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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.

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

AECLIN

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 HISTORY

11. Did the participant's mother smoke 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?

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. 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 smokers in any household in which the participant spent time? (Include any households the participant regularly spent time in.) **(1650)** ❑1 Yes ❑0 No ❑8 Don't Know
➔ If ***NO or DON'T KNOW***, skip to Q14.

13a. Did the participant's mother (or stepmother or female guardian) smoke? **(1660)** ❑1 Yes ❑0 No ❑8 Don't Know

13b. Did the participant's father (or stepfather or male guardian) smoke? **(1670)** ❑1 Yes ❑0 No ❑8 Don't Know

13c. Were there any other smokers in the household? **(1680)** ❑1 Yes ❑0 No ❑8 Don't Know

14. At the present time, are there any smokers in any household in which the participant spends time? (Include any households the participant regularly spends time in.) **(1690)** ❑1 Yes ❑0 No ❑8 Don't Know

➔ If ***NO or DON'T KNOW***, ***STOP HERE***.

14a. Does the participant's mother (or stepmother or female guardian) smoke? **(1700)** ❑1 Yes ❑0 No ❑8 Don't Know

14b. Does the participant's father (or stepfather or male guardian) smoke? **(1710)** ❑1 Yes ❑0 No ❑8 Don't Know

14c. Are there any other smokers in the household? **(1720)** ❑1 Yes ❑0 No ❑8 Don't Know

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

CONCOMITANT MEDICATIONS FOR ASTHMA/ALLERGY AND ADVERSE EVENTS

(Coordinator completed)

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

Part. Initials: __ __ __

Visit: __ __ __

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

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

☐0 None

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

AsthmaNet

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)

_____

_____

_____

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

EFFECTS OF A CHILD'S ASTHMA FLARE-UP ON THE PARENTS

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

This deals with your child's **current flare-up only** (Please shade in one circle for **EACH** question)

SECTION A – please respond to all the questions

			Not at all			Moderately			Extremely	Cannot Answer
			⬇			⬇			⬇	
During my child's flare-up, I felt:			**0**	**1**	**2**	**3**	**4**	**5**	**6**	**9**
1.	Sad	**(1000)**	○	○	○	○	○	○	○	○
2.	Stressed	**(1010)**	○	○	○	○	○	○	○	○
3.	Nervous	**(1020)**	○	○	○	○	○	○	○	○
4.	Tired	**(1030)**	○	○	○	○	○	○	○	○
5.	Sorry for my child	**(1040)**	○	○	○	○	○	○	○	○

SECTION B

			Not at all			Moderately			Extremely	Cannot Answer
			⬇			⬇			⬇	
During my child's flare-up, I was concerned:			**0**	**1**	**2**	**3**	**4**	**5**	**6**	**9**
6.	About how severe the asthma flare-up could get.	**(1050)**	○	○	○	○	○	○	○	○
7.	That my child may lack oxygen.	**(1060)**	○	○	○	○	○	○	○	○
8.	About not being able to control the asthma flare-up at home.	**(1070)**	○	○	○	○	○	○	○	○
9.	About the possible lack of effectiveness of the asthma medication used for the flare-up.	**(1080)**	○	○	○	○	○	○	○	○
10.	About having difficulty assessing the severity of the asthma flare-up.	**(1090)**	○	○	○	○	○	○	○	○
11.	About a possibly long stay in the emergency, at the clinic, or at the hospital.	**(1100)**	○	○	○	○	○	○	○	○
12.	About the risk of giving my child too much medication.	**(1110)**	○	○	○	○	○	○	○	○
13.	About the side effects of the medications used to control the flare-up.	**(1120)**	○	○	○	○	○	○	○	○
14.	That, in my absence, the person taking care of my child might not know what to do.	**(1130)**	○	○	○	○	○	○	○	○
15.	That, in my absence, the person taking care of my child might not know how to administer the medications properly.	**(1140)**	○	○	○	○	○	○	○	○

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AsthmaNet

EFFECTS OF A CHILD'S ASTHMA FLARE-UP ON THE PARENTS

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

Visit: __ __ __

SECTION C

		Never			Half the time			All the time	Cannot Answer
During my child's flare-up, I experienced:		**0**	**1**	**2**	**3**	**4**	**5**	**6**	**9**
16. The need to change my family's sleeping arrangements.	**(1150)**	○	○	○	○	○	○	○	○
17. A decrease in my ability to take care of my responsibilities at home.	**(1160)**	○	○	○	○	○	○	○	○
18. A loss of sleep in order to take care of my child.	**(1170)**	○	○	○	○	○	○	○	○
19. A loss of sleep because I worried for my child.	**(1180)**	○	○	○	○	○	○	○	○
20. A disruption in family activities because of the asthma flare-up.	**(1190)**	○	○	○	○	○	○	○	○
21. A decrease in the amount of time that I set aside for my own needs during my child's flare-up.	**(1200)**	○	○	○	○	○	○	○	○

SECTION D

Because your child is your first priority, it may be difficult to consider your personal needs and feelings when he or she is sick. Please answer the following question considering that this questionnaire specifically evaluates the effects of a child's flare-up upon the parents:

		Not at all			Moderately			Extremely
		0	**1**	**2**	**3**	**4**	**5**	**6**
22. Overall, how did this asthma flare-up affect you?	**(1210)**	○	○	○	○	○	○	○

SECTION E

During your child's flare-up:

23. How many days of work or regular planned activities did you miss because you had to take care of your child? **(1220)** __ __ days

24. To what extent were you able to go about performing your work or regular planned activities? **(1230)** __ __ __ %

25. Do you currently work for pay? **(1240)** ① Yes ⓪ No

26. This questionnaire was completed by: **(1250-1250D)** ① Mother ② Father ③ Other (specify) _____

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AsthmaNet

PEDIATRIC RESPIRATORY ASSESSMENT MEASURE

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

(Coordinator Completed)

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

2. Time PRAM was started (*based on 24-hour clock)* **(1010)** __ __ __ __

3. 0_2 Saturation in room air* (actual value) **(1015)** __ __ __ . __ %

*If oxygen supplementation, remove 0_2 supplementation until oximetry level has stabilized for 1 minute or saturation has reached 90%, whichever comes first.

4. Suprasternal retractions **(1030)**
   - ❑$_0$ Absent
   - ❑$_2$ Present

5. Scalene muscle contraction **(1040)**
   - ❑$_0$ Absent
   - ❑$_2$ Present

6. Air entry+ **(1050)**
   - ❑$_0$ Normal
   - ❑$_1$ Decreased at base
   - ❑$_2$ Widespread decrease
   - ❑$_3$ Minimal/Absent

7. Wheezing+ **(1060)**
   - ❑$_0$ Absent
   - ❑$_1$ Expiratory
   - ❑$_2$ Inspiratory with/without expiratory
   - ❑$_3$ Audible without stethoscope or absent with no air entry

+In case of asymmetry such as between left and right lung fields or between the anterior and posterior regions of a lung, then rate the worst side/region.

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* P R A M *

AsthmaNet

PRIOR CONDITIONS FOR ALL PARTICIPANTS

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

(Coordinator Completed by Interview)

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

1. Who is the respondent?

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

PRIOR DISEASES, ILLNESSES, AND SURGERIES

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

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

PRIOR COND ALL

If Yes, Comment

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

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

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

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

5. Stomach or Intestines

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

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

6. Sleep Disorder

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

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

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

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

COMMENTS: (6000)

_____

_____

_____

AsthmaNet

PRIOR ASTHMA/ALLERGY TREATMENT

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

(Coordinator Completed by Interview)

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

1. Who is the respondent?

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

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

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

PRIOR TRT

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

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

7. Inhaled Anticholinergic by Inhaler (**e.g., Atrovent, Combivent, Spiriva**) **(1220)** ❑1 Yes ❑0 No ❑9 Don't Know — __ __ / __ __ / 20 __ __ (1230) (1240) (1250)

8. Leukotriene Antagonist / 5LO Inhibitors (**e.g., Accolate, Zyflo, Singulair**) **(1260)** ❑1 Yes ❑0 No ❑9 Don't Know — __ __ / __ __ / 20 __ __ (1270) (1280) (1290)

9. IgE Blocker (**e.g., Xolair**) **(1300)** ❑1 Yes ❑0 No ❑9 Don't Know — __ __ / __ __ / 20 __ __ (1310) (1320) (1330)

10. Oral Steroids FOR ASTHMA (**e.g., Prednisone, Prelone, Pediapred, Medrol, Orapred, Decadron, dexamethasone**) **(1340)** ❑1 Yes ❑0 No ❑9 Don't Know — __ __ / __ __ / 20 __ __ (1350) (1360) (1370)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

COMMENTS: (6000)

_____

_____

_____

AsthmaNet

SERIOUS ADVERSE EVENT REPORTING FORM

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

(Coordinator Completed)

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

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

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

   Describe: **(1010D)** _____

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

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

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

6. Why was the event serious?

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

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

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

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

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

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

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

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

SERIOUS

6g. Cancer **(1130)** ❑1 Yes ❑0 No

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

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

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

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

6l. Other **(1180)** ❑1 Yes ❑0 No

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

7. What in your opinion caused the event?

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

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

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

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

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

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

(Investigator Completed)

