AsthmaNet

ACUTE ASTHMA ASSESSMENT QUESTIONNAIRE

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

(Participant Completed)

Please check only one box for each question.

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

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

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

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

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

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

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

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

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

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

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

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

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

(1060)

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

(1060D) _____

Participant Source Documentation

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

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

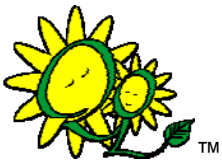
Time: __ __ __ __ *(based on a 24-hour clock)* **(1090)**

Part. ID: - -
Part. Initials:

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

ASTHMA CONTROL QUESTIONNAIRE (ACQ)

Modified for AsthmaNet's BARD Study with permission by Professor Elizabeth Juniper



For further information:

Elizabeth Juniper, MCSP, MSc
Professor
20 Marcuse Fields
Bosham, West Sussex
PO18 8NA, England
Telephone: +44 1243 572124
Fax: +44 1243 573680
E-mail: juniper@qoltech.co.uk
Web: http://www.qoltech.co.uk

DECEMBER 2002

Revised September 2010
ACQ-SA North American English Version

ASTHMA CONTROL QUESTIONNAIRE©

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

Please answer questions 1 - 6.

Circle the number of the response that best describes how you have been during the past week.

1. On average, during the past week, how often were you **woken by your asthma** during the night?

0 Never
1 Hardly ever
2 A few times
3 Several times
4 Many times
5 A great many times
6 Unable to sleep because of asthma

2. On average, during the past week, how **bad were your asthma symptoms when you woke up** in the morning?

0 No symptoms
1 Very mild symptoms
2 Mild symptoms
3 Moderate symptoms
4 Quite severe symptoms
5 Severe symptoms
6 Very severe symptoms

3. In general, during the past week, how **limited were you in your activities** because of your asthma?

0 Not limited at all
1 Very slightly limited
2 Slightly limited
3 Moderately limited
4 Very limited
5 Extremely limited
6 Totally limited

4. In general, during the past week, how much **shortness of breath** did you experience because of your asthma?

0 None
1 A very little
2 A little
3 A moderate amount
4 Quite a lot
5 A great deal
6 A very great deal

5.	In general, during the past week, how much of the time did you **wheeze?**	0 Not at all 1 Hardly any of the time 2 A little of the time 3 A moderate amount of the time 4 A lot of the time 5 Most of the time 6 All the time
6.	On average, during the past week, how many **puffs/inhalations of short-acting bronchodilator** (eg. Ventolin/Bricanyl) have you used each day? *(If you are not sure how to answer this question, please ask for help)*	0 None 1 1 - 2 puffs/inhalations most days 2 3 - 4 puffs/inhalations most days 3 5 - 8 puffs/inhalations most days 4 9 - 12 puffs/inhalations most days 5 13 - 16 puffs/inhalations most days 6 More than 16 puffs/inhalations most days

To be completed by a member of the clinic staff

7.	FEV_1pre-bronchodilator: ..... FEV_1predicted: ..... FEV_1%predicted: ..... (Record actual values on the dotted lines and score the FEV_1 % predicted in the next column)	0 > 95% predicted 1 95 - 90% 2 89 - 80% 3 79 - 70% 4 69 - 60% 5 59 - 50% 6 < 50% predicted

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 past 4 weeks, how much of the time did your asthma keep you from getting as much done at work, school or at home?**

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

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

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

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

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

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

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

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

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

To score the ACT

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

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

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

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

Part. ID: - - Visit:

Part. Initials: Visit Date: / / 2 0

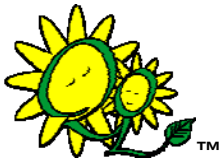
Coordinator ID:

ASTHMA QUALITY OF LIFE QUESTIONNAIRE WITH STANDARDISED ACTIVITIES (AQLQ(S))

SELF-ADMINISTERED

(≥12 years)

Modified for AsthmaNet's BARD Study with permission by Professor Elizabeth Juniper



For further information:

Elizabeth Juniper, MCSP, MSc
Professor
20 Marcuse Fields
Bosham, West Sussex
PO18 8NA, England
Telephone: +44 1243 572124
Fax: +44 1243 573680
E-mail: juniper@qoltech.co.uk
Web: http://www.qoltech.co.uk

APRIL 2008

Modified September 2010
AQLQ(S) ≥12 years SA North American English Version

ASTHMA QUALITY OF LIFE QUESTIONNAIRE (S)

SELF-ADMINISTERED

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

Please complete **all** questions by circling the number that best describes how you have been during the **last 2 weeks as a result of your asthma.**

HOW **LIMITED** HAVE YOU BEEN **DURING THE LAST 2 WEEKS** IN THESE ACTIVITIES **AS A RESULT OF YOUR ASTHMA**?

	Totally Limited	Extremely Limited	Very Limited	Moderate Limitation	Some Limitation	A Little Limitation	Not at all Limited
1. STRENUOUS ACTIVITIES (such as hurrying, exercising, running up stairs, sports)	1	2	3	4	5	6	7
2. MODERATE ACTIVITIES (such as walking, housework, gardening, shopping, climbing stairs)	1	2	3	4	5	6	7
3. SOCIAL ACTIVITIES (such as talking, playing with pets/children, visiting friends/relatives)	1	2	3	4	5	6	7
4. WORK/SCHOOL-RELATED ACTIVITIES* (tasks you have to do at work/in school)	1	2	3	4	5	6	7
5. SLEEPING	1	2	3	4	5	6	7

*If you are not employed or self-employed, these should be tasks you have to do most days.

HOW MUCH **DISCOMFORT OR DISTRESS** HAVE YOU FELT **DURING THE LAST 2 WEEKS**?

	A Very Great Deal	A Great Deal	A Good Deal	Moderate Amount	Some	Very Little	None
6. How much discomfort or distress have you felt over the last 2 weeks as a result of CHEST TIGHTNESS?	1	2	3	4	5	6	7

IN GENERAL, **HOW MUCH OF THE TIME DURING THE LAST 2 WEEKS** DID YOU:

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	Hardly Any of the Time	None of the Time
7. Feel CONCERNED ABOUT HAVING ASTHMA?	1	2	3	4	5	6	7
8. Feel SHORT OF BREATH as a result of your asthma?	1	2	3	4	5	6	7
9. Experience asthma symptoms as a RESULT OF BEING EXPOSED TO CIGARETTE SMOKE?	1	2	3	4	5	6	7
10. Experience a WHEEZE in your chest?	1	2	3	4	5	6	7
11. Feel you had to AVOID A SITUATION OR ENVIRONMENT BECAUSE OF CIGARETTE SMOKE?	1	2	3	4	5	6	7

HOW MUCH **DISCOMFORT OR DISTRESS** HAVE YOU FELT **DURING THE LAST 2 WEEKS**?

	A Very Great Deal	A Great Deal	A Good Deal	Moderate Amount	Some	Very Little	None
12. How much discomfort or distress have you felt over the last 2 weeks as a result of COUGHING?	1	2	3	4	5	6	7

IN GENERAL, **HOW MUCH OF THE TIME DURING THE LAST 2 WEEKS** DID YOU:

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	Hardly Any of the Time	None of the Time
13. Feel FRUSTRATED as a result of your asthma?	1	2	3	4	5	6	7
14. Experience a feeling of CHEST HEAVINESS?	1	2	3	4	5	6	7

IN GENERAL, **HOW MUCH OF THE TIME DURING THE LAST 2 WEEKS** DID YOU:

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	Hardly Any of the Time	None of the Time
15. Feel CONCERNED ABOUT THE NEED TO USE MEDICATION for your asthma?	1	2	3	4	5	6	7
16. Feel the need to CLEAR YOUR THROAT?	1	2	3	4	5	6	7
17. Experience asthma symptoms as a RESULT OF BEING EXPOSED TO DUST?	1	2	3	4	5	6	7
18. Experience DIFFICULTY BREATHING OUT as a result of your asthma?	1	2	3	4	5	6	7
19. Feel you had to AVOID A SITUATION OR ENVIRONMENT BECAUSE OF DUST?	1	2	3	4	5	6	7
20. WAKE UP IN THE MORNING WITH ASTHMA SYMPTOMS?	1	2	3	4	5	6	7
21. Feel AFRAID OF NOT HAVING YOUR ASTHMA MEDICATION AVAILABLE?	1	2	3	4	5	6	7
22. Feel bothered by HEAVY BREATHING?	1	2	3	4	5	6	7
23. Experience asthma symptoms as a RESULT OF THE WEATHER OR AIR POLLUTION OUTSIDE?	1	2	3	4	5	6	7
24. Were you WOKEN AT NIGHT by your asthma?	1	2	3	4	5	6	7
25. AVOID OR LIMIT GOING OUTSIDE BECAUSE OF THE WEATHER OR AIR POLLUTION?	1	2	3	4	5	6	7

IN GENERAL, **HOW MUCH OF THE TIME DURING THE LAST 2 WEEKS** DID YOU:

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	Hardly Any of the Time	None of the Time
26. Experience asthma symptoms as a RESULT OF BEING EXPOSED TO STRONG SMELLS OR PERFUME?	1	2	3	4	5	6	7
27. Feel AFRAID OF GETTING OUT OF BREATH?	1	2	3	4	5	6	7
28. Feel you had to AVOID A SITUATION OR ENVIRONMENT BECAUSE OF STRONG SMELLS OR PERFUME?	1	2	3	4	5	6	7
29. Has your asthma INTERFERED WITH GETTING A GOOD NIGHT'S SLEEP?	1	2	3	4	5	6	7
30. Have a feeling of FIGHTING FOR AIR?	1	2	3	4	5	6	7

HOW LIMITED HAVE YOU BEEN **DURING THE LAST 2 WEEKS**?

	Severely Limited Most Not Done	Very Limited	Moderately Limited Several Not Done	Slightly Limited	Very Slightly Limited Very Few Not Done	Hardly Limited At All	Not Limited Have Done All Activities
31. Think of the OVERALL RANGE OF ACTIVITIES that you would have liked to have done during the last 2 weeks. How much has your range of activities been limited by your asthma?	1	2	3	4	5	6	7

HOW LIMITED HAVE YOU BEEN **DURING THE LAST 2 WEEKS**?

	Totally Limited	Extremely Limited	Very Limited	Moderate Limitation	Some Limitation	A Little Limitation	Not at all Limited
32. Overall, among ALL THE ACTIVITIES that you have done during the last 2 weeks, how limited have you been by your asthma?	1	2	3	4	5	6	7

DOMAIN CODE:

Symptoms: 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 29, 30
Activity Limitation: 1, 2, 3, 4, 5, 11, 19, 25, 28, 31, 32
Emotional Function: 7, 13, 15, 21, 27
Environmental Stimuli: 9, 17, 23, 26

AsthmaNet

ADULT ASTHMA AND ALLERGY HISTORY

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

(Coordinator Completed by Interview)

ASTHMA HISTORY

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

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

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

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

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

   ➔ If participant is male, skip to Q2.

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

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

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

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

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

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

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

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

ASTHMA SYMPTOMS

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

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

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

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

   4d. Fall? **(1170)** ❑1 Yes ❑0 No

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

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

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

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

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

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

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

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

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

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

ASTHMA TRIGGERS

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

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

ALLERGIES

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

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

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

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

_____

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

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

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

8f. Other (1460) ❑1 Yes ❑0 No

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

_____

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

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

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

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

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

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

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

SMOKING HISTORY

11. Did you grow up in a household where you were exposed to tobacco smoke? **(1730)** ❑1 Yes ❑0 No

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

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

    ➔ **SKIP TO Q15.**

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

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

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

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

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

VAPING AND HOOKAH HISTORY

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

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

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

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

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

➔ **SKIP TO Q17.**

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

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

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

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

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

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

PEDIATRIC ASTHMA AND ALLERGY HISTORY

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

(Coordinator Completed by Interview)

ASTHMA HISTORY

1. Approximately how old was the participant when chest symptoms suggesting asthma first appeared? **(1000-1010)** __ __ years__ __ months

2. Has a doctor diagnosed the participant with asthma? **(1065)** ❑$_1$ Yes ❑$_0$ No

   2a. If ***YES***, how old was the participant when a doctor first diagnosed him/her with asthma? **(1070-1080)** __ __ years__ __ months

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

   3a. Mother **(1090)** ❑$_1$ Yes ❑$_0$ No ❑$_8$ Don't Know

   3b. Father **(1100)** ❑$_1$ Yes ❑$_0$ No ❑$_8$ Don't Know

   3c. Brother(s) or Sister(s) **(1110)** ❑$_1$ Yes ❑$_0$ No ❑$_8$ Don't Know ❑$_9$ N/A

   3d. Child(ren) **(1120)** ❑$_1$ Yes ❑$_0$ No ❑$_8$ Don't Know ❑$_9$ N/A

ASTHMA SYMPTOMS

4. How do you categorize the participant's 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 the participant's 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 has the participant had that required emergency care or an unscheduled office visit? **(1180)** __ __ episodes

5b. Overnight hospitalizations has the participant had due to asthma? **(1190)** __ __ hospitalizations

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

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

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

5e. Days of work, school, or housework has the participant's parent/guardian or another caretaker missed because of the participant's asthma symptoms? **(1230)** __ __ __ days
➔ If Q5e > 0, complete Q5ei.

