are received.

5. Is the participant's estimated GFR (by Cockcroft-Gault equation) < 30 ml/min? **(1030)** ❑1 Yes ❑0 No

6. Is the participant's serum calcium value > 10.2 mg/dL? **(1040)** ❑1 Yes ❑0 No

7. Is the participant's urine calcium/creatinine ratio > 0.37? **(1050)** ❑1 Yes ❑0 No

   ➔ If the participant has an elevated ratio but otherwise qualifies for the study, the local investigator may opt to allow the participant to proceed in the pre-randomization phases of the study at his/her discretion. The participant should be advised to increase fluid intake. The participant's ratio at Visit 3 must be ≤ 0.37 in order for him/her to be eligible for randomization at Visit 4.

P1 ELIG3

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

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

➔ ***If NO, complete a Termination of Study Participation (P1_TERM) form***.

COMMENTS: (6000)

AsthmaNet

VIDA ELIGIBILITY CHECKLIST 4

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: 2
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed)

Section 1

1. Have more than 8 weeks elapsed between the participant's Visit 0 and Visit 2? **(1000)** ☐1 Yes ☐0 No

2. Has the participant been on a stable dose of an asthma controller (i.e., inhaled corticosteroid or leukotriene modifier) for the past 2 weeks? **(1010)** ☐1 Yes ☐0 No

3. Has the participant experienced an asthma exacerbation requiring systemic corticosteroids since Visit 1? **(1020)** ☐1 Yes ☐0 No

4. Is the participant eligible to proceed? **(1030)** ☐1 Yes ☐0 No

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

➔ ***If YES, complete Q5 and proceed accordingly.***
➔ ***If NO, complete a Termination of Study Participation (P1_TERM) form.***

5. Did the participant meet the FEV_1 reversibility criterion at Visit 1? **(1040)** ☐1 Yes ☐0 No
   ➔ If ***YES***, skip to section 4 of this form. Spirometry and methacholine challenge are not required at this visit.
   ➔ If ***NO***, continue with section 2.

Section 2: Methacholine Challenge Source Documentation

6. Does the participant have valid source documentation for a methacholine challenge (AsthmaNet systems, methacholine, and procedures only) within the past 6 months? **(1050)** ☐1 Yes ☐0 No
   ➔ If ***NO***, skip to section 3 of this form. A methacholine challenge is required at this visit.
   ➔ If ***YES***, record information from source documentation below:

   6a. PC_{20}: **(1060)** __ __ . __ __ mg/ml

   6b. Source documentation date: **(1070)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

   6c. Technician ID: **(1080)** __ __ __ __

P1 ELIG4

6d. Supervisor ID: **(1090)** __ __ __ __

6e. Was the participant using ICS at the time the challenge was performed? **(1100)** ❑1 Yes ❑0 No
- ➔ If ***YES***, complete Q6f and skip to Q7.
- ➔ If ***NO***, complete Q6g and continue with rest of form.

6f. Was the participant's methacholine PC_{20} ≤ 16 mg/ml? **(1110)** ❑1 Yes ❑0 No

6g. Was the participant's methacholine PC_{20} ≤ 8 mg/ml? **(1120)** ❑1 Yes ❑0 No

7. Is the participant eligible to proceed? **(1130)** ❑1 Yes ❑0 No

If either of the shaded boxes in section 2 is completed, the participant must complete a methacholine challenge at Visit 2 to confirm eligibility.

- ➔ ***If YES,*** **continue with remaining visit procedures and skip to section 4 of this form.**
- ➔ ***If NO,*** **complete section 3 of this form.**

Section 3: Spirometry and Methacholine Challenge at Visit 2

Complete Q8 if IRB approval <u>has not yet been obtained</u> to implement the FEV_1 protocol change.

8. Is the participant's prebronchodilator (baseline) 50% ≤ FEV_1 ≤ 85% of predicted? **(1140)** ❑1 Yes ❑0 No
- ➔ If ***NO***, skip to Q14. Participant is ineligible for the study.

Complete Q9 if IRB approval <u>has been obtained</u> to implement the FEV_1 protocol change.

9. Is the participant's prebronchodilator (baseline) FEV_1 ≥ 50% of predicted? **(1145)** ❑1 Yes ❑0 No
- ➔ If ***NO***, skip to Q14. Participant is ineligible for the study.

10. Does the participant qualify for a methacholine challenge by the criteria on the Adult Methacholine Challenge Testing Checklist (METHACHK_ADULT)? **(1150)** ❑1 Yes ❑0 No
- ➔ If ***NO***, skip to Q14. Participant is ineligible for the study.

11. Is the participant taking an ICS at this time? **(1160)** ❑1 Yes ❑0 No
- ➔ If ***YES***, complete Q12 and skip to Q14.
- ➔ If ***NO***, complete Q13 and continue with rest of form.

12. Does the participant have a methacholine $PC_{20} \leq 16$ mg/ml at this visit? **(1170)** ❑1 Yes ❑0 No

13. Does the participant have a methacholine $PC_{20} \leq 8$ mg/ml at this visit? **(1180)** ❑1 Yes ❑0 No

14. Is the participant eligible to proceed? **(1190)** ❑1 Yes ❑0 No

If any of the shaded boxes in section 3 is completed, the participant is ineligible.

➔ ***If YES, continue with remaining visit procedures and complete section 4.***
➔ ***If NO, STOP here. The participant is ineligible for the study. Complete a Termination of Study Participation (P1_TERM) form.***

Section 4

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)? **(1200)** ❑1 Yes ❑0 No

16. 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) (TECH_MDI_NOSP)? **(1210)** ❑1 Yes ❑0 No

17. Is the participant eligible to proceed? **(1220)** ❑1 Yes ❑0 No

If either shaded box in section 4 is completed, the participant is ineligible.

➔ ***If YES, continue with remaining visit procedures.***
➔ ***If NO, STOP here. The participant is ineligible for the study. Complete a Termination of Study Participation (P1_TERM) form.***

COMMENTS: (6000)

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_____

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AsthmaNet

VIDA ELIGIBILITY CHECKLIST 5

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

Part. Initials: __ __ __

Visit: 3

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

Coordinator ID: __ __ __ __

(Coordinator Completed)

1. According to the Spirotel® VIDA Eligibility and Baseline Report:

   1a. Did the participant complete at least 10 of the last 14 days of diary entries and peak flows? **(1000)** ☐1 Yes ☐0 No

   1b. Did the participant report asthma symptoms on at least two days or one night per week, on average, over the last 2 weeks? **(1010)** ☐1 Yes ☐0 No

2. Since Visit 2, has the participant received treatment with any excluded medications (P1_EXCLDRUG)? **(1020)** ☐1 Yes ☐0 No

3. Has the participant been hospitalized or had an urgent medical care visit for asthma during the run-in? **(1030)** ☐1 Yes ☐0 No

4. Since Visit 2, has the participant had a need for additional controller medications (in addition to or in place of study Alvesco® at a dose of 2 puffs BID) for asthma symptoms? **(1040)** ☐1 Yes ☐0 No

5. Since Visit 2, has the participant experienced a treatment failure as defined in the protocol? **(1050)** ☐1 Yes ☐0 No

6. Using the history stored in the DOSER™, did the participant take at least 75% of the required puffs from his/her Alvesco® inhaler during the interval between Visit 2 and Visit 3? **(1060)** ☐1 Yes ☐0 No
   ➔ Use Q1c from P1_COMPLY to answer this question.