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

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

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

10. If participant died, cause of death: _____

_____

11. Was an autopsy performed? ❑ Yes ❑ No

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

REPORTING INVESTIGATOR:

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

COMMENTS: (6000)

_____

_____

_____

Name: _____

Signature:_____

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

AsthmaNet

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.***

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

APRIL COMPLIANCE CHECKLIST

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

(Clinic Coordinator Completed)

1.	Has the participant used APRIL therapy since the last visit? ➔ If ***NO*****,** STOP HERE.	**(1000)**	❑$_1$ Yes ❑$_0$ No
2.	Date of APRIL therapy usage	**(1010)**	__ __ / __ __ / 20 __ __ MM DD YYYY
3.	How many bottles did the participant require? ➔ If participant required 2 bottles, **SKIP** to Q9.	**(1020)**	❑$_1$ 1 bottle ❑$_2$ 2 bottles
4.	Bottle Number	**(1030)**	2 – APR - __ __ __ __
5.	Bottle Weight	**(1040)**	__ __ __ gm
6.	Participant's Dose per day	**(1050)**	__ __ . __ ml
7.	Total Dosage = Q6 X 5 x 1.9	**(1060)**	__ __ __ . __ __ gm
8.	Adherence = ((74 – Q5)/Q7) x 100 ➔ STOP HERE.	**(1070)**	__ __ __ **.** __ %

For Adherence for 2 bottles, complete #9 - #16

9.	1st Bottle Number	**(1080)**	2 – APR - __ __ __ __
10.	1st Bottle Weight	**(1090)**	__ __ __ gm
11.	2nd Bottle Number	**(1100)**	2 – APR - __ __ __ __
12.	2nd Bottle Weight	**(1110)**	__ __ __ gm
13.	Total Weight = Q10 + Q12	**(1120)**	__ __ __ gm
14.	Participant's Dose per day	**(1130)**	__ __ . __ ml
15.	Total Dosage = Q14 x 5 x 1.9	**(1140)**	__ __ __ . __ __ gm
16.	Adherence = ((148 – Q13)/Q15) x 100	**(1150)**	__ __ __ . __ %

➔ If more than one APRIL therapy was used since the last visit, please complete a P2_APRIL_COMPLY form for each APRIL therapy usage.

COMMENTS: (6000)

_____

_____

AsthmaNet	TERMINATION OF APRIL (Treatment Phase)	Part. ID: __ __ - __ __ __ - __ __ __ Part. Initials: __ __ __ Visit: __ __ Visit Date: __ __ / __ __ / 20 __ __ Coordinator ID: __ __ __ __

(Coordinator Completed)

Please indicate the reason for termination of the study participant

1. Has the participant completed the APRIL study? **(1000)** ❑$_1$ Yes ❑$_0$ No
   ➔ If **YES**, skip to Q3.

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

(1010)
- ❑$_1$ participant deemed study failure
- ❑$_2$ parent withdrew consent
- ❑$_3$ no longer interested in participating**
- ❑$_4$ no longer willing to follow protocol**
- ❑$_5$ difficult access to clinic (location, transportation, parking)
- ❑$_6$ participant experienced a serious adverse event*
- ❑$_7$ unable to continue due to personal constraints**
- ❑$_8$ moving out of the area
- ❑$_9$ participant lost to follow up
- ❑$_{10}$ unable to make visits during clinic hours
- ❑$_{11}$ dissatisfied with asthma control
- ❑$_{12}$ side effects of study medications**
- ❑$_{13}$ unable to continue due to medical condition unrelated to asthma
- ❑$_{14}$ physician initiated termination of study participation**
- ❑$_{15}$ other**

*** Please complete the Serious Adverse Event Reporting (SERIOUS) form.**
****Additional explanation required: (1010D)**

_____

_____

_____

DO NOT COMPLETE Q3 AND Q3A AFTER THE PARENT HAS CONSENTED TO STOP OCELOT.

3. Is the participant proceeding to OCELOT? **(1020)** ❑$_1$ Yes ❑$_0$ No

   3a. If ***NO***, did the participant use 4 courses of APRIL treatment and did not proceed to OCELOT? **(1030)** ❑$_1$ Yes ❑$_0$ No

   ➔ If **YES**, Visit 9 should be scheduled 14 days after the last dose of APRIL therapy.

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

I verify that all information collected on the AsthmaNet APRIL 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.

_____ **(1040)** __ __ / __ __ / 20 __ __ **(1050)**
Coordinator Signature MM DD YY

_____ **(1060)** __ __ / __ __ / 20 __ __ **(1070)**
Project Investigator Signature MM DD YY

COMMENTS: (6000)

_____

_____

_____

AsthmaNet

APRIL STUDY TREATMENT QUESTIONNAIRE

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

(Coordinator and Parent/Guardian Completed)

If a randomized participant terminates prior to Visit 9, please ask his or her parent/guardian to complete this form during the termination visit.

Participant and Parent/Guardian should complete Q1 – Q5.

1. How well were your child's wheezing symptoms controlled during the APRIL study? **(1000)**
   - ❑1 Not at all
   - ❑2 Hardly at all
   - ❑3 Somewhat
   - ❑4 Fairly
   - ❑5 Very well

2. Did your child use APRIL therapy? **(1010)** ❑1 Yes ❑0 No
   ➔ If ***NO***, STOP HERE.

3. For the APRIL study, your child was randomized to receive either Azithromycin or placebo. Please check the box that most closely represents your feelings about which of the two treatments your child was receiving. **(1020)**
   - ❑1 Azithromycin
   - ❑2 Placebo

4. In general, did you have difficulty in having your child take the drug? **(1030)** ❑1 Yes ❑0 No

   4a. If ***YES***, what was the primary reason for the difficulty? **(1040)**
   - ❑1 Tasted bad
   - ❑2 Smelled bad
   - ❑3 Inconvenient
   - ❑4 Forgot
   - ❑5 Too busy
   - ❑6 Doesn't like medicine
   - ❑7 Just didn't want to
   - ❑8 Other (specify)

   (1040D) _____

5. Did the child have any stomach-related problems while taking APRIL therapy? **(1050)** ❑1 Yes ❑0 No
   ➔ If ***NO***, STOP HERE.

   5a. Stomach Ache **(1060)** ❑1 Yes ❑0 No

   5b. Nausea **(1070)** ❑1 Yes ❑0 No

   5c. Upset Stomach **(1080)** ❑1 Yes ❑0 No

   5d. Vomiting **(1090)** ❑1 Yes ❑0 No

   5e. Diarrhea/Loose Stools **(1100)** ❑1 Yes ❑0 No

P2 APRIL TRTQX

Study Coordinator should complete Q6.

6. In your opinion, which of the two treatments was the participant receiving?

(1110)
- ❑1 Azithromycin
- ❑2 Placebo
- ❑3 No idea

Clinic Coordinator Completed
COMMENTS: (6000)

_____

_____

_____

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

Part. Initials: __ __ __

APRIL RUN IN DIARY

Return Visit: __ __ __

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

Complete with blue or black ink		Day 1:__	Day 2:__	Day 3:__	Day 4:__	Day 5:__	Day 6:__	Day 7:__
Date (month/day)		__ / __	__ / __	__ / __	__ / __	__ / __	__ / __	__ / __
Complete each morning: Covers period of time from when your child went to bed for the night to when he/she awoke this morning.								
1. How much albuterol did your child use since being put to bed? (if none, enter '0')								
Albuterol Inhaler: number of puffs	**(1000)**	__ __	__ __	__ __	__ __	__ __	__ __	__ __
Albuterol by nebulizer: number of treatments	**(1010)**	__ __	__ __	__ __	__ __	__ __	__ __	__ __
Complete each night after child goes to bed: Covers period of time since your child awoke for the day.								
2. How severe was your child's cough today? 0 = No cough 3 = Moderate cough 1 = Very mild cough 4 = Severe cough 2 = Mild cough 5 = Very severe cough	**(1020)**	___	___	___	___	___	___	___
3. How severe was your child's wheezing today? 0 = No wheezing 1 = Very mild wheezing 2 = Mild wheezing 3 = Moderate wheezing 4 = Severe wheezing 5 = Very severe wheezing	**(1030)**	___	___	___	___	___	___	___
4. How severe was your child's trouble breathing today? 0 = No trouble breathing 1 = Very mild trouble breathing 2 = Mild trouble breathing 3 = Moderate trouble breathing 4 = Severe trouble breathing 5 = Very severe trouble breathing	**(1040)**	___	___	___	___	___	___	___
5. How much did your child's asthma symptoms interfere with your child's activities today? 0 = Did not interfere 3 = Moderately interfered 1 = Very mildly interfered 4 = Severely interfered 2 = Mildly interfered 5 = Very severely interfered	**(1050)**	___	___	___	___	___	___	___
6. Did your child's asthma require a visit to the doctor/ER, hospitalization, or treatment with prednisone?	**(1060)**	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0
7. How much albuterol did your child use since waking up? (if none, enter '0')								
Albuterol Inhaler: number of puffs	**(1070)**	__ __	__ __	__ __	__ __	__ __	__ __	__ __
Albuterol by nebulizer: number of treatments	**(1080)**	__ __	__ __	__ __	__ __	__ __	__ __	__ __

AsthmaNet

APRIL ELIGIBILITY CHECKLIST 1

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

(Coordinator Completed)

1. Has the parent/legal guardian appropriately signed and dated the Informed Consent? **(1000)** ☐1 Yes ☐0 No

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

   ➔ Consent should be reviewed and signed on the day Visit 1 is performed.