5ei. In the past 3 months, how many days of work, school, or housework has the participant's parent/guardian or another caretaker missed due to asthma? **(1240)** __ __ days

6. Has the participant ever been admitted to an intensive care unit for asthma? **(1250)** ❑$_1$ Yes ❑$_0$ No
➔ If ***NO***, skip to Q7.

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

6b. Has the participant ever had invasive mechanical ventilation? **(1270)** ❑$_1$ Yes ❑$_0$ No ❑$_8$ Don't Know

6c. Has the participant 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 the participant's asthma?

7a.	Exercise/Sports/Play	(1290)	❑1 Yes	❑0 No	❑8 Don't Know
7b.	Menstrual cycle *(If participant is male or a pre-menarche 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 the participant was 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 the participant breathes in or is 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. Has the participant ever had eczema / atopic dermatitis (i.e., prolonged itchy, scaly skin rash)? (1470) ❑1 Yes ❑0 No ❑8 Don't Know
➔ If ***NO*** or ***DON'T KNOW***, skip to Q10.

9a. At what age did the participant FIRST have eczema? (1480-1490) __ __ years__ __ months

9b. Was the eczema diagnosed by a doctor? (1500) ❑1 Yes ❑0 No

9c. During the past 12 months, how would you generally describe the participant's eczema? (1510)
➔ If ***NONE***, skip to Q10.
❑1 None
❑2 Mild
❑3 Moderate
❑4 Severe

9d. Which parts of the participant's body were ever affected by eczema in the past 12 months?

9di. Head (1520) ❑1 Yes ❑0 No

9dii. Arms/Hands (1530) ❑1 Yes ❑0 No

9diii. Trunk (mid-section or torso) (1540) ❑1 Yes ❑0 No

9div. Legs/Feet (1550) ❑1 Yes ❑0 No

9dv. Other (1560) ❑1 Yes ❑0 No

If ***YES***, please specify **(1560D)** _____

10. Have any of the participant's 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 AND VAPING HISTORY

11. Did the participant's mother smoke tobacco or use a hookah (waterpipe) while she was pregnant with the participant? **(1610)** ❑$_1$ Yes ❑$_0$ No ❑$_8$ Don't Know
➔ If ***NO or DON'T KNOW***, skip to Q13.

12. During which part(s) of the pregnancy did the participant's mother smoke tobacco or use a hookah?

12a. First 3 months	**(1620)**	❑$_1$ Yes	❑$_0$ No	❑$_8$ Don't Know
12b. Middle 3 months	**(1630)**	❑$_1$ Yes	❑$_0$ No	❑$_8$ Don't Know
12c. Last 3 months	**(1640)**	❑$_1$ Yes	❑$_0$ No	❑$_8$ Don't Know

13. Did the participant's mother vape (i.e. use nicotine or any other substance in an e-cigarette device) while she was pregnant with the participant? **(1642)** ❑$_1$ Yes ❑$_0$ No ❑$_8$ Don't Know
➔ If ***NO or DON'T KNOW***, skip to Q15.

14.	During which part(s) of the pregnancy did the participant's mother vape?				
	14a. First 3 months	**(1644)**	❑$_1$ Yes	❑$_0$ No	❑$_8$ Don't Know
	14b. Middle 3 months	**(1646)**	❑$_1$ Yes	❑$_0$ No	❑$_8$ Don't Know
	14c. Last 3 months	**(1648)**	❑$_1$ Yes	❑$_0$ No	❑$_8$ Don't Know
15.	Between the time the participant was born and when he/she turned 5 years of age, or present if less than 5 years of age, were there any tobacco smokers or users of a hookah in any household in which the participant spent time? (Include any households the participant regularly spent time in.) ➔ If ***NO or DON'T KNOW***, skip to Q16.	**(1650)**	❑$_1$ Yes	❑$_0$ No	❑$_8$ Don't Know
	15a. Did the participant's mother (or stepmother or female guardian) smoke or use a hookah?	**(1660)**	❑$_1$ Yes	❑$_0$ No	❑$_8$ Don't Know
	15b. Did the participant's father (or stepfather or male guardian) smoke or use a hookah?	**(1670)**	❑$_1$ Yes	❑$_0$ No	❑$_8$ Don't Know
	15c. Were there any other smokers or users of a hookah in the household?	**(1680)**	❑$_1$ Yes	❑$_0$ No	❑$_8$ Don't Know
16.	At the present time, are there any tobacco smokers or users of a hookah in any household in which the participant spends time? (Include any households the participant regularly spends time in.) ➔ If ***NO or DON'T KNOW***, skip to Q17.	**(1690)**	❑$_1$ Yes	❑$_0$ No	❑$_8$ Don't Know
	16a. Does the participant's mother (or stepmother or female guardian) smoke or use a hookah?	**(1700)**	❑$_1$ Yes	❑$_0$ No	❑$_8$ Don't Know
	16b. Does the participant's father (or stepfather or male guardian) smoke or use a hookah?	**(1710)**	❑$_1$ Yes	❑$_0$ No	❑$_8$ Don't Know
	16c. Are there any other smokers or users of a hookah in the household?	**(1720)**	❑$_1$ Yes	❑$_0$ No	❑$_8$ Don't Know
17.	Between the time the participant was born and when he/she turned 5 years of age, or present if less than 5 years of age, were there any individuals who vaped in any household in which the participant spent time? (Include any households the participant regularly spent time in.) ➔ If ***NO or DON'T KNOW***, skip to Q18.	**(1730)**	❑$_1$ Yes	❑$_0$ No	❑$_8$ Don't Know

17a. Did the participant's mother (or stepmother or female guardian) vape? **(1740)** ❑1 Yes ❑0 No ❑8 Don't Know

17b. Did the participant's father (or stepfather or male guardian) vape? **(1750)** ❑1 Yes ❑0 No ❑8 Don't Know

17c. Were there any other individuals who vaped in the household? **(1760)** ❑1 Yes ❑0 No ❑8 Don't Know

18. At the present time, are there any individuals who vape in any household in which the participant spends time? (Include any households the participant regularly spends time in.) **(1770)** ❑1 Yes ❑0 No ❑8 Don't Know
➔ If ***NO or DON'T KNOW***, ***STOP HERE***.

18a. Does the participant's mother (or stepmother or female guardian) vape? **(1780)** ❑1 Yes ❑0 No ❑8 Don't Know

18b. Does the participant's father (or stepfather or male guardian) vape? **(1790)** ❑1 Yes ❑0 No ❑8 Don't Know

18c. Are there any other individuals who vape in the household? **(1800)** ❑1 Yes ❑0 No ❑8 Don't Know

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet	ADULT BODY MEASUREMENTS	Part. ID: __ __ - __ __ __ - __ __ __ Part. Initials: __ __ __ Visit: __ __ __ Visit Date: __ __ / __ __ / 20 __ __ Coordinator ID: __ __ __ __

(Coordinator Completed)

Height and Weight

The participant should remove shoes and heavy articles of clothing for these measurements.

1. Height **(1000)** __ __ __ cm

2. Weight **(1010)** __ __ __ . __ kg

Clinic Use Only

Body Mass Index (BMI) = Q2 / $(Q1/100)^2$

BMI = __ __ . __

Circumference Measurements

The participant should be standing, facing forward, with shoulders relaxed for these measurements. Use a plastic measuring tape.

3. Waist circumference **(1020)** __ __ __ . __ cm
   - ➔ Measure at the narrowest circumference between the bottom of the ribcage and the top of the iliac crest following normal expiration.

4. Hip circumference **(1030)** __ __ __ . __ cm
   - ➔ Measure at the largest point between the iliac crest and the symphysis pubis.

5. Neck circumference **(1040)** __ __ . __ cm
   - ➔ Measure at mid neck height between mid cervical spine to mid anterior neck. If an Adam's apple is present, measure just below the prominence.

COMMENTS: **(6000)**

_____

_____

_____

Part. ID: - -

Part. Initials: Visit: Visit Date: / / Coordinator ID:

Childhood Asthma Control Test for children 4 to 11 years old.

Know the score.

This test will provide a score that may help your doctor determine if your child's asthma treatment plan is working or if it might be time for a change.

How to take the Childhood Asthma Control Test

Step 1 Let your child respond to **the first four questions (1 to 4)**. If your child needs help reading or understanding the question, you may help, but let your child select the response. Complete the remaining **three questions (5 to 7)** on your own and without letting your child's response influence your answers. There are no right or wrong answers.

Step 2 Write the number of each answer in the score box provided.

Step 3 Add up each score box for the total.

Step 4 Take the test to the doctor to talk about your child's total score.

19 or less

If your child's score is 19 or less, it may be a sign that your child's asthma is not controlled as well as it could be. No matter what the score, bring this test to your doctor to talk about your child's results.

Have your child complete these questions.

1. How is your asthma today?

SCORE

 0 Very bad	 1 Bad	 2 Good	 3 Very good

2. How much of a problem is your asthma when you run, exercise or play sports?

 0 It's a big problem, I can't do what I want to do.	 1 It's a problem and I don't like it.	 2 It's a little problem but it's okay.	 3 It's not a problem.

3. Do you cough because of your asthma?

 0 Yes, all of the time.	 1 Yes, most of the time.	 2 Yes, some of the time.	 3 No, none of the time.

4. Do you wake up during the night because of your asthma?

 0 Yes, all of the time.	 1 Yes, most of the time.	 2 Yes, some of the time.	 3 No, none of the time.

Please complete the following questions on your own.

5. During the last 4 weeks, how many days did your child have any daytime asthma symptoms?

5 Not at all	4 1-3 days	3 4-10 days	2 11-18 days	1 19-24 days	0 Everyday

6. During the last 4 weeks, how many days did your child wheeze during the day because of asthma?

5 Not at all	4 1-3 days	3 4-10 days	2 11-18 days	1 19-24 days	0 Everyday

7. During the last 4 weeks, how many days did your child wake up during the night because of asthma?

5 Not at all	4 1-3 days	3 4-10 days	2 11-18 days	1 19-24 days	0 Everyday

TOTAL

Please turn this page over to see what your child's total score means.