7. Using the history stored in the DOSER™, did the participant take 4 puffs per day (correct daily dose) on at least 75% of the days during the interval between Visit 2 and Visit 3? **(1070)** ☐1 Yes ☐0 No
   ➔ Use Q1f from P1_COMPLY to answer this question.

8. Using the MEMS®6 monitor, did the participant take at least 75% of the required capsules within the protocol time window during the interval between Visits 2 and 3? **(1080)** ☐1 Yes ☐0 No
   ➔ Use Q2d from P1_COMPLY to answer this question.

Complete Q9-10a if IRB approval <u>has not yet been obtained</u> to implement the FEV_1 protocol change.

9. Is the participant's prebronchodilator (baseline) 50% ≤ FEV_1 ≤ 90% of predicted? **(1090)** ☐ 1 Yes ☐ 0 No

10. Did the participant meet the FEV_1 reversibility criterion at Visit 1? **(1100)** ☐ 1 Yes ☐ 0 No

    10a. If ***NO***, is the participant's prebronchodilator (baseline) FEV_1 ≤ 85% of predicted? **(1110)** ☐ 1 Yes ☐ 0 No

Complete Q11 if IRB approval <u>has been obtained</u> to implement the FEV_1 protocol change.

11. Is the participant's prebronchodilator (baseline) FEV_1 ≥ 50% of predicted? **(1115)** ☐ 1 Yes ☐ 0 No

12. Does the participant wish to withdraw consent? **(1120)** ☐ 1 Yes ☐ 0 No

13. Is there any new information that makes the participant ineligible according to the eligibility criteria? **(1130)** ☐ 1 Yes ☐ 0 No

Complete Q14 after local lab results are received.

14. Is the participant's urine calcium/creatinine ratio from this visit > 0.37? **(1140)** ☐ 1 Yes ☐ 0 No

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

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

➔ ***If NO, complete a Termination of Study Participation (P1_TERM) form.***

COMMENTS: **(6000)**

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AsthmaNet

VIDA
ICS TAPER STABILITY ASSESSMENT

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

(Coordinator Completed)

Complete this form at Visits 6 and 8 to determine if the participant meets criteria for tapering his/her Alvesco® dose.

1. Has the participant experienced a significant asthma exacerbation (documented on the VIDA Significant Asthma Exacerbation (P1_SIGEX) form)? **(1000)** ☐1 Yes ☐0 No

2. Has the participant experienced more than one treatment failure event since randomization at Visit 4? **(1010)** ☐1 Yes ☐0 No

3. Has the participant met treatment failure criteria in the past 2 weeks? **(1020)** ☐1 Yes ☐0 No

4. Is the participant eligible for an Alvesco® dose taper? **(1030)** ☐1 Yes ☐0 No

If any of the shaded boxes in Q1-Q3 is completed, the participant is NOT eligible for the dose taper.

➔ ***If NO, the participant should remain on his/her current Alvesco® dose or the dose deemed appropriate to treat his/her current condition.***

➔ ***If YES, the participant's Alvesco® dose should be decreased to 50% of his/her current dose. Complete a Change in Study Medications (P1_CHANGE_MEDS) form to document the dose change.***

COMMENTS: (6000)

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_____

_____

P1 ICS TAPER

AsthmaNet

VIDA LABORATORY RESULTS

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

Part. Initials: __ __ __

Visit: __ __

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

Coordinator ID: __ __ __ __

(Coordinator Completed)

Forward the local lab report with the participant ID recorded with this form to the DCC. All identifying information on the lab report should be blackened-out prior to forwarding the report to the DCC.

(Visit 1 only)

1. Serum creatinine **(1000)** __ . __ mg/dL

2. Estimated GFR **(1010)** __ __ __ . __ mL/min

➔ Use on-line calculator at www.mdcalc.com/creatinine-clearance-cockcroft-gault-equation to compute the Cockcroft-Gault estimate. If eGFR <30 mL/min, the participant is ineligible to continue in VIDA.

Clinic Use Only

The following values are required for using the on-line calculator to compute eGFR.

Gender ❑ Male ❑ Female

Age __ __ years

Weight (lbs) __ __ __ . __ lbs

(Visits 1, 3, 5, 6, 8, 10, and as-needed for safety follow-up)

3. Urine calcium (random) **(1020)** __ __ __ __ mg/L

4. Urine creatinine (random) **(1030)** __ __ __ __ mg/L

Clinic Use Only

Convert mg/dL to mg/L, if needed: Calcium: __ __ . __ mg/dL x 10 = __ __ __ mg/L

Creatinine: __ __ . __ mg/dL x 10 = __ __ __ mg/L

Compute Urine calcium:creatinine ratio: Urine calcium / Urine creatinine = __ . __ __

➔ ***If ratio is greater than 0.37, follow safety procedures in MOP and report as an adverse event on the Clinical Adverse Events (AECLIN) form using ICD-9 code 275.42 (hypercalcemia). If ratio exceeds this limit in follow-up testing during the run-in period, the participant is ineligible to continue in VIDA.***

(Visit 1 and as-needed for safety follow-up)

5. Serum calcium (total) **(1040)** __ __ . __ mg/dL

➔ If serum calcium is greater than 10.2 mg/dL at Visit 1, the participant is ineligible to continue in VIDA. If serum calcium is elevated during the post-randomization period, the participant must stop taking his/her scheduled study capsules; follow safety procedures in MOP and record as an adverse event on the Clinical Adverse Events (AECLIN) form using ICD-9 code 275.42 (hypercalcemia).

COMMENTS: (6000)

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_____

_____

VIDA MELANIN RECORDING FORM

(Visits 3 and 10)

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

Perform two calibration readings by placing the SmartProbe device on the white calibration tile. Press the button twice to conduct the first reading.