Study Medicines

2. Does the participant have an intolerance or allergy to azithromycin? **(1020)** ☐1 Yes ☐0 No ☐8 Don't know

3. Does the participant have an intolerance or allergy to oral corticosteroids (Decadron, Dexamethasone, Orapred, Prelone, Pediapred, prednisone)? **(1030)** ☐1 Yes ☐0 No ☐8 Don't know

4. Is the participant able to take albuterol (such as Proventil and Ventolin)? **(1040)** ☐1 Yes ☐0 No

Medical History Criteria

5. Is the participant 12 to 71 months old? **(1050)** ☐1 Yes ☐0 No

6. Was the participant born before 34 weeks gestation? **(1060)** ☐1 Yes ☐0 No

7. Does the parent report that the participant is up-to-date with immunizations? **(1070)** ☐1 Yes ☐0 No

8. Has the participant ever had chicken pox or received the chicken pox vaccine? (Refer to MOP for discussion on immunization records) **(1080)** ☐1 Yes ☐0 No

9. Is the participant receiving allergy shots? **(1090)** ☐1 Yes ☐0 No

   9a. If ***YES***, has the dose been changed in the past 3 months? **(1100)** ☐1 Yes ☐0 No

10. Does the participant have any immunodeficiency disorders? **(1110)** ☐1 Yes ☐0 No

11. Does the participant have uncontrolled gastroesophageal reflux? **(1120)** ☐1 Yes ☐0 No

12. Does the participant have concurrent medical problems other than asthma that are likely to require oral or injectable corticosteroids during the study? **(1130)** ☐1 Yes ☐0 No

13. Does the participant have a chronic or active lung disease other than asthma (cystic fibrosis, BPD, etc)? **(1140)** ☐1 Yes ☐0 No

14. Does the participant have a significant medical illness other than asthma (refer to P2_EXCLMED)? **(1150)** ☐1 Yes ☐0 No

Medication History

15. During the past 12 months, how many oral or systemic corticosteroid courses has the participant had? **(1160)** __ __ courses

    15a. Is Q15 ≥ 5? **(1170)** ☐1 Yes ☐0 No

16. Has the participant used an oral or systemic corticosteroid for any reason in the past 2 weeks? **(1180)** ☐1 Yes ☐0 No

17. During the past 4 weeks, has the participant used antibiotics? **(1190)** ☐1 Yes ☐0 No

18. During the past 12 months, has the participant been on daily controller therapy? **(1200)** ☐1 Yes ☐0 No
    ➔ If ***NO***, skip to Q20

    18a. If ***YES***, how many months has the participant been on daily controller therapy? **(1210)** __ __ months

        18ai. Is Q18a ≥ 4 months? **(1220)** ☐1 Yes ☐0 No

        18aii. Is Q18a ≥ 9 months? **(1230)** ☐1 Yes ☐0 No

19. During the past 4 weeks, has the participant been treated with a controller therapy? **(1240)** ☐1 Yes ☐0 No
    ➔ If ***NO***, skip to Q20. The participant should enter a 2-week Run-In.

    19a. If ***YES***, how many controller therapies has the participant been treated with during the last 4 weeks? **(1250)** __ __

    19b. If ***YES***, which controller therapies was the participant taking during the last 4 weeks?
    CHECK ONLY THOSE THAT APPLY.

Medication			Taking?	If ***YES***, Number of puffs/nebs/ inhalations per day	No more than this number puffs/day (limit)
Fluticasone	DPI: 250 mcg/inh	**(1260-1270)**	❑1 Yes	_ _ inhs/day	Any child on this medication does not qualify
Mometasone	DPI: 220 mcg/inh	**(1280-1290)**	❑1 Yes	_ _ puffs/day	Any child on this medication does not qualify
Advair (fluticasone-salmeterol)	DPI: 100/50 mcg/inh DPI: 250/50 mcg/inh DPI: 500/50 mcg/inh HFA: 45/21 mcg/inh HFA: 115/21 mcg/inh HFA: 230/21 mcg/inh	**(1300-1310)**	❑1 Yes	_ _ inhs/day	Any child on this medication does not qualify
Symbicort (budesonide-fomoterol)	80/4.5mcg/inhalation 160/4.5mcg/inhalation	**(1320-1330)**	❑1 Yes	_ _ inhs/day	Any child on this medication does not qualify
Dulera (mometasone-formoterol)	100/5 mcg/inhalation 200/5 mcg/inhalation	**(1340-1350)**	❑1 Yes	_ _ inhs/day	Any child on this medication does not qualify
➔ If ***YES*** to any of the medications listed above that indicate child does not qualify, PROCEED to Q19c.					
Beclomethasone	HFA: 40 mcg/puff	**(1360-1370)**	❑1 Yes	_ _ puffs/day	4 puffs
Beclomethasone	HFA: 80 mcg/puff	**(1380-1390)**	❑1 Yes	_ _ puffs/day	2 puffs
Budesonide	Nebulizer 0.25mg suspension	**(1400-1410)**	❑1 Yes	_ _ nebs/day	2 nebs
Budesonide	Nebulizer 0.5mg suspension	**(1420-1430)**	❑1 Yes	_ _ nebs/day	1 neb
Budesonide	Flexhaler: 90mcg/inh	**(1440-1450)**	❑1 Yes	_ _ inhs/day	4 inhalations
Budesonide	Flexhaler: 180mcg/inh	**(1460-1470)**	❑1 Yes	_ _ inhs/day	2 inhalations

Medication			Taking?	If ***YES***, Number of puffs/nebs/ inhalations per day	No more than this number puffs/day (limit)
Ciclesonide	HFA: 80 mcg/puff	**(1480-1490)**	❑1 Yes	_ _ puffs/day	2 puffs
Ciclesonide	HFA: 160 mcg/puff	**(1500-1510)**	❑1 Yes	_ _ puffs/day	1 puff
Flunisolide	HFA: 80 mcg/puff	**(1520-1530)**	❑1 Yes	_ _ puffs/day	2 puffs
Fluticasone	HFA 44 mcg/puff	**(1540-1550)**	❑1 Yes	_ _ puffs/day	4 puffs
Fluticasone	HFA 110 mcg/puff	**(1560-1570)**	❑1 Yes	_ _ puffs/day	2 puffs
Fluticasone	HFA 220 mcg/puff	**(1580-1590)**	❑1 Yes	_ _ puffs/day	1 puff
Fluticasone	DPI: 50 mcg/inh	**(1600-1610)**	❑1 Yes	_ _ inhs/day	4 inhalations
Fluticasone	DPI: 100 mcg/inh	**(1620-1630)**	❑1 Yes	_ _ inhs/day	2 inhalations
Mometasone	DPI: 110 mcg/inh	**(1640-1650)**	❑1 Yes	_ _ puffs/day	1 puff
Singulair	4 or 5 mg/tablet	**(1660-1670)**	❑1 Yes	_ _ tablets/day	No upper limit
Triamcinolone	MDI: 75 mcg/puff	**(1680-1690)**	❑1 Yes	_ _ puffs/day	8 puffs

19c. Are any of the doses greater than the limit or is the participant taking more than 1 controller therapy? **(1700)** ❑1 Yes ❑0 No

➔ If ***YES***, the participant is ineligible for APRIL.

➔ If ***NO,*** the participant needs to stop the controller medication and enter a 4 week Run-In. Please refer to the APRIL MOP for further details.

Wheezing Criteria

20. During the past 12 months, how many wheezing episodes has the participant had? **(1710)** __ __ wheezing episodes

20a. Is Q20 ≥ 3? **(1720)** ❑1 Yes ❑0 No
➔ If ***NO***, skip to Q20b

20ai. If ***YES***, was at least one of the wheezing episodes clinically significant*? **(1730)** ❑1 Yes ❑0 No
➔ If ***YES***, skip to Q21

*Clinically significant episode: requiring any of the following: systemic corticosteroids, unscheduled physician office visit, ED visit, urgent care visit, or hospitalization.