AsthmaNet

CONCOMITANT MEDICATIONS FOR ASTHMA/ALLERGY AND ADVERSE EVENTS

(Coordinator completed)

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

Part. Initials: __ __ __

Visit: __ __ __

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

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

❑0 None

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

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

AsthmaNet

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

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

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

AsthmaNet

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)**

_____

_____

_____

COLD HX

AsthmaNet

HOME ENVIRONMENT QUESTIONNAIRE

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

(Coordinator Completed by Interview)

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

1. Who is the respondent?

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

GENERAL HOUSE CHARACTERISTICS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14e. Your bedroom (1310) ❑1 Yes ❑0 No

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

14g. Garage (1330) ❑1 Yes ❑0 No

14h. Other (1340) ❑1 Yes ❑0 No

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

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

15a. Barns (1350) ❑1 Yes ❑0 No

15b. Hay (1360) ❑1 Yes ❑0 No

15c. Woodsheds (1370) ❑1 Yes ❑0 No

15d. Firewood (1380) ❑1 Yes ❑0 No

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

15f. Corral (1400) ❑1 Yes ❑0 No

CHARACTERISTICS OF THE PARTICIPANT'S BEDROOM

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

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

(1410D) _____

- ❑9 Don't know

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

(1420D) _____

- ❑9 Don't know

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

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

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

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

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

PETS

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

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

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

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

25a. Cat **(1570)** ❑1 Yes ❑0 No

25b. Dog **(1580)** ❑1 Yes ❑0 No

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

25d. Bird **(1600)** ❑1 Yes ❑0 No

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

25f. Other **(1620)** ❑1 Yes ❑0 No

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

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

DAY CARE

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

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

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

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

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

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

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

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

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

Coordinator Completed
COMMENTS
(6000):_____

_____

_____

AsthmaNet

HOUSEHOLD SOCIO-ECONOMIC INFORMATION

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

(Parent/Legal Guardian or Participant Completed)

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

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

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

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

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

COMMENTS: **(6000)**

_____

_____

_____

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

AsthmaNet

PEDIATRIC LONG PHYSICAL EXAM

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

(Coordinator Completed)

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

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

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

PARTICIPANT MEASUREMENTS – Complete at all applicable study visits

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

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

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

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

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

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

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

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

   _____

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

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

ORAL CANDIDIASIS

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

LEXAM PED

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

(Licensed Medical Practitioner Completed)

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

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

Licensed Medical Practitioner Source Documentation

Licensed Medical Practitioner Signature: _____

Printed Name: _____

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

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

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

METHACHOLINE CHALLENGE TESTING

Supervisor ID: __ __ __ __

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

(Technician Completed)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

COMMENTS: (6000)

_____

* M E T H A *

AsthmaNet

ADULT METHACHOLINE CHALLENGE TESTING CHECKLIST

Supervisor ID: __ __ __ __

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

(Technician Completed)

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

Exclusions and Confounders

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

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

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

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

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

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

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

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

COMMENTS: **(6000)**

_____

METHACHK ADULT

AsthmaNet

PEDIATRIC METHACHOLINE CHALLENGE TESTING CHECKLIST

Supervisor ID: __ __ __ __

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

(Technician Completed)

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

Exclusions and Confounders

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

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

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

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

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

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

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

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

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

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

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

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

ADDITIONAL TREATMENT POST METHACHOLINE CHALLENGE TESTING

Supervisor ID: __ __ __ __

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

(Technician Completed)

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

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

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

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

   1b. Nebulized Beta-agonist **(1030)** ❑1 Yes ❑0 No

   1c. Subcutaneous epinephrine **(1040)** ❑1 Yes ❑0 No

   1d. Implementation of clinic emergency protocol or algorithm **(1050)** ❑1 Yes ❑0 No

   1e. Other **(1060)** ❑1 Yes ❑0 No

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

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

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

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

   2c. Was the FEV_1 from Q2a ≥ the methacholine reversal reference value (B) in the gray box on the Methacholine Challenge Testing (METHA) form? **(1100)** ❑1 Yes ❑0 No
   ➔ If ***YES, STOP HERE*** and continue with remaining visit procedures.

   ➔ If ***NO***, proceed to Q3.

3. Was additional treatment used after one hour? **(1110)** ❑1 Yes ❑0 No
   ➔ If ***NO***, skip to Q4.

   3a. Additional albuterol by MDI **(1120)** ❑1 Yes ❑0 No
   ➔ If ***NO***, skip to Q3b.

METHA ADD TRT

Number of additional puffs of albuterol administered	**(1130)**	❑$_1$ 2	❑$_2$ 4	❑$_3$ > 4
3b. Nebulized Beta-agonist	**(1140)**	❑$_1$ Yes	❑$_0$ No	
3c. Subcutaneous epinephrine	**(1150)**	❑$_1$ Yes	❑$_0$ No	
3d. Implementation of clinic emergency protocol or algorithm	**(1160)**	❑$_1$ Yes	❑$_0$ No	
3e. Treatment in the emergency room	**(1170)**	❑$_1$ Yes	❑$_0$ No	
3f. Overnight hospitalization ➔ If ***YES***, please complete the Serious Adverse Event (SERIOUS) form.	**(1180)**	❑$_1$ Yes	❑$_0$ No	
3g. Other	**(1190)**	❑$_1$ Yes	❑$_0$ No	
If ***YES***, specify:	**(1190D)**	_____		

4. Participant's final FEV_1 after methacholine challenge

4a. FEV_1	**(1200)**	__ . __ __ L
4b. Time of FEV_1 in Q4a *(based on 24-hour clock)*	**(1220)**	__ __ __ __
4c. Was the FEV_1 from Q4a ≥ the methacholine reversal reference value (B) in the gray box on the Methacholine Challenge Testing (METHA) form? ➔ If ***NO***, complete the source documentation box below.	**(1230)**	❑$_1$ Yes ❑$_0$ No

Physician Source Documentation

Physician's Signature: _____ **(1240)**

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

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

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

POST-ALBUTEROL (4 puffs) SPIROMETRY TESTING

Supervisor ID: __ __ __ __

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

Part. Initials: __ __ __

Visit: __ __ __

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

Technician ID: __ __ __ __

(Technician Completed)

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

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

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

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

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

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

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

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

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

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

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

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

COMMENTS: (6000)

_____

_____

_____

PALB4 SPIRO

PAEDIATRIC ASTHMA QUALITY OF LIFE QUESTIONNAIRE WITH STANDARDISED ACTIVITIES (PAQLQ(S))

INTERVIEWER-ADMINISTERED

Modified for AsthmaNet's BARD Study with
permission by Professor Elizabeth Juniper

For further information:

Elizabeth Juniper, MCSP, MSc
Professor
20 Marcuse Fields Bosham,
West Sussex PO18 8NA,
England
Telephone: +44 1243 572124
Fax: +44 1243 573680
E-mail: juniper@qoltech.co.uk
Web: http://www.qoltech.co.uk

JANUARY 2001

PAEDIATRIC ASTHMA QUALITY OF LIFE QUESTIONNAIRE WITH STANDARDISED ACTIVITIES (PAQLQ(S))

THE PAEDIATRIC ASTHMA QUALITY OF LIFE QUESTIONNAIRE HAS BEEN TESTED AND VALIDATED USING THE WORDING AND FORMAT THAT FOLLOWS. IT IS IMPORTANT THAT INTERVIEWERS ADHERE TO THE EXACT WORDING WHEN ADDRESSING THE PATIENT (REGULAR TYPE) AND FOLLOW THE INSTRUCTIONS (ITALICS). DEVIATION FROM BOTH WORDING AND INSTRUCTIONS MAY IMPAIR THE RELIABILITY AND VALIDITY OF THE QUESTIONNAIRE.

PARENTS SHOULD NOT BE PRESENT DURING THE INTERVIEW. IT IS THE CHILD'S OWN EXPERIENCES THAT YOU WANT TO EVALUATE. SOME PARENTS MAY WANT TO INFLUENCE THIS EVALUATION AND SOME CHILDREN MAY WANT TO LOOK TO THE PARENT FOR GUIDANCE.

REASSURE THE CHILD THAT THERE ARE NO RIGHT OR WRONG ANSWERS. DO NOT INTERPRET QUESTIONS FOR CHILDREN. IF THEY HAVE DIFFICULTY, JUST ASK THEM TO DO THE BEST THEY CAN.

MAKE SURE THAT THE CHILD UNDERSTANDS THE TIME FRAME OF "DURING THE LAST WEEK". IF IN DOUBT, ASK THE PARENT TO IDENTIFY AN EVENT THAT OCCURRED A WEEK PREVIOUSLY (E.G., A FOOTBALL MATCH) AND THEN ASK THE CHILD TO THINK ABOUT HOW SHE/HE HAS BEEN SINCE THAT EVENT.

SHOW THE BLUE AND GREEN RESPONSE CARDS TO THE CHILD AND EXPLAIN THE OPTIONS. FOR CHILDREN WHO CAN READ, WE SUGGEST THAT YOU ASK THEM TO READ ALOUD EACH OF THE RESPONSE OPTIONS. FOR YOUNGER CHILDREN, READ THROUGH EACH OF THE RESPONSES WITH THEM. MAKE SURE THAT THE CHILD UNDERSTANDS THE CONCEPT OF THE GRADING FROM 1 (EXTREMELY BOTHERED/ALL OF THE TIME) TO 7 (NOT BOTHERED/NONE OF THE TIME)

I want you to tell me how much you have been bothered by your asthma during the past week. I will tell you which card to use. Pick the number that best describes how much you were bothered by your asthma during the past week.

A 1. How much have you been bothered by your asthma in **PHYSICAL ACTIVITIES** (such as running, swimming, sports, walking uphill/upstairs and bicycling) during the past week? [BLUE CARD]

A 2. How much have you been bothered by your asthma in **BEING WITH ANIMALS** (such as playing with pets and looking after animals) during the past week? [BLUE CARD]

A 3. How much have you been bothered by your asthma in **ACTIVITIES WITH FRIENDS AND FAMILY** (such as playing at recess and doing things with your friends and family) during the past week? [BLUE CARD]

S 4. How much did **COUGHING** bother you in the past week? [BLUE CARD]

E 5. How often did your asthma make you feel **FRUSTRATED** during the past week? [GREEN CARD]

S 6. How often did your asthma make you feel **TIRED** during the past week? [GREEN CARD]

E 7. How often did you feel **WORRIED, CONCERNED, OR TROUBLED** because of your asthma during the past week? [GREEN CARD]

S 8. How much did **ASTHMA ATTACKS** bother you during the past week? [BLUE CARD]

E 9. How often did your asthma make you feel **ANGRY** during the past week? [GREEN CARD]

S 10. How much did **WHEEZING** bother you during the past week? [BLUE CARD]

E 11. How often did your asthma make you feel **IRRITABLE (cranky, grouchy*)** during the past week? [GREEN CARD]
(*use only if patient does not understand the word "irritable")

S 12. How much did **TIGHTNESS IN YOUR CHEST** bother you during the past week? [BLUE CARD]

E 13. How often did you feel **DIFFERENT OR LEFT OUT** because of your asthma during the past week? [GREEN CARD]

S 14. How much did **SHORTNESS OF BREATH** bother you during the past week? [BLUE CARD]

E 15. How often did you feel **FRUSTRATED BECAUSE YOU COULDN'T KEEP UP WITH OTHERS** during the past week? [GREEN CARD]

S 16. How often did your asthma **WAKE YOU UP DURING THE NIGHT** during the past week? [GREEN CARD]

E 17. How often did you feel **UNCOMFORTABLE** because of your asthma during the past week? [GREEN CARD]

S 18. How often did you feel **OUT OF BREATH** during the past week? [GREEN CARD]

A 19. How often did you feel **YOU COULDN'T KEEP UP WITH OTHERS** because of your asthma during the past week? [GREEN CARD]

S 20. How often did you have trouble **SLEEPING AT NIGHT**, because of your asthma, during the past week? [GREEN CARD]

E 21. How often did you feel **FRIGHTENED BY AN ASTHMA ATTACK** during the past week? [GREEN CARD]

A 22. Think about all the activities that you did in the past week. How much were you bothered by your asthma doing these activities? [BLUE CARD]

S 23. How often did you have difficulty taking a **DEEP BREATH** in the past week? [GREEN CARD]

DOMAIN CODE:

S = Symptoms
A = Activity Limitation
E = Emotional Function

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

RESPONSE SHEET

NAME: _____ **NUMBER:** _____

DATES OF COMPLETION:

1st: _____ **2nd:** _____

3rd: _____ **4th:** _____

ITEM	RESPONSES			
	1st	**2nd**	**3rd**	**4th**
1. Physical activities	____	____	____	____
2. Being with animals	____	____	____	____
3. Activities with friends and family	____	____	____	____
4. Cough	____	____	____	____
5. Frustrated	____	____	____	____
6. Tired	____	____	____	____
7. Worried/concerned/troubled	____	____	____	____
8. Asthma attacks	____	____	____	____
9. Angry	____	____	____	____
10. Wheezing	____	____	____	____
11. Irritable	____	____	____	____
12. Tightness in chest	____	____	____	____
13. Feeling different or left out	____	____	____	____
14. Shortness of breath	____	____	____	____
15. Frustrated can't keep up with others	____	____	____	____
16. Wake up during the night	____	____	____	____
17. Uncomfortable	____	____	____	____
18. Out of breath	____	____	____	____
19. Can't keep up with others	____	____	____	____
20. Trouble sleeping at night	____	____	____	____
21. Frightened by asthma attack	____	____	____	____
22. Bothered in activities overall	____	____	____	____
23. Deep breath	____	____	____	____

RESPONSE OPTIONS

GREEN CARD

1. ALL OF THE TIME
2. MOST OF THE TIME
3. QUITE OFTEN
4. SOME OF THE TIME
5. ONCE IN A WHILE
6. HARDLY ANY OF THE TIME
7. NONE OF THE TIME

BLUE CARD

1. EXTREMELY BOTHERED
2. VERY BOTHERED
3. QUITE BOTHERED
4. SOMEWHAT BOTHERED
5. BOTHERED A BIT
6. HARDLY BOTHERED AT ALL
7. NOT BOTHERED

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

PedsQL™
Pediatric Quality of Life Inventory

Version 4.0

PARENT REPORT for **YOUNG CHILDREN** (ages **5-7**)