		L	a	b
Calibration Tile Measurement #1	**(500-520)**			
Calibration Tile Measurement #2	**(530-550)**			

Perform two readings on the participant's <u>upper inner arm</u> (nearest to body if participant is standing with palms facing forward, 2 inches up from elbow joint)

		L	a	b
Upper Inner Arm Measurement #1	**(1000-1020)**			
Upper Inner Arm Measurement #2	**(1030-1050)**			

Perform two readings on the participant's <u>outer forearm</u> (surface that is continuous with the back of the participant's hand, halfway between wrist and elbow joints)

		L	a	b
Outer Forearm Measurement #1	**(1060-1080)**			
Outer Forearm Measurement #2	**(1090-1110)**			

Perform two readings on the participant's <u>exposed forehead</u> (center, about one inch above eyebrow line)

		L	a	b
Exposed Forehead Measurement #1	**(1120-1140)**			
Exposed Forehead Measurement #2	**(1150-1170)**			

Perform two readings on the participant's <u>abdomen</u> (one inch to the participant's right of the umbilicus)

		L	a	b
Abdomen Measurement #1	**(1180-1200)**			
Abdomen Measurement #2	**(1210-1230)**			

AsthmaNet

VIDA PARTICIPANT STUDY TREATMENT QUESTIONNAIRE (Visits 5-10, 88 and 90-92)

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

(Participant Completed)

This questionnaire is to be completed by the VIDA participant at the end of Visit 10. If a randomized participant terminates prior to Visit 10, please ask him/her to complete this form during the termination visit.

1. **Scheduled Capsules**

   As a VIDA study participant you were randomized to receive either a real Vitamin D capsule or a look-alike placebo (i.e., inactive) capsule. Please check the box that most closely represents your feelings about the scheduled capsules you took **since randomization at Visit 4**.

(1000)
- ❑1 I am certain the capsules contained placebo.
- ❑2 I think the capsules probably contained placebo.
- ❑3 I have no idea which type of capsules I received, but my guess would be:

(1010)
- ❑1 Placebo
- ❑2 Vitamin D

- ❑4 I think the capsules probably contained Vitamin D.
- ❑5 I am certain the capsules contained Vitamin D.

2. Please comment with respect to the **taste** of the medication you received from your scheduled capsules **since randomization at Visit 4**.

(1020)
- ❑1 Tasted good
  (Describe) _____
- ❑2 No noticeable taste
- ❑3 Tasted bad
  (Describe) _____

3. Please comment with respect to the **smell** of the medication you received from your scheduled capsules **since randomization at Visit 4**.

(1030)
- ❑1 Smelled good
  (Describe) _____
- ❑2 No noticeable smell
- ❑3 Smelled bad
  (Describe) _____

4. Please comment with respect to any **physical sensations** produced by the medication you received from your scheduled capsules **since randomization at Visit 4**.

(1040)
- ❑1 Pleasant sensations
  (Describe) _____
- ❑2 No noticeable sensations
- ❑3 Unpleasant sensations
  (Describe) _____

5. Please comment with respect to any other observations you may have made regarding your scheduled capsules.

(1050)
- ❑1 I have no further comments
- ❑2 I observed the following: *(Describe below)*

(1050D) _____

_____

_____

_____

Participant Source Documentation

Participant's Initials: __ __ __ **(1060)**

Date: __ __ / __ __ / 20 __ __ **(1070)**
MM DD YYYY

P1 PARTTXQX

AsthmaNet

VIDA 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 Alvesco® or rescue Xopenex® 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 **6** hours? **(1000)** ☐1 Yes ☐0 No
   Examples: *Pepsi, Coke, Coffee, Mountain Dew, Tea, Rootbeer, Red Bull*

2. Have you used medications with caffeine in the past **6** hours? **(1010)** ☐1 Yes ☐0 No
   Examples: *Anacin, Darvon compound, Esgic, Excedrin, Fiorinal, Fioricet, No Doz, Norgesic, Vivarin*

3. Have you used any weight loss medications in the past **6** hours? **(1020)** ☐1 Yes ☐0 No
   Examples: *bitter orange, Xenadrine, EFX, Thermorexin*

4. Have you consumed any food containing alcohol or beverages containing alcohol in the past **6** hours? **(1030)** ☐1 Yes ☐0 No

5. Have you used any oral antihistamines in the past **48** hours? **(1040)** ☐1 Yes ☐0 No
   Examples: *Allegra, Chlor-Trimeton, Claritin, Tylenol PM*

6. Have you used any nasal antihistamines in the past **6** hours? **(1050)** ☐1 Yes ☐0 No
   Examples: *Astelin, Livostin, Patanase*

7. Have you used any ophthalmic antihistamines in the past **6** hours? **(1060)** ☐1 Yes ☐0 No
   Examples: *Alaway, Elestat, Emadine, Opitvar, Pataday, Patanol, Zaditor*

8. Have you used any oral decongestants or cold remedies in the past **48** hours? **(1070)** ☐1 Yes ☐0 No
   Examples: *pseudoephedrine (Sudafed), Tylenol Allergy*

9. Have you used any nasal decongestants in the past **6** hours? **(1080)** ☐1 Yes ☐0 No
   Examples: *oxymetazoline (Afrin)*

10. Have you used a rescue intermediate-acting inhaled beta-agonist in the past **6** hours? **(1100)** ☐1 Yes ☐0 No
Examples: *albuterol (Ventolin or Proventil), study RESCUE Xopenex®*

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

12. At this time, is your asthma worse because of recent exposure to triggers? **(1130)** ☐1 Yes ☐0 No
Examples: *cold air, smoke, allergens, recent exercise, a recent respiratory tract infection, or other pulmonary infection*

13. Is there any other reason you should not proceed with spirometry testing? **(1140)** ☐1 Yes ☐0 No

If ***YES,*** explain: **(1140D)** _____

_____

14. Is the participant eligible to proceed with the spirometry testing? **(1150)** ☐1 Yes ☐0 No
If any of the shaded boxes is 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 treatment failure.

Exception: An ineligible participant may proceed with spirometry if he/she is already known to be a treatment failure at this visit.

If an exception is made, answer Q14 'Yes.'

➔ ***If YES, proceed to Q15 or the next form/procedure listed on the visit procedure checklist.***

If participant is less than 21 years old, complete Q15 at Visits 2-9, 88, 90-92.
At Visits 1 and 10, refer to height recorded on the Adult Body Measurements (BODYMEAS_ADULT) form; do not record on this form.

15. Height (without shoes) **(1160)** __ __ __ cm

COMMENTS: **(6000)**

_____

_____

AsthmaNet

SUN EXPOSURE QUESTIONNAIRE (Visit 10)

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: 1 0
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Participant Completed)

Please answer each question using the last 7 months (the time since you were randomized in the VIDA trial) as your frame of reference. Choose only one answer for each question.