20b. Is Q20 = 2? **(1740)** ❑1 Yes ❑0 No
➔ If ***NO***, skip to Q20c

20bi. If ***YES***, were both wheezing episodes clinically significant*? **(1750)** ❑1 Yes ❑0 No
➔ If ***YES***, skip to Q21

20c. Is Q20 in (1, 2)? **(1760)** ❑1 Yes ❑0 No

20ci. If ***YES***, was at least 1 wheezing episode clinically significant* and is Q18ai answered Yes? **(1770)** ❑1 Yes ❑0 No

Growth Criteria

21. Does the participant have significant developmental delay/failure to thrive? (If a child plots less than the 10th percentile for age and gender, a growth chart for the previous year will be obtained from the child's primary care provider. If the child has crossed two major percentile lines during the previous year, he/she has significant developmental delay/failure to thrive). **(1780)** ❑1 Yes ❑0 No

Other Criteria

22. During the past 12 months, how many times has the participant been hospitalized for wheezing illnesses? **(1790)** __ __ times

22a. Is Q22 ≥ 2? **(1800)** ❑1 Yes ❑0 No

23. During the past 2 weeks, has the participant had daily symptoms or 2 or more nocturnal awakenings? **(1810)** ❑1 Yes ❑0 No

24. Has the participant had respiratory failure resulting in mechanical ventilation or resulting in a hypoxic seizure? **(1820)** ❑1 Yes ❑0 No

25. Currently, or within the past month, has the participant been involved in an investigational drug trial? **(1830)** ❑1 Yes ❑0 No

26. Does the participant's family have plans to move out of the area before the end of the study? **(1840)** ❑1 Yes ❑0 No

27. Is there any other reason for which this participant should not be included in this study? **(1850)** ❑1 Yes ❑0 No

If ***YES***, describe **(1850D)** _____

_____

28. Is the participant eligible? **(1860)** ❑1 Yes ❑0 No

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

➔ If YES, proceed with remaining Visit 1 procedures.

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

APRIL ELIGIBILITY CHECKLIST 2

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

(Coordinator Completed)

Medications

1. Has the participant used any asthma medications other than albuterol since Visit 1? **(1000)** ❑1 Yes ❑0 No

2. Has the participant used oral corticosteroids or antibiotics since Visit 1? **(1010)** ❑1 Yes ❑0 No

If the participant is in a 2 week Run-In, all days should be used (excluding today and Visit 1 day). If the participant is in a 4 week Run-In, only the last 14 days should be used (excluding today) and the count should be 13 days.

3. Number of days between Visit 1 and Visit 2 **(1015)** __ __ days

Run-In Symptoms

4. During the time period defined in Q3, how many days did the participant have asthma-related symptoms or use albuterol for breathing problems? Do not count any day more than once. (If P2_DIARY Q1020 ≥ 2, count that day. If P2_DIARY Q1030-Q1080 ≥ 1, count that day). **(1020)** __ __ days

5. Average number of days per week with asthma-related symptoms or albuterol use:

   5a. Average = (7 X Q4)/Q3 **(1030)** __ __.__ days

   5b. Is Q5a ≥ 4.0? **(1040)** ❑1 Yes ❑0 No

6. During the time period defined in Q3, how many nights did the participant awake and require albuterol? Do not count any night more than once. (If P2_DIARY Q1000 or Q1010 ≥ 1, count that night.) **(1050)** __ __ nights

   6a. Is Q6 ≥ 2? **(1060)** ❑1 Yes ❑0 No

Diary Adherence

7. During the time period defined in Q3, how many questions were completed? [Questions that count toward adherence include Q1000-Q1080]. Each set of albuterol questions (Q1000-Q1010 and Q1070-Q1080) should only be counted once. **(1070)** __ __ __ questions

8. Percent adherence = [Q7/(Q3 X 7)] X 100 **(1080)** __ __ __.__%

9. Is Q8 ≥ 80%? **(1090)** ❑1 Yes ❑0 No

Other

10. Is there any other reason for which this participant should not be included in this study? **(1100)** ☐1 Yes ☐0 No

    If ***YES***, describe **(1100D)** _____

    _____

11. Is the participant eligible? **(1110)** ☐1 Yes ☐0 No

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

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

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

FONEMED

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

(Coordinator Completed)

1. Date of call to FoneMed **(1000)** __ __ / __ __ / 20 __ __
   MM DD YYYY

2. What was the primary reason for the call? **(1010)**
   - ❑1 Child having respiratory symptoms
   - ❑2 Reschedule/cancel visit
   - ❑3 Starting APRIL meds
   - ❑4 Other (specify in Q6000)

   ➔ If it was to reschedule/cancel a visit then ***STOP HERE***.

   ➔ If it was due to starting APRIL meds then ***STOP HERE***. If the parent hasn't called the clinical center within 72 hours of starting APRIL meds, contact the parent/guardian.

   ➔ If it was 'other', ***STOP HERE***, specify the reason in Q6000 on page 2, then go to the APRIL MOP for further details.

3. Was the child currently taking APRIL medications? **(1020)** ❑1 Yes ❑0 No

DO NOT COMPLETE Q4 AFTER THE PARENT HAS CONSENTED TO STOP OCELOT.

4. Was the child currently taking OCELOT medications? **(1030)** ❑1 Yes ❑0 No

5. Did the child have current symptoms that required immediate medical attention [severe respiratory distress, including (but not limited to) nasal flaring, retractions not immediately responsive to bronchodilator, altered level of consciousness, cyanosis, signs of dehydration, rapidly progressive symptoms]? **(1040)** ❑1 Yes ❑0 No

   5a. If ***YES***, was the child referred to an urgent care/emergency department for evaluation? **(1050)** ❑1 Yes ❑0 No

   ➔ ***STOP HERE***, then go to the APRIL MOP for further details.

6. Is the child a study failure? **(1060)** ❑1 Yes ❑0 No
   ➔ If ***YES***, please complete the study failure (P2_STUDY_FAILURE) form.

7. Is the child an APRIL treatment failure? **(1070)** ❑1 Yes ❑0 No
   ➔ If ***YES,*** please complete the APRIL treatment failure (P2_TRTFAIL) form.

P2 FONE MED

DO NOT COMPLETE Q8 AFTER THE PARENT HAS CONSENTED TO STOP OCELOT.

8. Was the parent/guardian instructed to start OCELOT therapy? **(1080)** ❑$_1$ Yes ❑$_0$ No
   ➔ If ***YES,*** please complete the OCELOT scheduling (P2_OCELOT_SCHED) form.

9. Was the parent/guardian instructed to start APRIL therapy? **(1090)** ❑$_1$ Yes ❑$_0$ No
   ➔ If ***YES,*** please be sure that the parent/guardian is contacted within 72 hours to complete the P2_ILLNESS form and the P2_SYMP_CC form.

10. Did the child have additional problems that the parent/guardian wanted to discuss with on-call physician? **(1100)** ❑$_1$ Yes ❑$_0$ No
    ➔ If ***YES,*** please provide a brief description in Q6000.

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

APRIL RESPIRATORY ILLNESS FOLLOW-UP CONTACT

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

(Coordinator Completed)

This form is completed when the participant calls within 72 hours of beginning the APRIL medication.

Check the response that best describes how the participant has been during the time since he/she started the illness?

1. Who is the respondent?

(1000)
- ❑1 Parent/Guardian
- ❑2 Other (specify)

(1000D) _____

2. When was the start of the illness?

(1010) __ __ / __ __ / 20 __ __
MM DD YYYY

3. On average, since the start of the illness, how often was your child awakened by breathing problems during the night?

(1020)
- ❑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

4. On average, since the start of the illness, how bad were your child's breathing problems when he/she woke up in the morning?

(1030)
- ❑0 No symptoms
- ❑1 Very mild symptoms
- ❑2 Mild symptoms
- ❑3 Moderate symptoms
- ❑4 Quite severe symptoms
- ❑5 Severe symptoms
- ❑6 Very severe symptoms

5. In general, since the start of the illness, how limited were your child's activities because of breathing problems?

(1040)
- ❑0 Not limited at all
- ❑1 Very slightly limited
- ❑2 Slightly limited
- ❑3 Moderately limited
- ❑4 Very limited
- ❑5 Extremely limited
- ❑6 Totally limited

* P 2 I L L N E S S *

6. In general, since the start of the illness, how much shortness of breath did your child experience because of breathing problems? **(1050)**
   - ❑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

7. In general, since the start of the illness, how much of the time did your child wheeze? **(1060)**
   - ❑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

8. Have you started the APRIL medication? **(1070)** ❑1 Yes ❑0 No

   ➔ If NO, instruct the parent/guardian to start the APRIL medication immediately and SKIP to Q10.

   8a. Date the APRIL medication started **(1080)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

   8b. Time the APRIL medication started *(based on a 24-hour clock)* **(1090)** __ __ __ __

9. Have you been giving your child the APRIL medication once daily? **(1100)** ❑1 Yes ❑0 No

10. Have you been giving your child the albuterol? *(4 times a day for the first 48 hours, then PRN)* **(1110)** ❑1 Yes ❑0 No

11. Was a first nasal sample collected? **(1120)** ❑1 Yes ❑0 No

    ➔ If NO, instruct the parent/guardian to collect a nasal sample immediately.