DIRECTIONS

On the following page is a list of things that might be a problem for **your child**. Please tell us **how much of a problem** each one has been for **your child** during the **past ONE month** by circling:

0 if it is **never** a problem
1 if it is **almost never** a problem
2 if it is **sometimes** a problem
3 if it is **often** a problem
4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

Part. ID: - - Visit: Coordinator ID:

Part. Initials: Visit Date: / / 2 0 PedsQL 2

*In the past **ONE month**, how much of a **problem** has your child had with …*

PHYSICAL FUNCTIONING ***(problems with…)***	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. Walking more than one block	0	1	2	3	4
2. Running	0	1	2	3	4
3. Participating in sports activity or exercise	0	1	2	3	4
4. Lifting something heavy	0	1	2	3	4
5. Taking a bath or shower by him or herself	0	1	2	3	4
6. Doing chores, like picking up his or her toys	0	1	2	3	4
7. Having hurts or aches	0	1	2	3	4
8. Low energy level	0	1	2	3	4

EMOTIONAL FUNCTIONING ***(problems with…)***	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. Feeling afraid or scared	0	1	2	3	4
2. Feeling sad or blue	0	1	2	3	4
3. Feeling angry	0	1	2	3	4
4. Trouble sleeping	0	1	2	3	4
5. Worrying about what will happen to him or her	0	1	2	3	4

SOCIAL FUNCTIONING ***(problems with…)***	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. Getting along with other children	0	1	2	3	4
2. Other kids not wanting to be his or her friend	0	1	2	3	4
3. Getting teased by other children	0	1	2	3	4
4. Not able to do things that other children his or her age can do	0	1	2	3	4
5. Keeping up when playing with other children	0	1	2	3	4

SCHOOL FUNCTIONING ***(problems with…)***	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. Paying attention in class	0	1	2	3	4
2. Forgetting things	0	1	2	3	4
3. Keeping up with school activities	0	1	2	3	4
4. Missing school because of not feeling well	0	1	2	3	4
5. Missing school to go to the doctor or hospital	0	1	2	3	4

AsthmaNet

URINE PREGNANCY TEST

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

(Coordinator Completed)

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

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

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

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

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

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

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

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

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

COMMENTS: **(6000)**

_____

_____

_____

* P R E G T E S T *

AsthmaNet

PRIOR CONDITIONS FOR ADULT PARTICIPANTS

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

(Coordinator Completed by Interview)

PRIOR DISEASES, ILLNESSES, AND SURGERIES

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

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

COMMENTS: (6000)

_____

_____

_____

AsthmaNet

PRIOR CONDITIONS FOR ALL PARTICIPANTS

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

(Coordinator Completed by Interview)

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

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

PRIOR DISEASES, ILLNESSES, AND SURGERIES

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

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

PRIOR COND ALL

If Yes, Comment

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

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

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

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

5. Stomach or Intestines

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

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

6. Sleep Disorder

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

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

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

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

COMMENTS: (6000)

_____

_____

_____

AsthmaNet

PRIOR ASTHMA/ALLERGY TREATMENT

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

(Coordinator Completed by Interview)

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

1. Who is the respondent?

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

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

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

PRIOR TRT

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

COMMENTS: **(6000)**

_____

_____

_____

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

AsthmaNet

PERCEIVED STRESS SCALE

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

(Participant Completed)

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

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

Participant Source Documentation

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

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

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

AsthmaNet

RAND IMPACT OF ASTHMA ON QOL SF-12

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

(Participant Completed)

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

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

Participant Source Documentation

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

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

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

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

(Coordinator Completed by Interview)

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

ADMINISTRATIVE

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

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

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

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

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

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

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

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

DEMOGRAPHICS

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

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

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

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

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

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

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

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

(1160) _____

Registry Form Storage Instructions:

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

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

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

REGISTRY

AsthmaNet

SERIOUS ADVERSE EVENT REPORTING FORM

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

(Coordinator Completed)

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

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

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

   Describe: **(1010D)** _____

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

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

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

6. Why was the event serious?

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

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

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

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

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

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

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

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

6g. Cancer **(1130)** ❑1 Yes ❑0 No

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

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

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

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

6l. Other **(1180)** ❑1 Yes ❑0 No

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

7. What in your opinion caused the event?

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

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

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

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

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

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

(Investigator Completed)

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

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

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

10. If participant died, cause of death: _____

_____

11. Was an autopsy performed? ❑ Yes ❑ No

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

REPORTING INVESTIGATOR:

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

COMMENTS: (6000)

_____

_____

_____

Name: _____

Signature:_____

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

AsthmaNet

PEDIATRIC SHORT PHYSICAL EXAM

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

(Coordinator Completed)

PARTICIPANT MEASUREMENTS – Complete at all applicable study visits

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

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

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

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

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

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

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

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

   _____

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

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

ORAL CANDIDIASIS

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

SEXAM PED

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

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

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

6a. If Abnormal:

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

Coordinator Source Documentation

Coordinator Signature: _____

Printed Name: _____

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

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

COMMENTS: (6000)

_____

_____

_____

AsthmaNet

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 READ

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

(Technician Completed)

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

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

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

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

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

Differential Cell Counts

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

The parameters below are calculated following exclusion of squamous cells.

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

SPUTREAD

AsthmaNet

SPUTUM INDUCTION

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

(Technician Completed)

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

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

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

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

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

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

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

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

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

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

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

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

SPUTUM

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

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

Reference = FEV_1 used for assessment of eligibility for SI.

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

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

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

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet	SPUTUM INDUCTION CHECKLIST	Part. ID: __ __ - __ __ __ - __ __ __ Part. Initials: __ __ __ Visit: __ __ __ Visit Date: __ __ / __ __ / 20 __ __ Technician ID: __ __ __ __

(Technician Completed)

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

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

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

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

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

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

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

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

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

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

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

   _____

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

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

COMMENTS: (6000)

_____

_____

AsthmaNet

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

0 1 2 3 4 5 6 7 8 9 10

Asthma completely prevented me from working

CIRCLE A NUMBER

Coordinator Completed

(1030) __ __

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

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

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

WPAI ASTHMA

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

Asthma had no effect on my class work

0 1 2 3 4 5 6 7 8 9 10

CIRCLE A NUMBER

Asthma completely prevented me from doing my class work

Coordinator Completed

(1070) __ __

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

Asthma had no effect on my daily activities

0 1 2 3 4 5 6 7 8 9 10

CIRCLE A NUMBER

Asthma completely prevented me from doing my daily activities

Coordinator Completed

(1080) __ __

Participant Source Documentation

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

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

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

AsthmaNet

BARD COMPLIANCE CHECKLIST

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

(Coordinator Completed)

Complete Question 1 at all visits 0A1, 0B, 0C, 0D, and 1-13.

1. Diary and Peak Flow Compliance

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

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

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

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

Complete Question 2 for post-randomization visits and early post-randomization terminations only.

2. Scheduled Diskus® Compliance

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

   ➔ ***Do not count puffs during the 12 hour hold period prior to the visit.***

   2b. Number of remaining puffs reflected on scheduled Diskus® counter(s) **(1040)** __ __ __ puffs

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

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

   ➔ ***60 x (# used Diskuses®) – Q2b***

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

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

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

BARD CONTACT FORM VISITS 1-13

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

(Coordinator Completed by Interview)

Complete this form during post-randomization visits and scheduled phone contacts. Log attempts at phone contacts in the table below.

For Clinic Use Only				
Phone Contact Attempt	***Coordinator ID***	***Date***	***Time***	***Contact Occurred?***
1	__ __ __ __	__ __ / __ __ / __ __ __ __	__ __ : __ __ AM ❑ PM ❑	❑ Yes ❑ No
2	__ __ __ __	__ __ / __ __ / __ __ __ __	__ __ : __ __ AM ❑ PM ❑	❑ Yes ❑ No
3	__ __ __ __	__ __ / __ __ / __ __ __ __	__ __ : __ __ AM ❑ PM ❑	❑ Yes ❑ No
4	__ __ __ __	__ __ / __ __ / __ __ __ __	__ __ : __ __ AM ❑ PM ❑	❑ Yes ❑ No
5	__ __ __ __	__ __ / __ __ / __ __ __ __	__ __ : __ __ AM ❑ PM ❑	❑ Yes ❑ No

1. Who is the respondent?

(1000) ❑$_1$ Self/Participant
❑$_2$ Parent/Guardian
❑$_3$ Other (specify)
(1000D) _____

2. Type of contact

(1010) ❑$_1$ Phone
❑$_2$ Study visit

➔ If phone contact, ask the participant to retrieve his/her Asthma Monitoring Log for reference.

If you are interviewing a parent or guardian responding for a child, remind them that "you" is referring to the child who is the study participant.

Ask the participant the following questions:

3. Since your last study contact, have you had any increase in asthma symptoms (e.g., cough, wheeze, phlegm, shortness of breath)?

(1020) ❑$_1$ Yes ❑$_0$ No

3a. If ***YES***, explain:

(1020D) _____
_____

4. Have you been taking your study Diskus® every morning and evening? **(1030)** ❑1 Yes ❑0 No

   ➔ If ***NO***, review study procedures with participant or his/her parent/guardian.

5. Have you been completing the spirotel® diary every morning and evening? **(1040)** ❑1 Yes ❑0 No

   ➔ If ***NO***, review study procedures with participant or his/her parent/guardian.

6. Have you been performing three peak flow maneuvers every morning and evening? **(1050)** ❑1 Yes ❑0 No

   ➔ If ***NO***, review study procedures with participant or his/her parent/guardian.

7. Since your last study contact, have you been admitted to a hospital for an overnight stay of at least one night for your asthma? **(1060)** ❑1 Yes ❑0 No

   ➔ If ***YES***, complete a Significant Asthma Exacerbation (P5_SIGEX) form and a Serious Adverse Event Reporting Form (SERIOUS) for each event.

   7a. If ***YES***, how many times were you admitted? **(1070)** __ __

8. Since your last study contact, have you been seen at an emergency department or urgent care facility for your asthma? **(1080)** ❑1 Yes ❑0 No

   8a. If ***YES***, how many times were you seen? **(1090)** __ __

9. Since your last study contact, have you been seen for a clinic/office visit to a physician (primary care physician or other), physician's assistant, or nurse practitioner for your asthma? *Do not consider/include study visits.* **(1100)** ❑1 Yes ❑0 No

   9a. If ***YES***, how many times were you seen? **(1110)** __ __

10. Since your last study contact, have you missed at least one half day of work, housework, school or daycare because of your asthma? *Do not count time off to attend study visits.* **(1120)** ❑1 Yes ❑0 No

    10a. If ***YES***, how many full or half days were missed due to asthma? **(1130)** __ __ . __ days

10b. If ***YES***, what was the primary activity missed? **(1140)**
- ❑1 Work
- ❑2 School
- ❑3 Daycare
- ❑4 Housework
- ❑5 Other (specify)

(1140D) _____

10c. If ***YES***, was the activity missed due to:

10ci. worsening of asthma symptoms? **(1150)** ❑1 Yes ❑0 No

10cii. time off to see your healthcare provider? *Do not consider/include study visits.* **(1160)** ❑1 Yes ❑0 No

10ciii. side effects of your asthma medication? **(1170)** ❑1 Yes ❑0 No

11. Since your last study contact, have you been prescribed any new medications <u>for your asthma</u>? **(1180)** ❑1 Yes ❑0 No

11a. If ***YES***, were you treated with prednisone or another systemic corticosteroid? **(1190)** ❑1 Yes ❑0 No

➔ If ***YES***, complete a Significant Asthma Exacerbation (P5_SIGEX) form and update CMED and AECLIN.

11b. If ***YES***, did you receive any other treatments for your asthma? **(1200)** ❑1 Yes ❑0 No

11bi. If ***YES***, list and update CMED: **(1200D)** _____

_____

12. Since your last study contact, have you had any medical problems unrelated to asthma? **(1210)** ❑1 Yes ❑0 No

12a. If ***YES***, comment: **(1210D)** _____

_____

➔ If ***YES***, complete AECLIN.

13. Since your last study contact, have you had any changes to your medications for conditions other than asthma? **(1220)** ❑1 Yes ❑0 No

13a. If ***YES***, explain: **(1220D)** _____

_____

➔ If ***YES***, complete or update the appropriate Concomitant Medications form (CMED, CMED_NON), if applicable.