1. In summer, during your leisure time, how much time do you normally spend in the sun? **(1000)**
   - ❑1 <1 hour a day
   - ❑2 1 to 2 hours per day
   - ❑3 2 to 3 hours per day
   - ❑4 3 to 4 hours per day
   - ❑5 ≥ 4 hours a day
   - ❑9 Non-applicable in the past 7 months

2. In winter, during your leisure time, how much time do you normally spend in the sun? **(1010)**
   - ❑1 <1 hour a day
   - ❑2 1 to 2 hours per day
   - ❑3 2 to 3 hours per day
   - ❑4 3 to 4 hours per day
   - ❑5 ≥ 4 hours a day
   - ❑9 Non-applicable in the past 7 months

3. In summer, how much do your activities (playing, day sports, spectator sports, gardening, walking, etc.) take you outside? **(1020)**
   - ❑1 Not that often
   - ❑2 A moderate amount
   - ❑3 Quite a lot
   - ❑4 Virtually all the time
   - ❑9 Non-applicable in the past 7 months

4. In winter, how much do your activities (playing, day sports, spectator sports, gardening, walking, etc.) take you outside? **(1030)**
   - ❑1 Not that often
   - ❑2 A moderate amount
   - ❑3 Quite a lot
   - ❑4 Virtually all the time
   - ❑9 Non-applicable in the past 7 months

5. When outside in summer, how often do you use a sunscreen or make sure you are 'covered up'? **(1040)**
   - ❑1 Never/rarely
   - ❑2 Occasionally
   - ❑3 Most of the time
   - ❑4 Always/almost always
   - ❑9 Non-applicable in the past 7 months

6. In the last 7 months, have you ever used a sunlamp or a tanning bed at a tanning salon? **(1050)** ❑$_1$ Yes ❑$_0$ No

6a. If ***YES***, how often? **(1060)**
- ❑$_1$ At least once a week
- ❑$_2$ Less than once a week, but at least once a month
- ❑$_3$ Less than once a month, but more than two times
- ❑$_4$ Less than or equal to two times

P1 SEQ 10

AsthmaNet

SUN EXPOSURE QUESTIONNAIRE (Visit 3)

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: 3
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Participant Completed)

Please answer each question using the last 3 years as your frame of reference. Choose only one answer for each question.

1. In summer, during your leisure time, how much time do you normally spend in the sun? **(1000)**
   - ❑1 <1 hour a day
   - ❑2 1 to 2 hours per day
   - ❑3 2 to 3 hours per day
   - ❑4 3 to 4 hours per day
   - ❑5 ≥4 hours a day

2. In winter, during your leisure time, how much time do you normally spend in the sun? **(1010)**
   - ❑1 <1 hour a day
   - ❑2 1 to 2 hours per day
   - ❑3 2 to 3 hours per day
   - ❑4 3 to 4 hours per day
   - ❑5 ≥4 hours a day

3. In summer, how much do your activities (playing, day sports, spectator sports, gardening, walking, etc.) take you outside? **(1020)**
   - ❑1 Not that often
   - ❑2 A moderate amount
   - ❑3 Quite a lot
   - ❑4 Virtually all the time

4. In winter, how much do your activities (playing, day sports, spectator sports, gardening, walking, etc.) take you outside? **(1030)**
   - ❑1 Not that often
   - ❑2 A moderate amount
   - ❑3 Quite a lot
   - ❑4 Virtually all the time

5. When outside in summer, how often do you use a sunscreen or make sure you are 'covered up'? **(1040)**
   - ❑1 Never/rarely
   - ❑2 Occasionally
   - ❑3 Most of the time
   - ❑4 Always/almost always

6. In the last 3 years, have you ever used a sunlamp or a tanning bed at a tanning salon? **(1050)** ❑1 Yes ❑0 No

   6a. If ***YES***, how often? **(1060)**
   - ❑1 At least once a week
   - ❑2 Less than once a week, but at least once a month
   - ❑3 Less than once a month, but more than two times a year
   - ❑4 Less than or equal to two times a year

AsthmaNet	VIDA SIGNIFICANT ASTHMA EXACERBATION (Visits 2-10, 88 and 90-92)	Part. ID: __ __ - __ __ __ - __ __ __ Part. Initials: __ __ __ Visit: __ __ Visit Date: __ __ / __ __ / 20 __ __ Coordinator ID: __ __ __ __

(Coordinator Completed)

For participants who meet treatment failure criteria, complete this form to assess for the occurrence of a significant asthma exacerbation. Submit this form to the DCC only if the participant meets exacerbation criteria.

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 of PRN levalbuterol per 24 hours for a period of 48 hours? **(1010)** ❑1 Yes ❑0 No

(Do not complete Q3 at Visits 2 and 3)

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

(Do not complete Q4 at Visits 2 and 3)

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? **(1035)** ❑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? **(1040)** ❑1 Yes ❑0 No

7. Did the participant experience a significant asthma exacerbation? If any of the shaded boxes in Q1-Q6 is filled in, the participant experienced an asthma exacerbation. **(1050)** ❑1 Yes ❑0 No
   ➔ ***If YES, complete Q8 and record the exacerbation on the Clinical Adverse Events (AECLIN) form using ICD-9 code 493.92.***
   ➔ ***If NO, STOP HERE and continue with remaining visit procedures. Do NOT submit this form to the DCC.***

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

COMMENTS: (6000)

_____

_____

P1 SIGEX

VIDA Diary Questions and Home Procedures
(Diary questions and PEFs stored by spirotel® device)

Scheduled AM Assessment (4AM – Noon, inclusive)

1. Number of times you woke up last night due to asthma __ (numeric 0-9)
2. Number of puffs you will take from your Alvesco® inhaler this morning __ (numeric 0-9)
3. Number of scheduled capsules you will take this morning __ (numeric 0-9)
4. Have you taken any puffs from your RESCUE Xopenex® inhaler during the past 4 hours? __ (3= yes, 0=no)

Symptoms during the night

5. Shortness of breath score __ (0, 1, 2, 3)
6. Chest tightness score __ (0, 1, 2, 3)
7. Wheezing score __ (0, 1, 2, 3)
8. Cough score __ (0, 1, 2, 3)
9. Phlegm/Mucus score __ (0, 1, 2, 3)

End AM Diary Assessment

Three AM PEF maneuvers follow with the best being saved in the spirotel device.

Dosing follows PEF maneuvers.

Scheduled PM Assessment (6PM - 3AM, inclusive)

10. Number of puffs you will take from your Alvesco® inhaler tonight __ (numeric 0-9)
11. Have you taken any puffs from your RESCUE Xopenex® inhaler during the past 4 hours? __ (3= yes, 0=no)

Symptoms since you woke

12. Shortness of breath score __ (0, 1, 2, 3)
13. Chest tightness score __ (0, 1, 2, 3)
14. Wheezing score __ (0, 1, 2, 3)
15. Cough score __ (0, 1, 2, 3)
16. Phlegm/Mucus score __ (0, 1, 2, 3)
17. Number of RESCUE Xopenex® puffs taken during past 24 hours __ __ (numeric 0-40)
18. Number of times used RESCUE Xopenex® inhaler past 24 hours __ __ (numeric 0-20)
19. Did you have a cold today? __ (3=yes, 0=no)

End PM Diary Assessment

Three PM PEF maneuvers follow with the best being saved in the device.

Dosing follows PEF maneuvers.