    11a. Date nasal sample was collected **(1130)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

    11b. Which collection technique was used? **(1140)**
    - ❑1 Nasal Blow
    - ❑2 Nasal Swab

12. Was a second nasal sample collected? **(1150)** ❑$_1$ Yes ❑$_0$ No

➔ **If NO, instruct the parent/guardian to collect a second nasal sample on Day 4 of the illness.**

12a. Date nasal sample was collected **(1160)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

12b. Which collection technique was used? **(1170)**
❑$_1$ Nasal Blow
❑$_2$ Nasal Swab

COMMENTS: (6000)

AsthmaNet

APRIL LABORATORY RESULTS

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

(Coordinator Completed)

BLOOD TESTS and SPECIMEN COLLECTIONS (Visit 2)

1. Total WBC **(1000)** __ __ __ __ __ /cu.mm

2. Eosinophils **(1010)** __ __ . __ %

NASAL SAMPLING (Visits 2, 9, and 21)

3. Were you able to collect a nasal sample from the participant today? **(1030)** ❑1 Yes ❑0 No

   3a. If ***YES***, which collection technique was used? **(1040)** ❑1 Nasal Blow
   ❑2 Nasal Swab

ST. LOUIS ONLY:
THROAT SWAB (V2, V9 or V21, and V3-V8, 8b, 8c, 8d as directed by the APRIL MOP)

4. Were you able to collect a throat swab from the participant today? **(1050)** ❑1 Yes ❑0 No

COMMENTS: (6000)

_____

_____

_____

P2 LAB

AsthmaNet

OCELOT COMPLIANCE CHECKLIST

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

(Clinic Coordinator Completed)

1.	Has the participant used OCELOT therapy since the last visit?	**(1000)**	❑$_1$ Yes ❑$_0$ No
	➔ If ***NO*****,** STOP HERE.		
2.	Date of OCELOT therapy usage	**(1010)**	__ __ / __ __ / 20 __ __ (MM / DD / YYYY)
3.	Bottle Number	**(1020)**	2 – OCE - __ __ __ __
4.	Bottle Weight	**(1030)**	__ __ __ gm
5.	Participant's Total Dose per day (Dose per administration X 2)	**(1040)**	__ __ __ ml
6.	Total Dosage = Q5 X 5 x 1.23	**(1050)**	__ __ __ . __ __ gm
7.	Adherence = ((168 – Q4)/Q6) x 100	**(1060)**	__ __ __ . __ %

COMMENTS: (6000)

_____

_____

_____

AsthmaNet

OCELOT SCHEDULING FORM

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

(Coordinator Completed)

Instructions: The parent/guardian should be contacted within 24 hours after starting OCELOT therapy to schedule Visit 20 (Visit 20 should take place 36 – 72 hours after starting OCELOT therapy). This form should be completed during that call.

1. Was OCELOT therapy started? **(1000)** ❑1 Yes ❑0 No

   1a. If ***NO***, what was the reason? **(1000D)** _____

   1b. If ***YES,*** record date and time OCELOT therapy was started.
   Date the OCELOT therapy started **(1010)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

   Time the OCELOT therapy started (based on a 24-hour clock) **(1020)** __ __ __ __

2. Has the participant had any of the following symptoms requiring immediate medical attention? (Severe respiratory distress, including (but not limited to) nasal flaring, retractions not immediately responsive to bronchodilator, altered level of consciousness, Cyanosis, signs of dehydration, rapidly progressive symptoms) **(1030)** ❑1 Yes ❑0 No

3. Was there an unscheduled visit for acute asthma (physician office, urgent care, emergency department)? **(1040)** ❑1 Yes ❑0 No
   ➔ If ***YES,*** did the participant receive:

   3a. more than 1 albuterol* treatment? **(1050)** ❑1 Yes ❑0 No

   3b. 1 albuterol* treatment lasting more than 1 hour? **(1060)** ❑1 Yes ❑0 No

   *albuterol treatment is defined as any treatment that includes albuterol (i.e., albuterol, albuterol + atrovent, etc.)

4. Has the participant had an unscheduled visit for acute asthma care in a physician's office during which the child was transferred to urgent care or the emergency department due to severity of respiratory symptoms? **(1070)** ❑1 Yes ❑0 No

5. Has the participant received systemic steroids for respiratory symptoms? **(1080)** ❑1 Yes ❑0 No

6. Has the participant been hospitalized for asthma? **(1090)** ❑1 Yes ❑0 No

7. Has the participant developed persistent symptoms (Significant Persistent Asthma is defined as daytime symptoms of cough or wheeze which on average 5 or more days a week on average over the past 4 weeks or if nighttime symptoms of cough and wheeze that wake the child up and occur at least once a week on average over the past 4 weeks)? **(1100)** ❑1 Yes ❑0 No

8. Has a physician deemed the participant a study failure? **(1110)** ❑1 Yes ❑0 No

   If ***YES***, please provide a detailed reason: **(1110D)** _____

   _____

   _____

9. Is the participant a Study Failure? **(1120)** ❑1 Yes ❑0 No
   If any of the shaded boxes are completed, the participant is a study failure.
   ➔ If ***NO,*** skip to Q10.

   9a. If ***YES***, date study failure occurred **(1130)** __ __ / __ __ / 20 __ __
   STOP HERE. MM DD YYYY

10. Date scheduled for Visit 20 **(1140)** __ __ / __ __ / 20 __ __
    MM DD YYYY

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

TERMINATION OF OCELOT (Treatment Phase)

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

(Coordinator Completed)

Please indicate the reason for termination of the study participant

1. Has the participant completed the OCELOT study? **(1000)** ❑1 Yes ❑0 No
   ➔ If **YES**, skip to the SIGNATURES section.

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

(1010)
- ❑1 participant deemed study failure
- ❑2 parent withdrew consent
- ❑3 participant experienced a serious adverse event*
- ❑4 side effects of study medications**
- ❑5 physician initiated termination of study participation**
- ❑6 other**

*** Please complete the Serious Adverse Event Reporting (SERIOUS) form.**
****Additional explanation required: (1010D)**

_____

_____

_____

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

I verify that all information collected on the AsthmaNet APRIL 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.

_____ **(1020)** __ __ / __ __ / 20 __ __ **(1030)**
Coordinator Signature MM DD YY

_____ **(1040)** __ __ / __ __ / 20 __ __ **(1050)**
Project Investigator Signature MM DD YY

COMMENTS: (6000)

_____

AsthmaNet

OCELOT STUDY TREATMENT QUESTIONNAIRE

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

(Coordinator and Parent/Guardian Completed)

This questionnaire is to be completed at OCELOT Follow-up Visit (Visit 21).

Participant and Parent/Guardian should complete Q1 – Q4.

1. How well were your child's wheezing symptoms controlled during the OCELOT study?

(1000)
- ❑1 Not at all
- ❑2 Hardly at all
- ❑3 Somewhat
- ❑4 Fairly
- ❑5 Very well

2. For the OCELOT study, your child was randomized to receive either prednisolone or placebo. Please check the box that most closely represents your feelings about which of the two treatments your child was receiving.

(1010)
- ❑1 Prednisolone
- ❑2 Placebo

3. In general, did you have difficulty in having your child take the drug?

(1020) ❑1 Yes ❑0 No

3a. If ***YES***, what was the primary reason for the difficulty?

(1030)
- ❑1 Tasted bad
- ❑2 Smelled bad
- ❑3 Inconvenient
- ❑4 Forgot
- ❑5 Too busy
- ❑6 Doesn't like medicine
- ❑7 Just didn't want to
- ❑8 Other (specify)

(1030D) _____

4. Did the child have any stomach-related problems while taking OCELOT therapy?
➔ If ***NO***, STOP HERE.

(1040) ❑1 Yes ❑0 No

4a. Stomach Ache **(1050)** ❑1 Yes ❑0 No

4b. Nausea **(1060)** ❑1 Yes ❑0 No

4c. Upset Stomach **(1070)** ❑1 Yes ❑0 No

4d. Vomiting **(1080)** ❑1 Yes ❑0 No

P2 OCELOT TRTQX

Study Coordinator should complete Q5.

5. In your opinion, which of the two treatments was the participant receiving? **(1090)**

- ❑1 Prednisolone
- ❑2 Placebo
- ❑3 No idea

Clinic Coordinator Completed
COMMENTS: (6000)

_____

_____

_____

P2 OCELOT TRTQX

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

Part. Initials: __ __ __

PRE-SCHOOL ASTHMA SYMPTOM DIARY

Return Visit: __ __ __

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

Instructions: Please use this diary to record any asthma symptoms your child has experienced during the past 24 hours. **Complete this diary when you start APRIL or prednisolone and continue until symptom free for 2 days.** While symptoms may get better or worse rapidly, please answer EACH question by DARKENING only the circle that you feel BEST DESCRIBES what you have OBSERVED in your child over the past 24 hours.