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

BARD COORDINATOR STUDY TREATMENT QUESTIONNAIRE (Visits 1-13)

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

(Coordinator Completed)

This questionnaire is to be completed at Visits 4, 7, 10 and 13 by the AsthmaNet coordinator who was primarily responsible for the participant's BARD visits during the preceding 14 weeks. If a randomized participant terminates prior to the end of a given treatment period, this form should be completed at the time of the termination visit. If a participant achieves treatment arm drop-out or treatment failure status, or he/she has an exacerbation near the end of a treatment period, this form should be completed when he/she stops taking his/her blinded Diskus® and transitions to open-label Flovent®.

1. **Blinded Scheduled Diskus® Contents**

   Participants in the BARD study are randomized to receive a blinded Diskus®, the contents of which change from one 14-week treatment period to the next. You are blinded to the actual contents of the Diskus® at any given time. The Diskus® contains one of the following treatments (per puff). Please check the box next to the treatment that you believe the participant received **over the past 14 weeks.**

(1000)

- ❑1 fluticasone 100 mcg *(Age 5-11 Track only)*
- ❑2 fluticasone 100 mcg + salmeterol 50 mcg
- ❑3 fluticasone 250 mcg
- ❑4 fluticasone 250 mcg + salmeterol 50 mcg
- ❑5 fluticasone 500 mcg *(Age 12-17 and Age 18+ Tracks only)*

2. How sure are you about your answer in Q1?

(1010)

- ❑1 Absolutely sure – I know what the Diskus® contains
- ❑2 Moderately sure
- ❑3 Somewhat sure
- ❑4 Not sure at all – purely guess

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

_____

_____

_____

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

AsthmaNet

BARD ELIGIBILITY CHECKLIST 1

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

(Coordinator Completed)

1. Has the participant or parent/legal guardian signed the BARD main study informed consent document? **(1000)** ❑1 Yes ❑0 No

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

2. ***Age 5-11 and Age 12-17 Tracks Only:*** Has the participant signed and dated the assent form or, if the participant is less than the local age of assent, has the participant given verbal assent? **(1020)** ❑1 Yes ❑0 No

3. Has the participant consented to genetic testing? **(1030)** ❑1 Yes ❑0 No

   ➔ ***Participant must answer 'Yes' to the first question in the genetics consent section to participate. He/she may answer 'No' to the second question regarding consent for contact and still participate.***

4. Is the participant 5 years of age or older? **(1040)** ❑1 Yes ❑0 No

5. Does the participant report having at least one African American/Black biological grandparent? **(1050)** ❑1 Yes ❑0 No

6. Does the participant plan to move away from the clinical site in the upcoming 16 months? **(1060)** ❑1 Yes ❑0 No

7. 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 BARD study? **(1070)** ❑1 Yes ❑0 No

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

9. Has the participant received systemic corticosteroid treatment for any condition in the past 4 weeks? **(1090)** ❑1 Yes ❑0 No

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

11. Has the participant experienced a life-threatening asthma exacerbation requiring treatment with intubation and mechanical ventilation, or resulting in a hypoxic seizure in the past 2 years? **(1110)** ❑1 Yes ❑0 No

P5 ELIG1

Complete Q12 only if IRB approval <u>has NOT yet been obtained</u> for protocol version 24.1.

12. Has the participant had a respiratory tract infection in the past 4 weeks? **(1120)** ❑1 Yes ❑0 No

Complete Q13 only if IRB approval <u>has been obtained</u> for protocol version 24.1.

13. Has the participant had a respiratory tract infection in the past 2 weeks? **(1125)** ❑1 Yes ❑0 No

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

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

➔ **If *YES*, proceed with remaining Visit 0A procedures.**
➔ **If *NO*, STOP HERE.**

Participant/Guardian Source Documentation

Participant/Guardian Initials: __ __ __ **(1140)**

Date: __ __ / __ __ / 20 __ __ **(1150)**
MM DD YYYY

COMMENTS: (6000)

_____

_____

_____

AsthmaNet

BARD ELIGIBILITY CHECKLIST 2

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

(Coordinator Completed)

1. Has the participant required 6 or more courses of systemic corticosteroids for treatment of his/her asthma in the past year? **(1000)** ❑$_1$ Yes ❑$_0$ No

2. Has the participant been on a stable dose of his/her asthma controller (i.e., ICS or ICS/LABA) for the past 2 weeks? **(1010)** ❑$_1$ Yes ❑$_0$ No

Clinic Use Only

Record information on the participant's current ICS or ICS/LABA medications from the Prior Asthma/Allergy Treatment (PRIOR_TRT) form:

a. ICS Code from Q1470, Q1535, or Q1600: __ __ __ __

ai. ICS generic name (from PRIOR_TRT_CARD) _____

b. # Daily puffs/treatments from Q1480, Q1540, or Q1610: __ __ puffs/treatments

c. ICS mcg/puff or mg/neb (from PRIOR_TRT_CARD): __ __ __ mcg/mg

d. ICS daily dose in mcg/mg (b x c): __ __ __ __ mcg/mg

e. Is the participant currently using LABA or tiotropium/Spiriva? ❑ Yes ❑ No

➔ ***Compare d to values on the ICS Dose and Step Determination reference card (P5_ICS_DOSE_STEP). Record ICS dose level in Q3.***

➔ ***Use P5_ICS_DOSE_STEP to determine the participant's current asthma guideline therapy step. Record in Q4.***

3. Participant's current ICS dose level **(1020)**
❑$_1$ Low
❑$_2$ Medium
❑$_3$ High

4. Participant's current asthma guideline therapy step **(1030)** __

➔ ***Individuals on step 2 or 3 therapy will begin the run-in on 1xICS (refer to P5_FLOVENT_DOSE).***
➔ ***Individuals on step 4 or 5 therapy will begin the run-in on 2-2.5xICS (refer to P5_FLOVENT_DOSE).***

5. Open-label Flovent® Diskus® to be dispensed at this visit **(1035)**
❑$_1$ FP 50 mcg
❑$_2$ FP 100 mcg
❑$_3$ FP 250 mcg

Clinic Use Only

6. Participant's ACT/C-ACT score at this visit __ __
   ➔ ***Total the values across all questions to get the overall score.***

6a. Is the participant's ACT/C-ACT score <20? **(1040)** ❑1 Yes ❑0 No

6ai. If ***YES***, is the participant's guideline step ≤ 4? **(1050)** ❑1 Yes ❑0 No
➔ Skip to Q7.

Complete Q6aii only if IRB approval <u>has NOT been obtained</u> for protocol version 24.0.

6aii. If ***NO***, is the participant's guideline step ≥ 3? **(1060)** ❑1 Yes ❑0 No

7. Based on input from the participant and the study physician, will the participant need to use intranasal steroids at any time during the study? **(1070)** ❑1 Yes ❑0 No

7a. If ***YES***, is the participant willing to use a single intranasal steroid at a stable dose continuously for the duration of the study? **(1080)** ❑1 Yes ❑0 No

8. Is the participant currently receiving allergen immunotherapy (e.g., allergy shots) other than an established maintenance regimen implemented continuously for a minimum of 3 months? **(1090)** ❑1 Yes ❑0 No

9. Has the participant smoked cigarettes, a pipe, cigar, marijuana, electronic cigarettes (e-cigs), or any other substance in the past year? **(1100)** ❑1 Yes ❑0 No

10. ***Age 18+ Track Only:*** Does the participant have a smoking history less than 10 pack-years? **(1110)** ❑1 Yes ❑0 No

11. ***Age 5-11 and 12-17 Tracks Only:*** Does the participant have a smoking history less than 5 pack-years? **(1120)** ❑1 Yes ❑0 No

12. Is the participant potentially able to bear children? (*If participant is male, check N/A and skip to Q13)* **(1130)** ❑1 Yes ❑0 No ❑9 N/A

12a. If ***YES***, is the participant currently pregnant or lactating? **(1140)** ❑1 Yes ❑0 No

12b. If ***YES***, does the participant agree to use one of the approved methods indicated on the Birth Control Methods reference card (BIRTH_CTRL) for the duration of the study? **(1150)** ❑1 Yes ❑0 No

13. Does the participant have current evidence of any of the conditions listed on the Exclusionary Medical Conditions reference card (P5_EXCLMED), or any chronic diseases (other than asthma) that would prevent participation in the trial or put the participant at risk by participation? **(1160)** ❑1 Yes ❑0 No

    13a. If ***YES***, describe: **(1160D)** _____

    _____

14. During the past 2 weeks, has the participant used any medications known to significantly interact with corticosteroid disposition (e.g., carbamazepine, erythromycin or other macrolide antibiotics, phenobarbital, phenytoin, rifampin, ketoconazole)? **(1170)** ❑1 Yes ❑0 No

15. Has the participant used any of the drugs listed on the Exclusionary Drugs reference card (P5_EXCLDRUG) during the designated washout periods? **(1180)** ❑1 Yes ❑0 No

    15a. If ***YES***, list: **(1180D)** _____

    _____

16. Is the participant currently taking prescription or OTC medication(s) other than those listed on the Allowed Medications reference card (P5_MEDALLOW)? **(1190)** ❑1 Yes ❑0 No

    16a. If ***YES***, list: **(1190D)** _____

    _____

17. Is the participant eligible to proceed? **(1200)** ❑1 Yes ❑0 No

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

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

Participant/Guardian Source Documentation

Participant/Guardian Initials: __ __ __ **(1210)**

Date: __ __ / __ __ / 20 __ __ **(1220)**
MM DD YYYY

COMMENTS: **(6000)**

_____

_____

AsthmaNet

BARD ELIGIBILITY CHECKLIST 3

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

(Coordinator Completed)

Section 1: Spirometry

1. Is the participant able to perform reproducible spirometry according to ATS criteria? **(1000)** ❑1 Yes ❑0 No
   ➔ If ***NO***, STOP HERE. Participant is ineligible for the study.

2. Is the participant's pre-bronchodilator (baseline) FEV_1 ≥ 40% of predicted? **(1010)** ❑1 Yes ❑0 No

3. Is the participant's post-bronchodilator (after 4 puffs of albuterol) FEV_1 ≥ 40% of predicted? **(1020)** ❑1 Yes ❑0 No

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

If <u>both</u> of the shaded boxes in Q2 and Q3 are completed, the participant is ineligible.

➔ **If *YES*, continue with remaining visit procedures and complete Section 2.**
➔ **If *NO*, STOP HERE.**

Section 2: Spirotel® and Inhaler Technique

5. 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)? **(1040)** ❑1 Yes ❑0 No

6. Is the participant able to use a metered dose inhaler (MDI) properly, as evidenced by achieving a score of 11 on the MDI Inhalation Technique Checklist (Without Spacer) (TECH_MDI_NOSP) or a score of 12 on the MDI Inhalation Technique Checklist (With Spacer) (TECH_MDI_SP)? **(1050)** ❑1 Yes ❑0 No

7. Is the participant able to use a Diskus® properly, as evidenced by achieving a score of 10 on the Diskus® Inhalation Technique Checklist (TECH_DISKUS)? **(1060)** ❑1 Yes ❑0 No

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

If any of the shaded boxes in Section 2 is completed, the participant is ineligible.

➔ **If *YES*, continue with remaining visit procedures and complete Section 3.**
➔ **If *NO*, STOP HERE.**

P5 ELIG3

Section 3: Asthma Verification

9. Did the participant's FEV_1 improve ≥ 12% in response to four puffs of albuterol (as part of the pre/post procedure at this visit)? **(1080)** ❑$_1$ Yes ❑$_0$ No

10. Does the participant have valid source documentation within the past 12 months for an acceptable overread AsthmaNet albuterol reversibility test (AsthmaNet systems and procedures only) showing an improvement of ≥ 12% in response to albuterol? **(1090)** ❑$_1$ Yes ❑$_0$ No
    ➔ If ***NO***, skip to Q11.

    10a. Pre-bronchodilator FEV_1 **(1100)** __ . __ __ liters

    10b. Post-bronchodilator FEV_1 **(1110)** __ . __ __ liters

    10c. Total bronchodilator puffs administered **(1120)** __ __ puffs

    10d. Source documentation date **(1130)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

    10e. Technician ID **(1140)** __ __ __ __

    10f. Supervisor ID, if applicable **(1150)** __ __ __ __

11. Does the participant have valid source documentation within the past 12 months of two acceptable overread spirograms reflecting an absolute relative change in % predicted FEV_1 of ≥ 12% (AsthmaNet systems and procedures only)? **(1160)** ❑$_1$ Yes ❑$_0$ No
    ➔ If ***NO***, skip to Q12.