Symptom Score Scale:

0 = Absent: No symptom

1=Mild: Symptom was minimally troublesome (i.e., not sufficient to interfere with normal daily activity or sleep)

2=Moderate: Symptom was sufficiently troublesome to interfere with normal daily activity or sleep

3=Severe: Symptom was so severe as to prevent normal activity and/or sleep

RESCUE puff instruction: Preventive RESCUE Xopenex® puffs (e.g., prior to exercise) should not be counted towards total puffs or total times the RESCUE inhaler was used.

AsthmaNet

VIDA spirotel® Coordinator Reference Card

Scheduled AM Assessment (4 AM – noon, inclusive)

Q1.	Number of times you woke up last night due to asthma	__ (numeric 0 – 9)
Q2.	Number of puffs you will take from your Alvesco® inhaler this morning	__ (numeric 0 – 9)
Q3.	Number of scheduled capsules you will take this morning	__ (numeric 0 – 9)
Q4.	Have you taken any puffs from your RESCUE Xopenex® inhaler during the past 4 hours?	__ (3 = Yes, 0 = No)

Symptoms during the night

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

Scheduled PM Assessment (6 PM – 3 AM, inclusive)

Q10.	Number of puffs you will take from your Alvesco® inhaler tonight	__ (numeric 0 – 9)
Q11.	Have you taken any puffs from your RESCUE Xopenex® inhaler during the past 4 hours?	__ (3 = Yes, 0 = No)

Symptoms since you woke

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.	Cough score	__ (0, 1, 2, 3)
Q16.	Phlegm/Mucus score	__ (0, 1, 2, 3)
Q17.	Number of RESCUE Xopenex® puffs taken during past 24 hours	__ __ (numeric 0 – 40)
Q18.	Number of times used RESCUE Xopenex® inhaler past 24 hours	__ __ (numeric 0 – 20)
Q19.	Did you have a cold today?	__ (3 = Yes, 0 = No)

AsthmaNet

VIDA TERMINATION OF STUDY PARTICIPATION (Visits 0-10, 88 and 90-92)

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

(Coordinator Completed)

Complete this form only for participants who successfully completed Visit 0 and had a blood sample submitted for vitamin D determination.

(Complete Q1 at Visit 88 only)

1. Complete the number of the last regular visit completed **(1000)** __

2. Has the participant completed the study through Visit 10? **(1010)** ❑$_1$ Yes ❑$_0$ No
   ➔ If ***YES***, skip to Q7.

3. Is the participant being terminated from the study due to an ineligible Visit 0 vitamin D level? **(1020)** ❑$_1$ Yes ❑$_0$ No

   3a. If ***YES***, was the participant sent or given the standard AsthmaNet notification letter? **(1030)** ❑$_1$ Yes ❑$_0$ No
   ➔ ***All vitamin D ineligible participants must receive this letter.***
   ➔ ***Skip to the SIGNATURES section.***

4. Who initiated termination of the participant? **(1040)** ❑$_1$ Participant ❑$_2$ Clinical Staff
   ➔ ***If participant withdrew due to impending clinical staff termination, indicate termination by clinical staff.***
   ➔ ***If Clinical Staff, skip to Q6.***

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

   ❑$_1$ no longer interested in participating* **(1050)**
   ❑$_2$ 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: (1060D)**

_____

_____

➔ ***Skip to Q7.***

P1 TERM

6. Did clinical staff terminate the participant due to…

6a.	pregnancy? *(Check N/A if participant is male.)*	**(1070)**	❑1 Yes ❑0 No ❑9 N/A
6b.	loss to follow-up?*	**(1080)**	❑1 Yes ❑0 No
	6bi. If ***YES***, date of last contact with participant	**(1090)**	__ __ / __ __ / 20 __ __ (MM / DD / YYYY)
	6bi. If ***YES***, type of contact	**(1100)**	❑1 In-person visit ❑2 Phone call
6c.	an asthma-related adverse event?*	**(1110)**	❑1 Yes ❑0 No
6d.	a medication-related adverse event?*	**(1120)**	❑1 Yes ❑0 No
6e.	an adverse event not related to asthma or medications?*	**(1130)**	❑1 Yes ❑0 No
6f.	ineligibility during the screening period (Visits 0-2) for reasons other than vitamin D ineligibility?*	**(1140)**	❑1 Yes ❑0 No
6g.	non-compliance with medication dosing?*	**(1150)**	❑1 Yes ❑0 No
6h.	non-compliance with diary completion?*	**(1160)**	❑1 Yes ❑0 No
6i.	non-compliance with visit attendance?*	**(1170)**	❑1 Yes ❑0 No
6j.	non-compliance with peak flow monitoring?*	**(1180)**	❑1 Yes ❑0 No
6k.	significant asthma exacerbation or treatment failure during run-in or OCS response period (Visits 2-4)?*	**(1190)**	❑1 Yes ❑0 No
6l.	ineligibility during the run-in or OCS response period (Visits 2-4) for reasons other than compliance or exacerbation/treatment failure?*	**(1200)**	❑1 Yes ❑0 No
6m.	three treatment failure or exacerbation events during the post-randomization period?	**(1205)**	❑1 Yes ❑0 No
6n.	other reason?*	**(1210)**	❑1 Yes ❑0 No

***Additional explanation required: (1220D)**

_____

_____

_____

6o. Indicate the letter corresponding to the **primary** reason the participant was terminated. **(1230)** __

7. Was the participant sent or given the standard AsthmaNet vitamin D eligible termination letter? **(1235)** ❑$_1$ Yes ❑$_0$ No

➔ If ***NO***, explain: **(1235D)**

_____

_____

_____

➔ ***All participants with an eligible Visit 0 vitamin D level must receive this letter.***

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

I verify that all information collected on the AsthmaNet VIDA 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.

_____ **(1240)** __ __ / __ __ / 20 __ __ **(1250)**
Coordinator Signature MM DD YYYY

_____ **(1260)** __ __ / __ __ / 20 __ __ **(1270)**
Principal Investigator Signature MM DD YYYY

AsthmaNet	VIDA TREATMENT FAILURE INFORMATION	Part. ID: __ __ - __ __ __ - __ __ __ Part. Initials: __ __ __ Visit: __ __ Visit Date: __ __ / __ __ / 20 __ __ Coordinator ID: __ __ __ __

(Coordinator Completed)

Complete this form each time a participant meets treatment failure criteria.

1. Did the participant seek care for treatment failure conditions? **(1000)** ❑1 Yes ❑0 No
   ➔ If ***NO***, skip to Q4.

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

   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

3. Was the participant hospitalized? **(1060)** ❑1 Yes ❑0 No
   ➔ If ***YES***, complete the Serious Adverse Event Reporting Form (SERIOUS).

   If ***YES***,

   3a. Duration of hospital stay **(1070)** __ __ . __ days

   3b. Was intubation or ventilation assistance required? **(1080)** ❑1 Yes ❑0 No

4. Has the participant taken any of the following medications (excluding study Alvesco®) since treatment failure conditions started?
   ➔ If ***YES*** to any of Q4a, Q4c-Q4f, complete the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form.