Today's Date: **(DDATE)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

Please state HOW OFTEN your child has experienced each of the following symptoms in the last 24 hours:

		Not at all						All of the time	Cannot Answer
		1	2	3	4	5	6	7	8
Coughing	**(1000)**	○	○	○	○	○	○	○	○
Wheezing/whistling in the chest	**(1010)**	○	○	○	○	○	○	○	○
Loud breathing	**(1020)**	○	○	○	○	○	○	○	○
Fast breathing	**(1030)**	○	○	○	○	○	○	○	○
Gasping for air	**(1040)**	○	○	○	○	○	○	○	○
Stomach pushing out with each breath	**(1050)**	○	○	○	○	○	○	○	○
Skin pulling in the neck/throat	**(1060)**	○	○	○	○	○	○	○	○

Please state the DEGREE to which each symptom has been a PROBLEM observed in your child in the last 24 hours

		Not at all						Extremely	Cannot Answer
		1	2	3	4	5	6	7	8
Coughing	**(1070)**	○	○	○	○	○	○	○	○
Sleep disturbed by cough, wheeze or difficulty breathing	**(1080)**	○	○	○	○	○	○	○	○
Decrease in energy level	**(1090)**	○	○	○	○	○	○	○	○
Unwilling to move around (e.g. wants to be carried)	**(1100)**	○	○	○	○	○	○	○	○
Loss of appetite	**(1110)**	○	○	○	○	○	○	○	○
Requesting more attention and/or extra care	**(1120)**	○	○	○	○	○	○	○	○
Irritable/cranky/fussy	**(1130)**	○	○	○	○	○	○	○	○
Responds less well to albuterol	**(1140)**	○	○	○	○	○	○	○	○
Responds less rapidly to albuterol	**(1150)**	○	○	○	○	○	○	○	○
The effect of albuterol does not last as long as usual	**(1160)**	○	○	○	○	○	○	○	○

Have you noticed an improvement or a worsening of your child's asthma over the past 24 hours?(please circle one number only) **(1170)**

-7	-6	-5	-4	-3	-2	-1	0	1	2	3	4	5	6	7
A great deal worse			Moderately worse			Hardly any worse	Same	Hardly Any better			Moderately better			A great deal better

In the past 24 hours:

How many albuterol treatments were administered (1 treatment = 2 puffs = 1 nebule)? **(1180)** __ __ treatments

Has your child started prednisolone? **(1190)** ① Yes ⓪ No

How many hours have YOU spent with the child in the past 24 hours? **(1200)** __ __ hours

This questionnaire was filled by: **(1210-1210D)** ① Mother ② Father ③ Other (specify) _____

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P2 PAD

AsthmaNet

APRIL PERSISTENT SYMPTOMS

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

(Coordinator Completed)

1. During the past 2 weeks, did your child have wheezing or cough? **(1000)** ❑$_1$ Yes ❑$_0$ No

   1a. If ***YES***, how many days? **(1010)** __ __ days

   ➔ If Q1a > 8, then the child is having persistent symptoms and has met Study Failure Criteria. Complete the Study Failure form and refer to the APRIL MOP for further details.

   ➔ **STOP HERE.**

2. During the past 2 weeks, did your child awaken from sleep due to asthma symptoms? **(1040)** ❑$_1$ Yes ❑$_0$ No

   2a. If ***YES***, how many nights? **(1050)** __ __ nights

   ➔ If Q2a > 2, then the child is having persistent symptoms and has met Study Failure Criteria. Complete the Study Failure form and refer to the APRIL MOP for further details.

   ➔ **STOP HERE.**

3. During the past 2 weeks, did your child have to slow down his/her play or activities due to asthma symptoms? **(1020)** ❑$_1$ Yes ❑$_0$ No

   3a. If ***YES***, how many days? **(1030)** __ __ days

4. During the past 2 weeks, did your child take albuterol (excluding pre-exercise)? **(1060)** ❑$_1$ Yes ❑$_0$ No

   4a. If ***YES***, how many days? **(1070)** __ __ days

COMMENTS: **(6000)**

_____

_____

_____

P2 PERS SYMP

AsthmaNet

APRIL PHONE/VISIT SYMPTOM ASSESSMENT

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

(Coordinator Completed)

1. During the past 2 weeks, was your child absent from school or daycare due to breathing problems? **(1000)** ❑$_1$ Yes ❑$_0$ No ❑$_9$ N/A

   1a. If ***YES***, how many days were missed? **(1010)** __ __ days

2. During the past 2 weeks, was a parent unable to go to work or school due to your child's breathing problems? **(1020)** ❑$_1$ Yes ❑$_0$ No ❑$_9$ N/A

   2a. If ***YES***, how many days were missed? **(1030)** __ __ days

3. During the past 2 weeks, has your child been to a doctor for breathing problems? **(1040)** ❑$_1$ Yes ❑$_0$ No

   3a. If ***YES***, how many times? **(1050)** __ __ times

4. During the past 2 weeks, has your child been to an ER/urgent care facility for breathing problems? **(1060)** ❑$_1$ Yes ❑$_0$ No
   ➔ If **YES**, please see APRIL MOP for further details.

5. During the past 2 weeks, has your child been hospitalized for breathing problems? **(1070)** ❑$_1$ Yes ❑$_0$ No
   ➔ If **YES**, please see APRIL MOP for further details.

6. During the past 2 weeks, did your child have wheezing or cough? **(1080)** ❑$_1$ Yes ❑$_0$ No

   6a. If ***YES***, how many days? **(1090)** __ __ days

   ➔ If Q6a > 8, then a follow-up phone call should be scheduled for 2 weeks to assess if the child is having persistent symptoms. Please complete the Persistent Symptoms (P2_PERS_SYMP) form during the call.

7. During the past 2 weeks, did your child awaken from sleep due to asthma symptoms? **(1100)** ❑$_1$ Yes ❑$_0$ No

   7a. If ***YES***, how many nights? **(1110)** __ __ nights

   ➔ If Q7a > 2, then a follow-up phone call should be scheduled for 2 weeks to assess if the child is having persistent symptoms. Please complete the Persistent Symptoms (P2_PERS_SYMP) form during the call.

8. During the past 2 weeks, did your child have to slow down his/her play or activities due to asthma symptoms? **(1120)** ❑$_1$ Yes ❑$_0$ No

   8a. If ***YES***, how many days? **(1130)** __ __ days

9. During the past 2 weeks, did your child take any albuterol (excluding pre-exercise)? **(1140)** ❑$_1$ Yes ❑$_0$ No

   9a. If ***YES***, how many days? **(1150)** __ __ days

10. Since the last visit or phone contact, did your child start APRIL therapy? **(1160)** ❑$_1$ Yes ❑$_0$ No

    10a. If ***YES***, how many times? **(1170)** __ __ times

➔ ***If this was the participant's fourth usage of APRIL therapy and APRIL treatment failure has not* been achieved, then the participant should be termed from APRIL.**

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

APRIL PREDNISOLONE MEDICATION

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

(Coordinator Completed)

Complete this form each time an APRIL participant receives oral/systemic corticosteroids for treatment of asthma.

Prednisolone Checklist

1. Administer prednisolone at 2mg/kg per day for 2 days (maximum 60mg) followed by 1 mg/kg per day for 2 days (maximum 30mg).

   1a. Start date of prednisolone **(1000)** __ __ / __ __ / 20 __ __
   MM DD YYYY

   ➔ **Record prednisolone course on the CMED form**

2. Why was the prednisolone course prescribed? The APRIL protocol specifications are to prescribe oral steroids if: **(1010)**

   - ❑1 Symptoms did not improve after 3 albuterol treatments administered every 20 minutes
   - ❑2 2 albuterol treatments within 4 hours
   - ❑3 > 6 albuterol treatments were needed for > 24 hours
   - ❑4 Moderate-severe cough or wheeze occurred for at least 5 of the preceding 7 days
   - ❑5 Physician discretion **(If Physician discretion, please explain in the comments section below)**

3. Instruct the parents to call if the child's condition worsens.

4. A follow-up phone call should be made to the parents 48-96 hours after initiation of prednisolone to reassess the participant's symptoms.

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

STUDY FAILURE

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

(Coordinator Completed)

1. Has the participant had any of the following symptoms requiring immediate medical attention? (Severe respiratory distress, including (but not limited to) nasal flaring, retractions not immediately responsive to bronchodilator, altered level of consciousness, Cyanosis, signs of dehydration, rapidly progressive symptoms) **(1030)** ❑1 Yes ❑0 No

2. Was there an unscheduled visit for acute asthma (physician office, urgent care, emergency department)? **(1040)** ❑1 Yes ❑0 No
   ➔ If ***YES,*** did the participant receive:

   2a. more than 1 albuterol* treatment? **(1050)** ❑1 Yes ❑0 No

   2b. 1 albuterol* treatment lasting more than 1 hour? **(1060)** ❑1 Yes ❑0 No

   *albuterol treatment is defined as any treatment that includes albuterol (i.e., albuterol, albuterol + atrovent, etc.)

3. Has the participant had an unscheduled visit for acute asthma care in a physician's office during which the child was transferred to urgent care or the emergency department due to severity of respiratory symptoms? **(1070)** ❑1 Yes ❑0 No

4. Has the participant received systemic steroids for respiratory symptoms? **(1080)** ❑1 Yes ❑0 No

5. Has the participant been hospitalized for asthma? **(1090)** ❑1 Yes ❑0 No

6. Has the participant developed persistent symptoms (Significant Persistent Asthma is defined as daytime symptoms of cough or wheeze which on average 5 or more days a week on average over the past 4 weeks or if nighttime symptoms of cough and wheeze that wake the child up and occur at least once a week on average over the past 4 weeks)? **(1100)** ❑1 Yes ❑0 No

7. Has a physician deemed the participant a study failure? **(1110)** ❑1 Yes ❑0 No

   If ***YES***, please provide a detailed reason: **(1110D)** _____

   _____

   _____

8. Is the participant a study failure? ***If any of the shaded boxes are selected, the participant is a study failure.*** **(1120)** ☐ 1 Yes ☐ 0 No

9. Date study failure occurred. **(1130)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

Physician Source Documentation

Physician's Signature: _____ **(1140)**

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

Time: __ __ __ __ *(based on a 24-hour clock)* **(1160)**

Note:

A safety visit should occur within 72 hours. Visit 9 should be scheduled 14 days after study failure.