    11a. % predicted FEV_1 (first test) **(1170)** __ __ __ %

    11b. Source documentation date (first test) **(1180)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

    11c. Technician ID (first test) **(1190)** __ __ __ __

    11d. Supervisor ID, if applicable (first test) **(1200)** __ __ __ __

    11e. % predicted FEV_1 (second test) **(1210)** __ __ __ %

    11f. Source documentation date (second test) **(1220)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

    11g. Technician ID (second test) **(1230)** __ __ __ __

    11h. Supervisor ID, if applicable (second test) **(1240)** __ __ __ __

12. Does the participant have valid source documentation within the past 12 months for an acceptable overread AsthmaNet methacholine challenge (AsthmaNet systems, methacholine, and procedures only) with a $PC_{20} \leq 16$ mg/ml (on ICS) or a $PC_{20} \leq 8$ mg/ml (off ICS)? **(1250)** ❑1 Yes ❑0 No
    ➔ If ***NO***, skip to Q13.

    12a. ICS status at time of challenge **(1255)** ❑1 on ICS ❑2 off ICS

    12b. PC_{20} **(1260)** __ __ . __ __ mg/ml

    12c. Source documentation date **(1270)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

    12d. Technician ID **(1280)** __ __ __ __

    12e. Supervisor ID, if applicable **(1290)** __ __ __ __

13. Is the participant eligible for the study? **(1300)** ❑1 Yes ❑0 No

If <u>all</u> of the shaded boxes in Section 3 are completed, the participant has not yet met eligibility criteria concerning asthma verification. Results from spirometry and/or the methacholine challenge at Visit 0B must confirm eligibility for the participant to continue beyond 0B. Answer Q13 'No'.

If <u>any</u> of the shaded boxes in Section 3 is not completed, the participant has met asthma verification eligibility criteria. Answer Q13 'Yes'.

➔ **Continue with Section 4.**

Section 4: Relatives

14. Does the participant know of any first-degree blood relatives (i.e., parents, children, siblings/half-siblings) who have enrolled in BARD and successfully completed Screen Visit A (0A)? **(1310)** ❑1 Yes ❑0 No

    14a. If ***YES***, are any of the relatives the participant's identical siblings? **(1320)** ❑1 Yes ❑0 No
    ➔ If ***YES***, the participant is ineligible. STOP HERE.
    ➔ If ***NO***, complete the Biological Relative Tracking (P5_RELATIVE) form.

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

BARD ELIGIBILITY CHECKLIST 4

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

(Coordinator Completed)

1. Did the participant meet the asthma verification criteria at Visit 0A? **(1000)** ❑1 Yes ❑0 No

   ➔ If Q13 on P5_ELIG3 is answered 'Yes', then answer Q1 'Yes'.
   ➔ If ***YES***, STOP HERE and continue with remaining visit procedures.
   ➔ If ***NO***, continue with Q2.

2. Does the participant qualify for a methacholine challenge by the criteria on the METHACHK_ADULT (Age 18+ Track) or METHACHK_PED (Age 5-11 and Age 12-17 Tracks) form? **(1010)** ❑1 Yes ❑0 No

   ➔ If ***NO***, skip to Q4.

3. Does the participant have a methacholine $PC_{20} \leq 16$ mg/ml? **(1020)** ❑1 Yes ❑0 No

4. Does the participant's baseline (pre-methacholine) % predicted FEV_1 reflect an absolute relative change of ≥ 12% as compared to his or her <u>baseline</u> (pre-albuterol) % predicted FEV_1 at Visit 0A? **(1030)** ❑1 Yes ❑0 No

5. Does the participant's baseline (pre-methacholine) % predicted FEV_1 reflect an absolute relative change of ≥ 12% as compared to his or her <u>post-albuterol</u> % predicted FEV_1 at Visit 0A? **(1040)** ❑1 Yes ❑0 No

6. Is the participant eligible to proceed? **(1050)** ❑1 Yes ❑0 No

   If any of Q3-Q5 is answered 'Yes,' the participant is eligible.

   ➔ **If *YES*, continue with remaining visit procedures.**
   ➔ **If *NO*, STOP HERE. The participant is ineligible for the study. Complete a Termination of Study Participation (P5_TERM) form.**

COMMENTS: (6000)

_____

_____

_____

P5 ELIG4

AsthmaNet

BARD ELIGIBILITY CHECKLIST 5

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

(Coordinator Completed)

1. Since enrollment, has the participant received treatment with any excluded medications (P5_EXCLDRUG)? **(1000)** ❑1 Yes ❑0 No

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

   _____

2. Does the participant wish to withdraw consent? **(1010)** ❑1 Yes ❑0 No

3. Is there any new information that makes the participant ineligible according to the eligibility criteria? **(1020)** ❑1 Yes ❑0 No

   3a. If ***YES***, describe: **(1020D)** _____

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*, proceed with remaining visit procedures.**
➔ **If *NO*, STOP HERE. The participant is ineligible for the study. Complete a Termination of Study Participation (P5_TERM) form.**

COMMENTS: (6000)

_____

_____

_____

P5 ELIG5

AsthmaNet

BARD LABORATORY RESULTS

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

(Coordinator Completed)

(Complete Q1 and Q2 at Visit 1 only)

1. Local Lab Results: CBC with Differential Cell Count

   1a. WBC **(1000)** __ __ __ . __ K/µL

   1b. Eosinophils (absolute count) **(1010)** __ __ __ __ cells/µL

   1c. Eosinophils (differential) **(1020)** __ __ . __ %

   ➔ ***Forward the local lab report with the participant ID recorded to the DCC with this form. All identifying information on the report should be blackened out prior to sending it to the DCC.***

2. Denver Lab: Blood Sample for ImmunoCAP/Total IgE and Cotinine Measurements

   2a. Did you collect a blood sample (8 ml tiger-top tube) for these tests? **(1030)** ❑1 Yes ❑0 No
   ➔ If ***NO***, skip to Q3.

   2b. Was a serum sample processed? **(1040)** ❑1 Yes ❑0 No
   ➔ If ***NO***, skip to Q3.

   2bi. Was an aliquot labeled for ImmunoCAP/Total IgE? **(1050)** ❑1 Yes ❑0 No

   2bii. Was an aliquot labeled for cotinine? **(1060)** ❑1 Yes ❑0 No

   2biii. Number of aliquots labeled for storage/banking **(1070)** __

(Complete Q3 at Visits 0C, 0D, 1, 4, 7, 10, and 13 only)

Denver Lab: Overnight Urine Collection

➔ ***Complete Q3 for baseline samples obtained during the run-in at Visits 0C, 0D or 1 and for samples returned at the end of each treatment period (Visits 4, 7, 10, and 13). Each participant should have only one baseline sample.***

3. Did the participant return an overnight urine sample at this visit? **(1080)** ❑$_1$ Yes ❑$_0$ No
   ➔ If ***NO***, STOP HERE.

   3a. Total sample volume **(1090)** __ __ __ __ __ ml

   3b. Collection start date **(1100)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

   3c. Collection start time *(based on 24-hour clock)* **(1110)** __ __ __ __

   3d. Collection stop date **(1120)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

   3e. Collection stop time *(based on 24-hour clock)* **(1130)** __ __ __ __

   3f. Was an aliquot labeled for cortisol? **(1140)** ❑$_1$ Yes ❑$_0$ No

   3g. Was an aliquot labeled for creatinine? **(1150)** ❑$_1$ Yes ❑$_0$ No

   3h. Number of aliquots barcode labeled for storage/banking **(1160)** __

   ➔ ***Aliquots should be barcoded for storage/banking and entered into Biological Sample Tracking only for the <u>baseline</u> overnight sample.***

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

BARD PARTICIPANT STUDY TREATMENT QUESTIONNAIRE (Visits 1-13)

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

(Parent/Legal Guardian or Participant Completed)

This questionnaire is to be completed by the BARD participant or parent/guardian at Visits 4, 7, 10 and 13. If a randomized participant terminates prior to the end of a given treatment period, please ask the participant or parent/guardian to complete this form during the termination visit. If a participant achieves treatment arm drop-out or treatment failure status, or he/she has an exacerbation near the end of a treatment period, this form should be completed when he/she stops taking his/her blinded Diskus® and transitions to open-label Flovent®.

Coordinators should ensure that participants understand their choices for Question #2 before they begin to complete the form.

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

1. Who is the respondent?

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

(1000D) _____

2. **Blinded Scheduled Diskus® Contents**

As a BARD study participant, you were randomized to receive a Diskus® that contains one of the following treatments (per puff). The contents of the Diskus® change at certain points during the study. Please check the box next to the treatment that you believe you received **over the past 14 weeks.**

(1010)
- ❑1 fluticasone 100 mcg (Flovent® 100) *(Age 5-11 Track only)*
- ❑2 fluticasone 100 mcg + salmeterol 50 mcg (Advair® 100/50)
- ❑3 fluticasone 250 mcg (Flovent® 250)
- ❑4 fluticasone 250 mcg + salmeterol 50 mcg (Advair® 250/50)
- ❑5 fluticasone 500 mcg (Flovent® 500) *(Age 12-17 and Age 18+ Tracks Only)*

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

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

P5 PARTTXQX

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

(1030)
- ❑$_1$ I have no comments
- ❑$_2$ I noticed the following: *(Describe below)*

(1030D) _____

_____

_____

_____

Participant/Guardian Source Documentation

Participant/Guardian Initials: __ __ __ **(1040)**

Date: __ __ / __ __ / 20 __ __ **(1050)**
MM DD YYYY

AsthmaNet

BARD PULMONARY PROCEDURE CHECKLIST

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

(Parent/Legal Guardian or Participant Interview Completed)

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

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

11. Have you used any smokeless tobacco products today? **(1100)** ❑1 Yes ❑0 No
Examples: chewing tobacco, snuff

12. ***(Complete at Visit 0A)*** Have you used any long-acting inhaled beta-agonist in the past 24 hours? **(1110)** ❑1 Yes ❑0 No
Examples: salmeterol (Serevent, Advair), formoterol (Foradil, Symbicort, Dulera)

13. ***(Complete at Visits 2-13)*** Have you used your blinded scheduled Diskus® in the past 12 hours? **(1120)** ❑1 Yes ❑0 No ❑9 N/A

➔ **If participant is currently taking open-label Flovent®, answer N/A.**

14. 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

15. Is there any other reason you should not proceed with spirometry testing? **(1140)** ❑1 Yes ❑0 No
If ***YES,*** explain: **(1140D)** _____
_____

16. Is the participant eligible to proceed with the spirometry testing? **(1150)** ❑1 Yes ❑0 No

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

➔ **If *YES*, proceed to Q17 or the next form/procedure listed on the visit procedure checklist.**

If participant is in the Age 18+ Track and is less than 21 years old, complete Q17 at Visits 0A1, 0B, 0C/0D (if methacholine challenge is being performed), and 1-12.

At Visits 0A and 13, refer to height recorded on the Adult Body Measurements (BODYMEAS_ADULT) form; do not record on this form.

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

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

BARD RANDOMIZATION ELIGIBILITY CHECKLIST

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

(Coordinator Completed)

Complete Q1 and Q2 at Visit 1 Only. At Visits 0B, 0C, and 0D, skip to Q3.

1. Did the participant receive prednisone or another systemic corticosteroid during the run-in for treatment of an exacerbation or for an unrelated adverse event or any other reason? **(1000)** ❑1 Yes ❑0 No

   1a. If ***YES***, date of final dose of prednisone or other systemic corticosteroid **(1010)** __ __ / __ __ / 20 __ __ (MM DD YYYY)

   1b. If ***YES***, as of today, has the participant washed out from the final dose of prednisone or other systemic corticosteroid for at least 14 days? **(1020)** ❑1 Yes ❑0 No

   ➔ **If *NO*, Visit 1 needs to be delayed until the washout has been met. Stop the current visit and reschedule accordingly.**

2. Was the participant fully qualified for randomization on a P5_RAND_ELIG form at a prior screen visit? **(1025)** ❑1 Yes ❑0 No

   2a. If ***YES***, at which visit did the participant meet all randomization criteria? **(1030)** __ __
   ➔ **If Q2 is answered *YES*, skip to Q4.**

Section 1: Eligibility for Randomization Visit

3. Since the last visit, has the participant met 'lack of asthma control' conditions according to the information on the Spirotel® Eligibility Assessment Report (P5_ELIG_RPT)? **(1035)** ❑1 Yes ❑0 No

   ➔ **If the 'Lack of Asthma Control' column of the report indicates that lack of asthma control criteria were met on any of the days since the last visit, then answer Q3 'Yes'. If the participant required rescheduling of Visit 0B due to noncompliance, examine only the days following the previous 0B upload (i.e., days corresponding to the 2 week extension).**

4. E-Diary and Peak Flow Compliance for Eligibility

   4a. Has the participant completed at least 75% of the AM and PM sessions, including peak flows, since the last visit? **(1040)** ❑1 Yes ❑0 No ❑9 N/A

   ➔ **Refer to the Spirotel® Eligibility Assessment Report generated at this visit. If the participant required rescheduling of Visit 0B due to noncompliance, refer to the report that summarizes compliance since the previous 0B upload. At Visit 1, if only one day separated current visit from previous visit and there are no full days on which to assess this criterion, answer Q4a 'N/A.'**

P5 RAND ELIG

5. Diskus® Compliance

5a. Number of scheduled puffs since the last visit **(1050)** __ __ __ puffs

5b. Number of remaining puffs reflected on Diskus® counter(s) **(1060)** __ __ __ puffs

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

5c. Number of puffs taken **(1070)** __ __ __ puffs

➔ **If the same Diskus® was used across two visits, then the number of puffs taken is calculated as: Q5b (previous P5_RAND_ELIG) – Q5b (current P5_RAND_ELIG).**

➔ **If new Diskus(es)® were dispensed, then the number of puffs taken is calculated as: 60 x (# used Diskuses®) – Q5b.**

5d. Percent compliance = $\frac{Q5c}{Q5a}$ X 100 **(1080)** __ __ __ . __ %

5e. Has the participant taken at least 75% of the scheduled puffs from his/her Diskus® since the last visit? **(1090)** ❑1 Yes ❑0 No

6. Does the participant meet all eligibility criteria to schedule/complete the randomization visit (Visit 1)? **(1100)** ❑1 Yes ❑0 No

If any shaded boxes are completed, the participant may be ineligible to complete Visit 1.