4a. Inhaled corticosteroids **(1100)** ❑1 Yes ❑0 No

4b. Nebulized bronchodilator **(1110)** ❑1 Yes ❑0 No

4c. Oral corticosteroids **(1120)** ❑1 Yes ❑0 No
➔ If ***YES***, complete a VIDA Significant Asthma Exacerbation (P1_SIGEX) form.

4d. IM or IV steroids **(1130)** ❑1 Yes ❑0 No
➔ If ***YES***, complete a VIDA Significant Asthma Exacerbation (P1_SIGEX) form.

4e. Antibiotics **(1140)** ❑1 Yes ❑0 No

4f. Other **(1150)** ❑1 Yes ❑0 No

(1150D) _____

(Physician Completed)

5. From a clinical perspective, would you have considered this participant to have experienced a 'treatment failure' if he/she were not participating in the VIDA trial and, instead, you were seeing him/her in your outpatient clinic? **(1160)** ❑1 Yes ❑0 No

6. Based on the participant's clinical status at the time he/she met one of the treatment failure criteria, when do you think the participant reached this status? **(1170)**
❑1 Too early (asthma not that bad)
❑2 At the right time (asthma would be considered clinically unstable, but the participant not in jeopardy)
❑3 Too late (concerned about the participant's safety)

7. What was the participant's opinion of his/her asthma at the time he/she was deemed a treatment failure? **(1180)**
❑1 Rescued too soon
❑2 Rescued at the right time
❑3 Waited too long before being rescued

8. Based on your experience with this participant, are you satisfied with the VIDA treatment failure criteria? **(1190)** ❑1 Yes ❑0 No
If ***NO***, explain: **(1190D)** _____

9. Physician Narrative Assessment

_____

_____

_____

_____

_____

Physician Source Documentation

Physician's Signature: _____ **(1200)**

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

Time: __ __ __ __ *(based on a 24-hour clock)* **(1220)**

COMMENTS: (6000)

_____

_____

_____

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

(Coordinator Completed)

Complete this form at all visits from Visit 3 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 3, complete a single form using visit number 2.

(Visits 90-92 Only)

1. Complete the number of the last regular visit completed **(1000)** ___

2. Did the participant experience a fall in prebronchodilator PEF to ≤ 65% of baseline on two out of three consecutive, scheduled (AM or PM) measurements? **(1010)** ❑1 Yes ❑0 No
   ➔ Refer to the VIDA Baseline PEF and Rescue Use Values (P1_BASELINE) form.

3. Did the participant experience an increase in rescue levalbuterol use of 8 or more puffs per 24 hours over baseline use for a period of 48 hours? **(1020)** ❑1 Yes ❑0 No
   ➔ Refer to the VIDA Baseline PEF and Rescue Use Values (P1_BASELINE) form.

(Do not complete Q4 at Visits 2 and 3)

4. Did the participant experience prebronchodilator FEV_1 values ≤ 80% of the baseline prebronchodilator value obtained at Visit 3 on two consecutive spirometric determinations made on different days? **(1030)** ❑1 Yes ❑0 No ❑9 Not evaluated
   ➔ If the participant experienced a prebronchodilator FEV_1 value ≤ 80% of the baseline value obtained at Visit 3, but he/she was not evaluated a second time, select "Not Evaluated."

5. Did the study or treating physician prescribe the participant additional inhaled corticosteroids or oral/parenteral corticosteroids for the treatment of his/her asthma? **(1040)** ❑1 Yes ❑0 No
   ➔ If ***YES***, and oral/parenteral corticosteroids or non-study inhaled steroids were used, record them on the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form.
   ➔ If ***YES***, and oral/parenteral corticosteroids were used, complete a VIDA Significant Asthma Exacerbation (P1_SIGEX) form.

6. Did the participant require emergency treatment at a medical facility that was related to, or complicated by, his/her asthma and that resulted in systemic corticosteroid treatment or hospitalization for an acute asthma exacerbation? **(1050)** ❑1 Yes ❑0 No
   ➔ If ***YES***, and the participant was hospitalized, complete a Serious Adverse Event Reporting Form (SERIOUS).
   ➔ If ***YES***, and systemic corticosteroid treatment was received, record medications on the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form.

P1 TXFAIL CHK

7. Did the participant refuse to continue study drugs because of lack of satisfaction with treatment? **(1060)** ☐1 Yes ☐0 No

8. Based on clinical judgment, did the physician deem this participant a treatment failure for safety reasons? **(1070)** ☐1 Yes ☐0 No

9. Did the participant experience a significant asthma exacerbation? **(1080)** ☐1 Yes ☐0 No
   ➔ If ***YES***, complete the VIDA Significant Asthma Exacerbation (P1_SIGEX) form.

10. Did the participant experience a treatment failure?
    If any of the shaded boxes in Q2-Q9 is 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, complete a Treatment Failure Information (P1_TXFAIL) form.**
    ➔ **If NO, STOP HERE and continue with remaining visit procedures.**

11. Date treatment failure conditions were met **(1100)** __ __ / __ __ / 20 __ __
    MM DD YYYY

COMMENTS: (6000)

_____

_____

_____

AsthmaNet

VIDA VITAMIN D INTAKE QUESTIONNAIRE

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

(Coordinator Completed by Interview)

1. Do you take vitamin D supplements or multivitamins that include vitamin D on a regular basis (most months)? **(1000)** ❑$_1$ Yes ❑$_0$ No

➔ If ***YES***, what product(s) do you usually take? (Refer to information on bottles provided by participant.)

1a. Name of supplement #1 **(1010D)** _____

1ai. Vitamin D type (from bottle) **(1020)**
❑$_1$ Vitamin D (unspecified)
❑$_2$ Vitamin D_2 (ergocalciferol)
❑$_3$ Vitamin D_3 (cholecalciferol)

1aii. Vitamin D per capsule/tablet **(1030)** __ __ __ __ __ __ . __ IU

1aiii. On average, how many capsules/tablets do you take per day? **(1040)** __ __ . __ capsules/tablets

1b. Name of supplement #2 **(1050D)** _____

1bi. Vitamin D type (from bottle) **(1060)**
❑$_1$ Vitamin D (unspecified)
❑$_2$ Vitamin D_2 (ergocalciferol)
❑$_3$ Vitamin D_3 (cholecalciferol)

1bii. Vitamin D per capsule/tablet **(1070)** __ __ __ __ __ __ . __ IU

1biii. On average, how many capsules/tablets do you take per day? **(1080)** __ __ . __ capsules/tablets

1c. Name of supplement #3 **(1090D)** _____

1ci. Vitamin D type (from bottle) **(1100)**
❑$_1$ Vitamin D (unspecified)
❑$_2$ Vitamin D_2 (ergocalciferol)
❑$_3$ Vitamin D_3 (cholecalciferol)

1cii. Vitamin D per capsule/tablet **(1110)** __ __ __ __ __ __ . __ IU

1ciii. On average, how many capsules/tablets do you take per day? **(1120)** __ __ . __ capsules/tablets