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

APRIL SYMPTOMS OF RESPIRATORY ILLNESS SURVEY

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

(Coordinator Completed)

Please answer the following questions about your child's typical respiratory illness:

1. **What is <u>usually</u> the very first symptom you notice that leads you to believe your child is starting a respiratory illness?** Please choose one of the general categories in blue text from the list provided (P2_SYMPLIST). Then choose the symptom in red text from the specific list within that category. (If the very first symptom is not on the list, please indicate the very first symptom in the 'Other' space).

(1000) General: ___ ___ ___ ___
(1010) Specific: ___ ___ ___ ___
Other: _____

2. **Is there usually a symptom you notice that makes you very certain that the illness will lead to significant breathing problems?**
   ➔ If ***NO***, skip to Q3.

(1020) ❑$_1$ Yes ❑$_0$ No

   2a. **What is <u>usually</u> the most important symptom you notice that makes you feel certain the illness will lead to significant breathing problems?** Please choose one of the general categories in blue text from the list provided (P2_SYMPLIST). Then choose the symptom in red text from the specific list within that category. (If the very first symptom is not on the list, please indicate the very first symptom in the 'Other' space).

(1030) General: ___ ___ ___ ___
(1040) Specific: ___ ___ ___ ___
Other: _____

   2b. **Is there <u>usually</u> a second symptom you notice that makes you very certain that the illness will lead to significant breathing problems?**
   ➔ If ***NO***, skip to Q3.

(1050) ❑$_1$ Yes ❑$_0$ No

   2c. **What is <u>usually</u> the second symptom you notice that makes you feel certain the illness will lead to significant breathing problems?** Please choose one of the general categories in blue text from the list provided (P2_SYMPLIST). Then choose the symptom in red text from the specific list within that category. (If the very first symptom is not on the list, please indicate the very first symptom in the 'Other' space).

(1060) General: ___ ___ ___ ___
(1070) Specific: ___ ___ ___ ___
Other: _____

P2 SURVEY

3. When your child has a respiratory illness, how important are each of the symptoms?

Category		Not at all Important	Mildly Important	Moderately Important	Very Important	Not Applicable
Appearance Changes	(1080)	❑0	❑1	❑2	❑3	❑9
Appetite Changes	(1090)	❑0	❑1	❑2	❑3	❑9
Behavior Changes	(1100)	❑0	❑1	❑2	❑3	❑9
Breathing Problems	(1110)	❑0	❑1	❑2	❑3	❑9
Changes in Sleep Patterns	(1120)	❑0	❑1	❑2	❑3	❑9
Cough A	(1130)	❑0	❑1	❑2	❑3	❑9
Cough B	(1140)	❑0	❑1	❑2	❑3	❑9
Fever	(1150)	❑0	❑1	❑2	❑3	❑9
Noisy Breathing	(1160)	❑0	❑1	❑2	❑3	❑9
Noisy Chest	(1170)	❑0	❑1	❑2	❑3	❑9
Nose Symptoms	(1180)	❑0	❑1	❑2	❑3	❑9
Activity Changes	(1190)	❑0	❑1	❑2	❑3	❑9

AsthmaNet

APRIL SYMPTOMS OF RESPIRATORY ILLNESS

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

(Coordinator Completed)

This form is completed when the parent/guardian calls within 72 hours of beginning the respiratory illness medication. Instruct the parent/guardian to refer to the Symptoms of Respiratory Illness (P2_SYMP_PARENT) form. Record their responses onto this form using the symptom codes. Each specific symptom in red text corresponds to a general (blue text) symptom code and a specific (red text) symptom code. If the parent/guardian specified another symptom, be sure to record the general code that the symptom was written under as well as the parent/guardian's description of the other symptoms.

1. What was the very first symptom you noticed that led you to believe your child is starting a respiratory illness?

(1000) General: ___ ___ ___ ___
(1010) Specific: ___ ___ ___ ___
Other: _____

2. What was the most important symptom you noticed that made you feel certain that this illness would lead to significant breathing problems?

(1020) General: ___ ___ ___ ___
(1030) Specific: ___ ___ ___ ___
Other: _____

3. What were the two most important symptoms present that led you to start the respiratory illness medications?

3a. Symptom:

(1040) General: ___ ___ ___ ___
(1050) Specific: ___ ___ ___ ___
Other: _____

3b. Symptom:

(1060) General: ___ ___ ___ ___
(1070) Specific: ___ ___ ___ ___
Other: _____

* P 2 S Y M P C C *

4. For the respiratory illness that your child is currently experiencing, how important are each of the symptoms?

Category		Not at all Important	Mildly Important	Moderately Important	Very Important	Not Applicable
Appearance Changes	(1080)	❑0	❑1	❑2	❑3	❑9
Appetite Changes	(1090)	❑0	❑1	❑2	❑3	❑9
Behavior Changes	(1100)	❑0	❑1	❑2	❑3	❑9
Breathing Problems	(1110)	❑0	❑1	❑2	❑3	❑9
Changes in Sleep Patterns	(1120)	❑0	❑1	❑2	❑3	❑9
Cough A	(1130)	❑0	❑1	❑2	❑3	❑9
Cough B	(1140)	❑0	❑1	❑2	❑3	❑9
Fever	(1150)	❑0	❑1	❑2	❑3	❑9
Noisy Breathing	(1160)	❑0	❑1	❑2	❑3	❑9
Noisy Chest	(1170)	❑0	❑1	❑2	❑3	❑9
Nose Symptoms	(1180)	❑0	❑1	❑2	❑3	❑9
Activity Changes	(1190)	❑0	❑1	❑2	❑3	❑9

AsthmaNet

APRIL TERMINATION OF STUDY PARTICIPATION (Run-In)

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

(Coordinator Completed)

Please indicate the reason for termination of the study participant

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

(1010)
- ❑1 inability to demonstrate adherence with study diary
- ❑2 too many asthma symptoms during Run-In
- ❑3 asthma exacerbation during Run-In
- ❑4 participant required an asthma medication other than albuterol since Visit 1
- ❑5 parent withdrew consent
- ❑6 participant lost to follow up
- ❑7 participant experienced a serious adverse event*
- ❑8 physician initiated termination of study participation**
- ❑9 other**
- ❑10 participant required an antibiotic since Visit 1

*** Please complete the Serious Adverse Event Reporting (SERIOUS) form.**
****Additional explanation required: (1010D)**

_____

_____

_____

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

I verify that all information collected on the AsthmaNet APRIL 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.

_____ **(1020)** __ __ / __ __ / 20 __ __ **(1030)**
Coordinator Signature MM DD YY

_____ **(1040)** __ __ / __ __ / 20 __ __ **(1050)**
Project Investigator Signature MM DD YY

COMMENTS: (6000)

_____

P2 TERMR

AsthmaNet

APRIL TREATMENT FAILURE

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

(Coordinator Completed)

1. Has the participant used more than 6 albuterol treatments over a 24 hour period (the 3 back-to-back doses should be counted as 1 treatment)? **(1000)** ☐1 Yes ☐0 No

2. Has the participant had symptoms that are more than mild after 3 back-to-back albuterol treatments in 1 hour? **(1010)** ☐1 Yes ☐0 No

3. Has the participant received 2 albuterol treatments within 4 hours? **(1020)** ☐1 Yes ☐0 No

4. Has the participant had moderate-severe cough or wheeze for 5 or more days during which APRIL therapy was used? **(1030)** ☐1 Yes ☐0 No

5. Has a physician deemed the participant a treatment failure? **(1040)** ☐1 Yes ☐0 No

   If ***YES***, please provide a detailed reason: **(1040D)** _____

   _____

6. Is the participant a treatment failure? ***If any of the shaded boxes are selected, the participant is a treatment failure.*** **(1050)** ☐1 Yes ☐0 No

7. Date treatment failure occurred. **(1060)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

Physician Source Documentation

Physician's Signature: _____ **(1070)**

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

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

COMMENTS: (6000)

_____

_____

_____

AsthmaNet

APRIL Azithromycin Dosing Reference Card

Child's weight (kg)	Dose per day (ml)	Number of bottles needed		Child's weight (kg)	Dose per day (ml)	Number of bottles needed
≤ 4.2	1.0	1		20.9 - 22.5	6.5	2
4.3 - 5.8	1.5	1		22.6 - 24.2	7.0	2
5.9 - 7.5	2.0	1		24.3 - 25.8	7.5	2
7.6 - 9.2	2.5	1		25.9 - 27.5	8.0	2
9.3 - 10.8	3.0	1		27.6 - 29.2	8.5	2
10.9 - 12.5	3.5	1		29.3 - 30.8	9.0	2
12.6 - 14.2	4.0	1		30.9 - 32.5	9.5	2
14.3 - 15.8	4.5	1		32.6 - 34.2	10.0	2
15.9 - 17.5	5.0	1		34.3 - 35.8	10.5	2
17.6 - 19.2	5.5	1		35.9 - 37.5	11.0	2
19.3 - 20.8	6.0	1		37.6 - 39.2	11.5	2
				≥ 39.3	12.0	2

Drugs to be withheld prior to Visit 1.