➔ **If *YES*, then continue with Section 2 of this form.**

Visit 0B:

➔ **If *NO*, and the only gray box selected is for Q1035 (Q1035 = 0), complete Section 2 of this form. If Q1150 is answered Yes, complete Visit 0B and schedule Visit 0C.**

➔ **If *NO*, and the participant has not met both compliance criteria and this is his/her first attempt at Visit 0B, then complete Section 2 of this form. If Q1150 is answered Yes, retrain him/her on e-diary and peak flow procedures and Diskus® dosing, rerun the Visit 0A Visit Scheduler Report, and reschedule Visit 0B in 2 weeks. Enter this form as a single form at Visit 0B.**

➔ **If *NO*, and the participant has not met both compliance criteria and this is his/her second attempt at Visit 0B due to noncompliance, then he/she has failed to meet compliance requirements for two visits and is ineligible for further study participation. Complete Section 2 of this form and complete a Termination of Study Participation (P5_TERM) form. The participant is ineligible to continue regardless of the response to Q1150. Enter this form with the 0B packet.**

Visit 0C:

➔ **If *NO* and the participant has not failed to meet compliance criteria for two visits, then complete Section 2 of this form. If Q1150 is answered Yes, complete Visit 0C and schedule Visit 0D.**

➔ **If *NO* and the participant has failed to meet compliance criteria at two visits, then he/she is ineligible to continue. Complete Section 2 of this form and complete a Termination of Study Participation (P5_TERM) form. The participant is ineligible to continue regardless of the response to Q1150. Enter this form with the 0C packet.**

Visit 0D:

➔ **If *NO*, and this is Visit 0D, then the participant has reached the end of the run-in and is ineligible. Complete Section 2 of this form and complete a Termination of Study Participation (P5_TERM) form. The participant is ineligible to continue regardless of the response to Q1150. Enter this form with the 0D packet.**

Visit 1:

➔ **If *NO*, and this is Visit 1, and the participant was fully qualified for randomization at a prior screen visit (Q2 is answered 'Yes'), then continue with Section 2 of this form. Counsel participant on e-diary and/or Diskus® compliance, as appropriate.**

Section 2: Run-In Exacerbation Assessment

7. Has the participant experienced at least 1 asthma exacerbation requiring treatment with systemic corticosteroids since the last visit? **(1110)** ❑$_1$ Yes ❑$_0$ No

➔ **If *NO*, skip to Q8.**

7a. Did any of the exacerbations require hospitalization? **(1120)** ❑$_1$ Yes ❑$_0$ No

7b. Has the participant had three exacerbations during the run-in? **(1130)** ❑$_1$ Yes ❑$_0$ No

7c. Was the participant noncompliant with ICS dosing or e-diary/PEF completion as recorded in Q4 and Q5 above? **(1140)** ❑$_1$ Yes ❑$_0$ No

8. Does the participant meet eligibility criteria to continue in the study based on the run-in exacerbation assessment? **(1150)** ❑$_1$ Yes ❑$_0$ No

If any shaded boxes in Section 2 are completed, the participant is ineligible for the study.

➔ **If *NO*, complete a Termination of Study Participation (P5_TERM) form.**

➔ **If *YES*, but Q1100 is answered 'No', refer to the instructions in the gray box for Q6.**

➔ **If *YES*, continue with the current visit if the participant has been deemed eligible according to Q1100, or continue to Visit 1 if the participant has been deemed eligible at Visit 0C or 0D and can proceed with randomization today.**

COMMENTS: (6000)

_____

_____

AsthmaNet

BARD SIGNIFICANT ASTHMA EXACERBATION

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

(Coordinator Completed)

Complete this form each time a participant experiences an asthma exacerbation according to the definition below.

1. Did the participant experience a worsening of his/her asthma that required a prescription for a systemic corticosteroid to prevent a serious outcome? **(1000)** ❑1 Yes ❑0 No

   1a. If ***YES***, was the course of systemic corticosteroids separated from any previous courses for treatment of worsening asthma by at least 7 days? **(1010)** ❑1 Yes ❑0 No

2. Did the participant experience a new significant asthma exacerbation? **(1020)** ❑1 Yes ❑0 No

   If both of the shaded boxes above are completed, the participant experienced a new exacerbation event.

   ➔ **If *YES*, complete the rest of this form and record the event 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 enter or submit this form to the DCC.**

3. Date systemic corticosteroids were prescribed/started for exacerbation conditions **(1030)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

4. Has the participant been prescribed any of the following medications (excluding study Diskus®) since exacerbation conditions started? **(1040)** ❑1 Yes ❑0 No
   ➔ If ***YES*** to any of Q4a-Q4f, complete the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form.

   4a. Inhaled corticosteroids **(1050)** ❑1 Yes ❑0 No

   4b. Nebulized bronchodilator **(1060)** ❑1 Yes ❑0 No

   4c. Oral corticosteroids **(1070)** ❑1 Yes ❑0 No

   4ci. If ***YES***, total days of treatment for this event **(1080)** __ __ days

   4d. IM or IV steroids **(1090)** ❑1 Yes ❑0 No

4e. Antibiotics **(1100)** ❑1 Yes ❑0 No

4f. Other (describe) **(1110)** ❑1 Yes ❑0 No

(1110D) _____

5. Did the participant seek care for exacerbation conditions? **(1120)** ❑1 Yes ❑0 No

➔ If ***NO*** and participant is randomized, **skip to Q8**.
➔ If ***NO*** and participant is not yet randomized, **skip to Q12**.

6. What type of care was sought?

6a. Study Investigator or Coordinator? **(1130)** ❑1 Yes ❑0 No

6ai. If ***YES***, indicate type of contact **(1140)** ❑1 Scheduled clinic visit ❑2 Unscheduled clinic visit ❑3 Phone contact

6b. Primary Care or Other Physician? **(1150)** ❑1 Yes ❑0 No

6bi. If ***YES***, indicate the type of contact **(1160)** ❑1 Scheduled clinic visit ❑2 Unscheduled clinic visit ❑3 Phone contact

6c. Emergency Department visit? **(1170)** ❑1 Yes ❑0 No

6d. Urgent care visit? **(1180)** ❑1 Yes ❑0 No

7. Was the participant hospitalized? **(1190)** ❑1 Yes ❑0 No
➔ If ***YES***, complete the Serious Adverse Event Reporting Form (SERIOUS).

If ***YES***,

7a. Duration of hospital stay **(1200)** __ __ . __ days

7b. Was intubation or ventilation assistance required? **(1210)** ❑1 Yes ❑0 No

7c. Was the participant admitted to the intensive care unit? **(1220)** ❑1 Yes ❑0 No

➔ If participant is not yet randomized, **skip to Q12**.

(Visits 1-13 only) **Treatment Failure Assessment for Randomized Participants**

8. Has the participant been prescribed 10 or more days of prednisone treatment for asthma exacerbation(s) during the current treatment period? **(1230)** ❑1 Yes ❑0 No

9. Did the participant experience two distinct exacerbations during the current treatment period? **(1240)** ❑1 Yes ❑0 No

10. Did the participant experience treatment failure? **(1250)** ❑1 Yes ❑0 No

If any of the shaded boxes in Q7, Q8 or Q9 is completed, the participant is considered a treatment failure.

➔ **If *YES*, record the treatment failure event on the Clinical Adverse Events (AECLIN) form using ICD-9 code 000.00 and complete the rest of this form.**

➔ **If *YES*, the participant should stop dosing from his/her current blinded scheduled Diskus® and should be given open-label 5xICS (Age 5-11 Track: 250 mcg BID; Age 12-17 Track and Age 18+ Track: 500 mcg BID). While on 5xICS, the participant will wash out for 14-21 days from the final dose of prednisone and then complete the first visit of the next treatment period.**

➔ **If *NO*, skip to Q12.**

11. Date treatment failure conditions were met **(1260)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

12. Physician Narrative Assessment

_____

_____

_____

_____

_____

Physician Source Documentation

Physician's Signature: _____ **(1270)**

Printed Name: _____

Date: __ __ / __ __ / 20__ __ (MM / DD / YYYY) **(1280)**

Time: __ __ __ __ *(based on a 24-hour clock)* **(1290)**

COMMENTS: (6000)

_____

_____

_____

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

Q1. Number of times the participant woke up last night due to asthma symptoms	__ (numeric 0 – 9)
Q2. Number of puffs the participant will take from the study Diskus® this morning	__ (numeric 0 – 9)
Q3. Has the participant taken any puffs from his/her RESCUE albuterol inhaler in the past 4 hours?	__ (1 = Yes, 0 = No)

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

Q4. Shortness of Breath score	__ (0, 1, 2, 3)
Q5. Chest tightness score	__ (0, 1, 2, 3)
Q6. Wheezing score	__ (0, 1, 2, 3)
Q7. Coughing score	__ (0, 1, 2, 3)
Q8. Phlegm/Mucus score	__ (0, 1, 2, 3)

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

Q9. Number of puffs the participant will take from the study Diskus® tonight	__ (numeric 0 – 9)
Q10. Has the participant taken any puffs from his/her RESCUE albuterol inhaler during the past 4 hours?	__ (1 = Yes, 0 = No)

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

Q11. Shortness of Breath score	__ (0, 1, 2, 3)
Q12. Chest tightness score	__ (0, 1, 2, 3)
Q13. Wheezing score	__ (0, 1, 2, 3)
Q14. Coughing score	__ (0, 1, 2, 3)
Q15. Phlegm/Mucus score	__ (0, 1, 2, 3)

Q16. Number of albuterol puffs taken in the past 24 hours to prevent symptoms (for example: before exercise, before smoke exposure, or before exposure to pets) __ __ (numeric 0 – 40)

Q17. Number of RESCUE albuterol puffs taken for asthma symptoms or low peak flow during past 24 hours __ __ (numeric 0 – 40)

Q18. Was the participant absent from daycare, school, or work during the past 24 hours due to asthma symptoms? __ (1 = Yes, 0 = No, 9 = N/A)

Q19. Was the participant seen by a healthcare provider (doctor's office, ER, urgent care, study site) for an unscheduled visit in the past 24 hours due to asthma symptoms? __ (1 = Yes, 0 = No)

Q20. Did the participant take prednisone in the past 24 hours for treatment of his/her asthma? __ (1 = Yes, 0 = No)

The spirotel® diary questions and peak flow (PEF) measurements are important records of your asthma treatment and condition. All diary questions must be answered to complete a session.

You will have 20 minutes to complete a scheduled AM or PM session. For specific instructions on how to use the spirotel® device refer to the How to Use Your spirotel® Electronic Diary and Peak Flow Meter (HTSPIROTEL) handout. Start completing diary assessments the night of your visit.

Scheduled Morning (AM) Evaluation: Turn on device between 4 AM and 1 PM. Device will ask 'Scheduled Session?'. Select Yes and select ">" on the screen to proceed.

1. # **Times woke up due to asthma**: The number of times you woke up last night due to asthma.
2. # **Puffs from study Diskus in AM**: The number of puffs you will take from the study Diskus this morning.
3. **Took RESCUE albuterol in past 4 hours?**: Have you taken any puffs from your RESCUE albuterol inhaler in the past 4 hours?