2. Do you take cod liver oil in liquid form on a regular basis (most months)? **(1130)** ❑$_1$ Yes ❑$_0$ No

   2a. If ***YES***, on average how many teaspoons do you take per day? **(1140)** __ __ teaspoons

3. Do you take cod liver oil in capsule form on a regular basis (most months)? **(1150)** ❑$_1$ Yes ❑$_0$ No

   3a. If ***YES***, on average how many capsules do you take per day? **(1160)** __ __ capsules

4. Do you drink vitamin D fortified milk on a regular basis? **(1170)** ❑$_1$ Yes ❑$_0$ No

   4a. If ***YES***, on average how many 8 oz glasses do you drink per day? **(1180)** __ __ glasses

   4b. If ***YES***, on average how many 8 oz glasses do you drink per week? **(1190)** __ __ glasses

5. Do you eat salmon on a regular basis? **(1200)** ❑$_1$ Yes ❑$_0$ No

   5a. If ***YES***, on average how many 4 oz servings (about the size of a deck of cards) do you eat per week? **(1210)** __ __ servings

   5b. If ***YES***, on average how many 4 oz servings do you eat per month? **(1220)** __ __ servings

6. Do you eat sardines on a regular basis? **(1230)** ❑$_1$ Yes ❑$_0$ No

   6a. If ***YES***, on average how many servings (about the size of a 3.7 oz can) do you eat per week? **(1240)** __ __ servings

   6b. If ***YES***, on average how many servings do you eat per month? **(1250)** __ __ servings

COMMENTS: **(6000)**

_____

_____

_____

Alvesco® Distribution Reference Card

Alvesco® doses during the VIDA study are variable depending on the phase of the trial and a participant's treatment failure status. This reference card provides a summary of the number of Alvesco® MDIs to dispense at a given visit based on the participant's current daily dose and the interval between visits, allowing for maximum use of visit windows.

Each Alvesco® MDI contains 60 metered actuations. If a participant has exceeded the maximum duration between visits (through a protocol exception), his/her drug needs must be calculated to ensure an adequate supply.

Visit Interval
(Dispensation Visits)

Daily Dose (# puffs)	**1-week** (V3)	**4-week** (V2 (run-in))	**4-week** (V6, V7, V8, V9)	**6-week** (V4, V5)
1			1 MDI	
2			2 MDIs	
4	1 MDI	3 MDIs	3 MDIs	4 MDIs

P1 ALV DIST REF

Drugs to be withheld throughout the study.

Excluded Drug	Generic Names (may not be inclusive)	Trade Names (may not be inclusive)	Washout Prior to Visits 1 & 2
Steroid Medications			
Oral or intravenous steroids for any reason, except prednisone as provided in study		Medrol, Prednisone	6 weeks
Inhaled steroids, except Alvesco as provided in study	beclomethasone, budesonide, ciclesonide, flunisolide, fluticasone, mometasone, triamcinolone acetonide	Aerobid, Alvesco, Asmanex, Azmacort, Flovent, Pulmicort, QVAR	None
Nonsteroidal Antiinflammatory Medications			
Leukotriene modifiers	montelukast, zafirlukast, zileuton	Accolate, Singulair, Zyflo	None
Cromolyn/Nedocromil for asthma	cromolyn, nedocromil	Intal, Tilade	1 week
Bronchodilators			
Oral β-agonists	albuterol, metaproterenol, terbutaline	Alupent, Brethine, Bricanyl, Metaprel, Proventil, Repetabs, Ventolin, Volmax	1 week
Short-acting inhaled β-agonists	epinephrine	Bronkaid Mist, Duo-Medihaler, Medihaler-Epi, Primatene Mist	6 hours
Intermediate-acting inhaled β-agonists (except study RESCUE drug)	albuterol, bitolterol, levalbuterol, metaproterenol, pirbuterol, terbutaline	Alupent, Brethaire, Brethine, Bronkometer, Maxair, Metaprel, Proventil, Tornalate, Ventolin, Xopenex	6 hours
Long-acting inhaled β-agonists	formoterol, salmeterol	Advair, Dulera, Foradil, Serevent, Symbicort	24 hours
Short-acting anticholinergics	atropine, ipratropium bromide, pirenzepine, scopolamine	Atrohist, Atrovent, Bellatal, Combivent, Donnatal, Scopoderm, Transderm-Scop	6 hours
Long-acting anticholinergics	tiotropium	Spiriva	72 hours

P1 EXCLDRUG

Drugs to be withheld throughout the study.

Excluded Drug	Generic Names (may not be inclusive)	Trade Names (may not be inclusive)	Washout Prior to Visits 1 & 2
Xanthine Derivatives			
Short-acting theophylline	theophylline	Aminophylline, Slo-Phyllin	12 hours
Long-acting theophylline	theophylline	Slo-bid, Theo-Dur	24 hours
Ultra long-acting theophylline	theophylline	Theo-24, Uniphyl	48 hours
Drugs that Alter Vitamin D Metabolism			
Cardiac glycosides	digoxin, digitoxin, deslanoside	Cedilanid-D, Crystodigin, Lanoxin, Lanoxicaps	1 week
	phenobarbital	Luminal, Solfoton	1 week
	phenytoin	Di-Phen, Dilantin, Phenytek	1 week
Drugs that Alter Vitamin D Absorption			
	cholestyramine	Questran	1 week
	colestipol	Cholestid	1 week
Lipase inhibitors	orlistat	Alli, Xenical	1 week
Cardiac Drugs			
Alpha-beta blockers	labetalol	Normodyne	2 weeks
Beta blockers	acebutolol, atenolol, betaxolol, bisoprolol, carteolol, metoprolol, nadolol, penbutolol, pindolol, propranolol, timolol	Blocadren, Cartrol, Corgard, Inderal, Kerlone, Levatol, Lopressor, Sectral, Tenormin, Visken, Zebeta	2 weeks
Psych or CNS-Related Drugs			
Monoamine oxidase (MAO) inhibitors	harmaline, iproclozide, iproniazid, isocarboxazid, nialamide, phenelzine, selegiline, toloxatone, tranylcypromine	Nardil, Parnate	4 weeks
Antibiotics			
Macrolide antibiotics, chronic use excluded	azithromycin, clarithromycin, dirithromycin, erythromycin, roxithromycin, troleandomycin	Biaxin, Dynabac, Rulid, Surlid, TAO, Zithromax, Zitromax	4 weeks

Drugs to be withheld throughout the study.

Excluded Drug	Generic Names (may not be inclusive)	Trade Names (may not be inclusive)	Washout Prior to Visit 0
Other Excluded Drugs/Substances			
Vitamin D Supplements > 1000 IU/day			6 weeks
Calcium supplements > 2500 mg/day			6 weeks
Allergen immunotherapy			4 weeks

Drugs/substances to be withheld prior to Visits 1-10, 88, 90-92*[+].