Excluded Drug	Generic Names (may not be inclusive)	Trade Names (may not be inclusive)	Washout Prior to Visit 1
Oral or systemic steroids for any reason.	Prednisone, prednisolone, dexamethasone	Medrol, Decadron, Orapred, Prelone, Pediapred	2 weeks
All Antibiotics	tetracycline, penicillin, cephalosporin, quinolones, monobactam, erythromycin, clarithromycin, telithromycin, azithromycin	Sumycin, Amoxicillin, Cipro, Aztreonam, E-Mycin, Biaxin, Ketek, Zithromax	4 weeks

Drugs to be withheld prior to Visit 1 and between Visit 1 and Visit 2.

Excluded Drug	Generic Names (may not be inclusive)	Trade Names (may not be inclusive)	Washout Prior to Visit 1
Oral or systemic steroids for any reason.	Prednisone, prednisolone, dexamethasone	Medrol, Decadron, Orapred, Prelone, Pediapred	2 weeks
ORAL/INJECTABLE/ INTRAVENOUS Antibiotics (Topical antibiotics for ears, eyes, skin are permitted)	tetracycline, penicillin, cephalosporin, quinolones, monobactam, erythromycin, clarithromycin, telithromycin, azithromycin	Sumycin, Amoxicillin, Cipro, Aztreonam, E-Mycin, Biaxin, Ketek, Zithromax	4 weeks

P2 EXCLDRUG

AsthmaNet

Exclusionary Medical Conditions for APRIL (may not be inclusive)

- Addison's disease
- Cardiac arrhythmias (clinically significant)
- Cardiac disorder (except hemodynamically insignificant ASD, VSD, or heart murmur)
- Cataract's
- Chest surgery (call for exception)
- Congenital anomalies of the lung and chest, including growth abnormalities that affect predictability of expected lung function parameter
- Cushing's disease
- Diabetes mellitus (poorly controlled)
- Dyspnea by any cause other than asthma
- Eating disorder (e.g. anorexia or bulimia)
- Eczema, severe (if likely to require oral/systemic corticosteroid treatment)
- Failure to Thrive
- Gastroesophageal reflux (not controlled by standard medical therapy)
- Glaucoma
- Hematologic disease
- Hepatic disease
- HIV/AIDS
- Hypertension (poorly controlled)
- Inflammatory bowel disease (if likely to require oral/systemic corticosteroid treatment)
- Immunologic compromise
- Lung disease other than asthma (COPD, emphysema, chronic bronchitis, pulmonary embolism, malignancy, cystic fibrosis, among others)
- Lupus
- Malignancy
- Mental illness (bipolar disorder, schizophrenia, oppositional defiance disorder, conduct disorder, uncontrolled panic disorders)
- Mental retardation
- Myasthenia gravis
- Neurologic disease including any seizure disorder (except febrile seizure in infancy)
- Peptic ulcer disease (active)
- Renal disease (active)
- Rheumatoid arthritis (if likely to require oral/systemic corticosteroid treatment)
- Thyrotoxicosis
- Tuberculosis (active)
- Vocal cord dysfunction (active)

P2 EXCLMED

Allowed Medications for APRIL (may not be inclusive)

- acetaminophen
- acyclovir (e.g., Zovirax) for herpes
- non-macrolide antibiotics (e.g. tetracycline, penicillin, cephalosporin, quinolones, monobactam, macrolides)
- all antihistamines
- anti-fungal therapy
- calcium-based antacids (e.g. TUMS®)
- calcium supplements
- CNS stimulants (e.g. Ritalin, Dexedrine)
- eye preparations for allergic eye symptoms (topical)
- laxatives
- nasal cromolyn
- all nasal decongestants (e.g., Afrin)
- nasal steroids (beclomethasone, budesonide, flunisolide, fluticasone, mometasone, triamcinolone)
- nasal saline spray
- non-steroidal anti-inflammatory medications (e.g. aspirin, ibuprofen, naproxen, ketoprofen)
- all oral decongestants (e.g., Sudafed)
- oxymetazoline (e.g., Afrin)
- Selective Serotonin Reuptake Inhibitor (SSRI) class antidepressants (e.g., Paxil, Prozax, Zoloft, Effexor)
- study medications
- tacrolimus and pimecrolimus (e.g., Elidel) – avoid daily use
- thyroid replacement medication (e.g. Levothroid, Levoxyl, Synthroid)
- Topical corticosteroids - low potency (aciometasone dipropionate, desonide, dexamethasone, dexamethasone sodium phosphate, fluocinolone acetonide, hydrocortisone, hydrocortisone acetate)
- Topical corticosteroids - medium potency (betamethasone benzoate, betamethasone dipropionate, betamethasone valerate, clocortolone pivalate, desoximetasone, fluocinolone acetonide, flurandrenolide, fluticasone propionate, hydrocortisone butyrate, hydrocortisone valerate, mometasone furoate, triamcinolone acetonide)
- Vitamins, minerals

Allowed Medications for APRIL (may not be inclusive)

- acetaminophen
- acyclovir (e.g., Zovirax) for herpes
- non-macrolide antibiotics (e.g. tetracycline, penicillin, cephalosporin, quinolones, monobactam, non-macrolides)
- all antihistamines
- anti-fungal therapy
- calcium-based antacids (e.g. TUMS®)
- calcium supplements
- CNS stimulants (e.g. Ritalin, Dexedrine)
- eye preparations for allergic eye symptoms (topical)
- laxatives
- nasal cromolyn
- all nasal decongestants (e.g., Afrin)
- nasal steroids (beclomethasone, budesonide, flunisolide, fluticasone, mometasone, triamcinolone)
- nasal saline spray
- non-steroidal anti-inflammatory medications (e.g. aspirin, ibuprofen, naproxen, ketoprofen)
- all oral decongestants (e.g., Sudafed)
- oxymetazoline (e.g., Afrin)
- Selective Serotonin Reuptake Inhibitor (SSRI) class antidepressants (e.g., Paxil, Prozax, Zoloft, Effexor)
- study medications
- tacrolimus and pimecrolimus (e.g., Elidel) – avoid daily use
- thyroid replacement medication (e.g. Levothroid, Levoxyl, Synthroid)
- Topical corticosteroids - low potency (aciometasone dipropionate, desonide, dexamethasone, dexamethasone sodium phosphate, fluocinolone acetonide, hydrocortisone, hydrocortisone acetate)
- Topical corticosteroids - medium potency (betamethasone benzoate, betamethasone dipropionate, betamethasone valerate, clocortolone pivalate, desoximetasone, fluocinolone acetonide, flurandrenolide, fluticasone propionate, hydrocortisone butyrate, hydrocortisone valerate, mometasone furoate, triamcinolone acetonide)
- Vitamins, minerals

AsthmaNet

OCELOT Prednisolone Dosing Reference Card

Child's weight (kg)	Dose per administration (ml)	Dose per day (ml)		Child's weight (kg)	Dose per administration (ml)	Dose per day (ml)
≤ 7.4	2.0	4.0		19.5 - 20.9	6.5	13.0
7.5 - 8.9	2.5	5.0		21.0 - 22.4	7.0	14.0
9.0 - 10.4	3.0	6.0		22.5 - 23.9	7.5	15.0
10.5 - 11.9	3.5	7.0		24.0 - 25.4	8.0	16.0
12.0 - 13.4	4.0	8.0		25.5 - 26.9	8.5	17.0
13.5 - 14.9	4.5	9.0		27.0 - 28.4	9.0	18.0
15.0 - 16.4	5.0	10.0		28.5 - 29.9	9.5	19.0
16.5 - 17.9	5.5	11.0		≥ 30.0	10.0	20.0
18.0 - 19.4	6.0	12.0				

P2 PRED DOSE

AsthmaNet

APRIL Prednisolone Dosing Reference Card

Prednisolone Dosing: 2mg/kg/day for 2 days (maximum 60mg/day), followed by 1mg/kg/day for 2 days (maximum 30mg/day).

Child's weight (kg)	Dose for Days 1 & 2 (ml)	Dose for Days 3 & 4 (ml)		Child's weight (kg)	Dose for Days 1 & 2 (ml)	Dose for Days 3 & 4 (ml)
≤ 7.4	4.0	2.0		19.5 - 20.9	13.0	6.5
7.5 - 8.9	5.0	2.5		21.0 - 22.4	14.0	7.0
9.0 - 10.4	6.0	3.0		22.5 - 23.9	15.0	7.5
10.5 - 11.9	7.0	3.5		24.0 - 25.4	16.0	8.0
12.0 - 13.4	8.0	4.0		25.5 - 26.9	17.0	8.5
13.5 - 14.9	9.0	4.5		27.0 - 28.4	18.0	9.0
15.0 - 16.4	10.0	5.0		28.5 - 29.9	19.0	9.5
16.5 - 17.9	11.0	5.5		≥ 30.0	20.0	10.0
18.0 - 19.4	12.0	6.0				

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

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

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

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

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

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

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

AsthmaNet

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

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

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

FREQUENTLY USED ASTHMA & ALLERGY DRUG CODES

AsthmaNet

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

FREQ USED DC

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

FREQ USED DC