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

4. Shortness of Breath Score overnight
5. Chest Tightness Score overnight
6. Wheezing Score overnight
7. Coughing Score overnight
8. Phlegm/Mucus Score overnight

Review Diary Data? Press Yes and then ">" to review your responses. Press No and then ">" to save the responses and proceed to PEFs.

After you complete the diary questions, you will perform 3 PEF blows and the highest will be reported to you. The 'Highest PEF (L/M)' will have a "traffic light" indicator with it. The indicator will point to green if your PEF is good, yellow if your PEF is in the "caution" zone, and red if your PEF is less than your 50% PEF value.

Morning Alerts: You will receive an alert reminding you to take your morning medications. If your PEF is in the yellow or red zone, you will receive an alert to follow your Action Plan. During the Run-In you may receive an alert indicating that you might be ready for randomization. Please call your clinic after receiving the alert.

* See symptom score scale on back

Scheduled Evening (PM) Evaluation: Turn on device between 5 PM and 3 AM. Device will ask 'Scheduled Session?'. Select Yes and select ">" on the screen to proceed.

1. # **Puffs from study Diskus in PM**: The number of puffs you will take from the study Diskus tonight.
2. **Took RESCUE albuterol in past 4 hours?**: Have you taken any puffs from your RESCUE albuterol inhaler in the past 4 hours?

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

3. Shortness of Breath Score since waking this morning
4. Chest Tightness Score since waking this morning
5. Wheezing Score since waking this morning
6. Coughing Score since waking this morning
7. Phlegm/Mucus Score since waking this morning

Evening evaluation continues on the back.

* See symptom score scale on back

8. **#preventive puffs in 24 hours**: Number of albuterol puffs taken in the past 24 hours to prevent symptoms (for example: before exercise, before smoke exposure, or before exposure to pets)
9. **# RESCUE Puffs in 24 hours for asthma**: Number of RESCUE albuterol puffs taken for asthma symptoms or low peak flow during past 24 hours. Preventive RESCUE albuterol puffs (e.g., prior to exercise, smoke exposure, or exposure to pets) should not be counted when answering this question.
10. **Absent from work or school/daycare in past 24 hrs for asthma?**: Were you absent from daycare, school, or work/ housework during the past 24 hours due to asthma symptoms?
11. **Unscheduled visit in past 24 hours for asthma symptoms**: Were you seen by a healthcare provider (doctor's office, ER, urgent care, study site) for an unscheduled visit in the past 24 hours due to asthma symptoms?
12. **Prednisone for asthma treatment in past 24 hours?**: Did you take prednisone in the past 24 hours for treatment of your asthma?

Review Diary Data? Press Yes and then ">" to review your responses. Press No and then ">" to save the responses and proceed to PEFs.

After you complete the diary questions, you will perform 3 PEF blows and the highest will be reported to you with traffic light indicator.

Evening Alerts: You will receive an alert reminding you to take your evening medications. If your PEF is in the yellow or red zone, you will receive an alert to follow your Action Plan. During the Run-In you may receive an alert indicating that you might be ready for randomization. Please call your clinic after receiving the alert.

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

AsthmaNet

BARD spirotel® Reference Card

01/13/2014 Version 1.0 P5_SPIROTEL_REF

AsthmaNet

BARD ICS STEP-DOWN ASSESSMENT

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

(Coordinator Completed)

Section 1: Eligibility for Study

1. Since Visit 0A, has the participant experienced an asthma exacerbation requiring treatment with systemic corticosteroids? **(1000)** ❑1 Yes ❑0 No

Complete Q2 only if IRB approval <u>has NOT yet been obtained</u> for protocol version 23.0.

2. Has the participant met 'lack of asthma control' conditions according to the information on the Spirotel® Eligibility Assessment Report (P5_ELIG_RPT)? **(1010)** ❑1 Yes ❑0 No

   ➔ ***If the 'Lack of Asthma Control' column of the report indicates that lack of asthma control criteria were met on any of the days since the participant enrolled at 0A, then answer Q2 'Yes'.***

Complete Q3 only if IRB approval <u>has been obtained</u> for protocol version 23.0.

3. Does the participant have an ACQ score ≥ 1.50 at today's visit? **(1015)** ❑1 Yes ❑0 No

Clinic Use Only

Calculate the participant's ACQ score: sum the values across the 7 questions, then divide by 7. Round to the nearest hundredth.

__	+	__	+	__	+	__	+	__	+	__	+	__	=	__ __
Q1		Q2		Q3		Q4		Q5		Q6		Q7		Total

ACQ Score = Total / 7 = __ . __ __

4. Is the participant eligible to continue in the study? **(1020)** ❑1 Yes ❑0 No

   If any shaded box above is completed, the participant is ineligible for the study.

   ➔ **If *YES*, continue to Q5 and complete the remainder of this form.**

   ➔ **If *NO*, complete a Termination of Study Participation (P5_TERM) form.**

Section 2: Compliance Assessment

5. E-Diary and Peak Flow Compliance for Eligibility

5a. Has the participant completed at least 75% of the AM and PM sessions, including peak flows, since the last visit (Visit 0A or the initial attempt at Visit 0A1)? **(1040)** ❑$_1$ Yes ❑$_0$ No

➔ ***Refer to the Spirotel® Eligibility Assessment Report generated at this visit.***

6. Diskus® Compliance

6a. Number of scheduled puffs since the last visit (0A or initial attempt at 0A1) **(1050)** __ __ puffs

6b. Number of remaining puffs reflected on Diskus® counter **(1060)** __ __ puffs

6c. Number of puffs taken **(1070)** __ __ puffs

➔ ***If Visit 0A1 was rescheduled due to lack of compliance and the same Diskus® was used, then the number of puffs taken is calculated as: Q6b (previous P5_STEPDOWN_ASSESS) – Q6b (current P5_STEPDOWN_ASSESS).***

➔ ***If a new Diskus® was dispensed, then number of puffs taken is calculated as: 60 – Q6b.***

6d. Percent compliance = $\frac{\text{Q6c}}{\text{Q6a}}$ X 100 **(1080)** __ __ __ . __ %

6e. Has the participant taken at least 75% of the scheduled puffs from his/her Diskus® since Visit 0A or the initial attempt at Visit 0A1? **(1090)** ❑$_1$ Yes ❑$_0$ No

➔ ***If the participant has taken less than 75% of the prescribed puffs, retrain him/her on the study dosing schedule.***

7. Is the participant eligible for step-down of his/her ICS dose to 1xICS? **(1100)** ❑$_1$ Yes ❑$_0$ No

If IRB approval <u>has been obtained</u> for protocol version 23.0, answer Q7 'Yes' regardless of compliance, then step the participant's ICS dose down to 1xICS for the remainder of the run-in (refer to P5_FLOVENT_DOSE) and continue to Q8. Complete Visit 0A1, run the Visit 0A1 Scheduler Report, and schedule Visit 0B.

If IRB approval <u>has not yet been obtained</u> for protocol version 23.0, follow the instructions below:

➔ ***If Q5a is 'No,' the participant is ineligible for the ICS dose reduction. Answer Q7 'No.'***

➔ **If *NO*, and this is the participant's first attempt at Visit 0A1, STOP HERE. Retrain him/her on e-diary and peak flow procedures (and Diskus® dosing, if necessary), rerun the Visit 0A Scheduler Report, and reschedule Visit 0A1 in 2 weeks. Enter this form as a 0A1 single form.**

➔ **If *NO*, and this is the participant's second attempt at Visit 0A1, then he/she has failed to meet compliance requirements for two visits and is ineligible for further study participation. STOP HERE and complete a Termination of Study Participation (P5_TERM) form. Enter this form with the 0A1 packet.**

➔ ***If Q5a is 'Yes,' the participant is eligible for the ICS dose reduction. Answer Q7 'Yes,' then step the participant's ICS dose down to 1xICS for the remainder of the run-in (refer to P5_FLOVENT_DOSE) and continue to Q8. Complete Visit 0A1, run the Visit 0A1 Scheduler Report, and schedule Visit 0B.***

8. Open-label Flovent® Diskus® to be dispensed at this visit **(1110)** ❑$_1$ FP 50 mcg ❑$_2$ FP 100 mcg

COMMENTS: (6000)

_____

_____

_____

AsthmaNet	BARD TERMINATION OF STUDY PARTICIPATION (Visits 0A-0D and 1-13)	Part. ID: __ __ - __ __ __ - __ __ __ Part. Initials: __ __ __ Visit: __ __ __ Visit Date: __ __ / __ __ / 20 __ __ Coordinator ID: __ __ __ __

(Coordinator Completed)

Complete this form only for participants who successfully completed Visit 0A and formally entered the run-in.

1. Has the participant completed the study through Visit 13? **(1000)** ❑$_1$ Yes ❑$_0$ No
   ➔ If ***YES***, skip to the SIGNATURES section.

2. Who initiated termination of the participant? **(1010)** ❑$_1$ Participant ❑$_2$ Clinical Staff
   ➔ ***If participant withdrew due to impending clinical staff termination, indicate termination by clinical staff.***
   ➔ ***If Clinical Staff, skip to Q4.***

3. Indicate the **primary** reason the participant has withdrawn from the study or the participant's parent/guardian has withdrawn consent.

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

***Additional explanation required:** **(1020D)**

_____

_____

➔ ***Skip to the SIGNATURES section.***

4. Did clinical staff terminate the participant due to… (*Select **YES** for all that apply)*

4a.	pregnancy? *(Check N/A if participant is male.)* ➔ If ***YES***, make arrangements to follow up with participant to gather information on pregnancy outcome.	**(1030)**	❑$_1$ Yes	❑$_0$ No ❑$_9$ N/A
4b.	loss to follow-up?*	**(1040)**	❑$_1$ Yes	❑$_0$ No
	4bi. If ***YES***, date of last contact with participant	**(1050)**	__ __ / __ __ / 20 __ __ (MM / DD / YYYY)	
	4bii. If ***YES***, type of contact	**(1060)**	❑$_1$ In-person visit ❑$_2$ Phone call	
4c.	an asthma-related adverse event?*	**(1070)**	❑$_1$ Yes	❑$_0$ No
4d.	a medication-related adverse event?*	**(1080)**	❑$_1$ Yes	❑$_0$ No
4e.	an adverse event not related to asthma or medications?*	**(1090)**	❑$_1$ Yes	❑$_0$ No
4f.	non-compliance with medication dosing?*	**(1100)**	❑$_1$ Yes	❑$_0$ No
4g.	non-compliance with diary completion?*	**(1110)**	❑$_1$ Yes	❑$_0$ No
4h.	non-compliance with visit attendance?*	**(1120)**	❑$_1$ Yes	❑$_0$ No
4i.	non-compliance with peak flow monitoring?*	**(1130)**	❑$_1$ Yes	❑$_0$ No
4j.	significant asthma exacerbation or lack of control criteria met while on 2-2.5xICS (Visit 0A1)?*	**(1140)**	❑$_1$ Yes	❑$_0$ No
4k.	participant reached end of run-in without meeting lack of asthma control criteria (Visit 0D)?	**(1150)**	❑$_1$ Yes	❑$_0$ No
4l.	ineligibility during the run-in (Visits 0A-1) for reasons other than compliance or failure to meet lack of control criteria?*	**(1160)**	❑$_1$ Yes	❑$_0$ No
4m.	recruitment ended?	**(1170)**	❑$_1$ Yes	❑$_0$ No
4n.	physician determination that study continuation is not in participant's best interest?*	**(1180)**	❑$_1$ Yes	❑$_0$ No
4o.	treatment failure during period 4?*	**(1185)**	❑$_1$ Yes	❑$_0$ No
4p.	hypoxic seizure due to asthma?*	**(1190)**	❑$_1$ Yes	❑$_0$ No

4q. intubation due to asthma?* **(1200)** ❑1 Yes ❑0 No

4r. need for long-term systemic corticosteroids for illness other than asthma?* **(1210)** ❑1 Yes ❑0 No

4s. other reason?* **(1220)** ❑1 Yes ❑0 No

***Additional explanation required: (1230D)**

_____

_____

_____

4t. Indicate the letter (a - s) corresponding to the **primary** reason the participant was terminated. **(1240)** __

SIGNATURES

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

I verify that all information collected on the AsthmaNet BARD 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.

_____ **(1250)** __ __ / __ __ / 20 __ __ **(1260)**
Coordinator Signature MM DD YYYY

_____ **(1270)** __ __ / __ __ / 20 __ __ **(1280)**
Site Investigator Signature MM DD YYYY