Drug/Substance	Trade Names (may not be inclusive)	Washout Prior to Visits
Levalbuterol (study RESCUE inhaler)	Xopenex	6 hours
Oral Antihistamines (chlorpheniramine, desloratadine, diphenhydramine, fexofenadine, loratadine and others)	Allegra, Allegra-D, Benadryl, Chlor-Trimeton, Clarinex, Claritin and others	48 hours
Nasal Antihistamines (azelastine nasal, olopatadine, levocabastine)	Astelin, Astepro, Patanase, Livostin	6 hours
Ophthalmic Antihistamines (azelastine ophthalmic, emedastine difumarate, epinastine ophthalmic, ketotifen fumarate, olopatadine ophthalmic)	Alaway, Elestat, Emadine, Opitvar, Pataday, Patanol, Zaditor	6 hours
Oral Decongestants (pseudoephedrine and others)	Sudafed and others	48 hours
Nasal Decongestants (oxymetazoline and others)	Afrin and others	6 hours
Methylxanthine-containing food or beverages (caffeinated colas, coffee, tea)	Coke, Barq's Rootbeer, Mello-Yellow, Mountain Dew, Pepsi, Red Bull	6 hours
Methylxanthine-containing medications	Anacin, Darvon, Esgic, Excedrin, No-Doz, Norgesic, Vivarin	6 hours
Alcohol-containing foods or beverages		6 hours

*These drugs/substances are allowed between visits, but not prior to pulmonary function testing.
[+]Holds are required at Visit 2 only if spirometry and methacholine challenge are being done.

P1 EXCLDRUG

Exclusionary Medical Conditions for VIDA (may not be inclusive)

- Addison's disease
- AIDS
- Cardiac arrhythmias (clinically significant)
- Congenital anomaly, including growth abnormalities (clinically significant)
- Congestive heart failure
- Coronary artery disease (unstable or severe)
- Cushing's disease
- Diabetes mellitus (poorly controlled)
- Dyspnea by any cause other than asthma
- Eating disorder (e.g. anorexia or bulimia (active disease))
- Hematologic disease (unstable, e.g. severe anemia)
- Hepatic disease
- Hypertension (poorly controlled)
- Hyperthyroidism
- Immunologic compromise
- Chronic kidney disease (glomerulonephritis, polycystic kidney disease, etc.)
- Lactation
- Lung disease other than asthma (COPD, emphysema, chronic bronchitis, pulmonary embolism, malignancy, cystic fibrosis, among others)
- Lupus (active disease requiring immunosuppressant)
- Any malignancy other than basal cell skin cancers
- Mental illness (uncontrolled)
- Mental retardation
- Nephrolithiasis/ureterolithiasis (physician-diagnosed)
- Neurologic disease (including epilepsy requiring treatment)
- Peptic ulcer disease (active)
- Pregnancy
- Renal insufficiency (creatinine > 1.2 mg/dl)
- Schizophrenia
- Skeletal disorders, including osteoporosis and rheumatoid arthritis
- Sleep apnea (untreated)
- Sleep disorder (history of)
- Substance abuse (including active drug or alcohol abuse)
- Tuberculosis (history of positive skin test with negative chest x-ray allowed)
- Urinary retention (active symptoms within last 6 months)
- Vocal cord dysfunction (diagnosis of)

P1 EXCLMED

VIDA Inhaled Corticosteroids Equivalency

AsthmaNet

The following inhaled corticosteroid doses (µg) may be considered equivalent to 1000 µg of fluticasone DPI (Flovent® Diskus®, Advair® Diskus®):

• beclomethasone HFA (QVAR®)	800
• budesonide DPI (Pulmicort Flexhaler®)	1800
• budesonide/formoterol MDI (Symbicort®)	1600
• ciclesonide HFA (Alvesco®)	960
• fluticasone HFA (Flovent®)	880
• fluticasone/salmeterol HFA MDI (Advair® MDI)	920
• mometasone DPI (Asmanex® Twisthaler®)	880
• mometasone/formoterol MDI (Dulera®)	1000

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

- intranasal steroids (any drug) at a stable dose throughout study
- laxatives
- Librax
- lithium
- migraine analgesics/preventatives (e.g. butalbital, Midrin, sumatriptan, topiramate)
- nasal antiallergic spray (Cromolyn/Atrovent)
- nasal saline spray
- non-steroidal anti-inflammatory medications (e.g. aspirin, ibuprofen, naproxen, ketoprofen)
- Norplant®
- oral contraceptives
- proton pump inhibitors (e.g. omeprazole (Prilosec), lansoprazole (Prevacid), esomeprazole (Nexium)) for GERD
- psyllium
- stool softeners
- study medications
- thyroid replacement medication (e.g. Levothroid, Levoxyl, Synthroid)
- tretinoin (Retin-A) for acne
- vitamins, minerals (vitamin D supplements allowed if ≤ 1000 IU/day; calcium supplements allowed if ≤ 2500 mg/day)
- Xolair (omalizumab) at stable dose throughout study

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

- Medium potency topical corticosteroids (BID)

betamethasone benzoate	fluocinonide .05%
betamethasone dipropionate	flurandrenolide
betamethasone valerate	fluticasone propionate
clocortolone pivalate	hydrocortisone butyrate
desoximetasone	hydrocortisone valerate
diflorasone .05%	mometasone furoate
fluocinolone acetonide	triamcinolone acetonide

AsthmaNet

VIDA spirotel® Coordinator Reference Card

Scheduled AM Assessment (4 AM – noon, inclusive)

Q1.	Number of times you woke up last night due to asthma	__ (numeric 0 – 9)
Q2.	Number of puffs you will take from your Alvesco® inhaler this morning	__ (numeric 0 – 9)
Q3.	Number of scheduled capsules you will take this morning	__ (numeric 0 – 9)
Q4.	Have you taken any puffs from your RESCUE Xopenex® inhaler during the past 4 hours?	__ (3 = Yes, 0 = No)

Symptoms during the night

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

Scheduled PM Assessment (6 PM – 3 AM, inclusive)

Q10.	Number of puffs you will take from your Alvesco® inhaler tonight	__ (numeric 0 – 9)
Q11.	Have you taken any puffs from your RESCUE Xopenex® inhaler during the past 4 hours?	__ (3 = Yes, 0 = No)

Symptoms since you woke

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.	Cough score	__ (0, 1, 2, 3)
Q16.	Phlegm/Mucus score	__ (0, 1, 2, 3)
Q17.	Number of RESCUE Xopenex® puffs taken during past 24 hours	__ __ (numeric 0 – 40)
Q18.	Number of times used RESCUE Xopenex® inhaler past 24 hours	__ __ (numeric 0 – 20)
Q19.	Did you have a cold today?	__ (3 = Yes, 0 = No)

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

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

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

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

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

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

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

AsthmaNet

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

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

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

FREQUENTLY USED ASTHMA & ALLERGY DRUG CODES

AsthmaNet

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

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