Drugs to be withheld throughout the study.

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

Drugs to be withheld throughout the study.

Excluded Drug	Generic Names (may not be inclusive)	Trade Names (may not be inclusive)	Washout Prior to Visit 1
Xanthine Derivatives			
Short-acting theophylline	theophylline	Aminophylline, Slo-Phyllin	None
Long-acting theophylline	theophylline	Slo-bid, Theo-Dur	None
Ultra long-acting theophylline	theophylline	Theo-24, Uniphyl	None

Drugs to be withheld after Visit 2.

Excluded Drug	Generic Names (may not be inclusive)	Trade Names (may not be inclusive)
Non-Steroidal Anti-Inflammatory Medications		
NSAID	acetaminophen, aspirin, ibuprofen, naproxen, ketoprophen	Tylenol, Advil, Motrin

P4 EXCLDRUG

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Exclusionary Medical Conditions for INFANT/AVICA (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)]
- Clotting disorders
- Congenital anomalies of the lung and chest, including growth abnormalities that affect predictability of expected lung function parameter
- Crohn's disease
- 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)
- Factor deficiency
- Failure to Thrive
- Gastroesophageal reflux (not controlled by standard medical therapy)
- G6PD deficiency
- 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, bronchiectasis, bronchopulmonary dysplasia, 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 (including febrile seizure in infancy)
- Osteogenesis imperfecta
- Peptic ulcer disease (active)
- Phenylketonuria
- Premature birth (before 35 weeks gestation)

- Renal disease (active)
- Rheumatoid arthritis (if likely to require oral/systemic corticosteroid treatment)
- Thyrotoxicosis
- Tracheomalacia
- Tuberculosis (active)
- Ulcerative colitis
- Vocal cord dysfunction (active)

Allowed Medications for INFANT/AVICA (may not be inclusive)

Allowed During Run-In and Treatment Phase:

- acyclovir (e.g., Zovirax) for herpes
- 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
- 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 During <u>Run-In</u> Only:

- Acetaminophen
- Non-steroidal anti-inflammatory medications (e.g. aspirin, ibuprofen, naproxen, ketoprofen)

AsthmaNet

AVICA COMPLIANCE CHECKLIST

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

(Clinic Coordinator Completed)

1. Has the participant used AVICA therapy since the last visit? **(1000)** ❑$_1$ Yes ❑$_0$ No

   ➔ If ***NO*****,** STOP HERE.

2. Did the parent/guardian complete and return the Parental AVICA Study Medication Diary? **(1010)** ❑$_1$ Yes ❑$_0$ No

3. Did the parent/guardian return the AVICA medication bottle? **(1020)** ❑$_1$ Yes ❑$_0$ No

   ➔ If ***NO*****,** STOP HERE.

4. Bottle Number **(1030)** 4 - A - __ __ __ __

5. Bottle Weight **(1040)** __ __ __ gm

COMMENTS: (6000)

_____

_____

_____

AsthmaNet

AVICA MEDICATION DIARY

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

Record Number (1000)	Date of AVICA Medication Use (1010) (1020) (1030)	Number Doses Given (1040)	Primary Reason for Use* (1050)	Cold/Flu Symptoms (1060)
___ ___	___ ___ / ___ ___ / 20 ___ ___	___ ___	___	❑1 Yes ❑0 No
___ ___	___ ___ / ___ ___ / 20 ___ ___	___ ___	___	❑1 Yes ❑0 No
___ ___	___ ___ / ___ ___ / 20 ___ ___	___ ___	___	❑1 Yes ❑0 No
___ ___	___ ___ / ___ ___ / 20 ___ ___	___ ___	___	❑1 Yes ❑0 No
___ ___	___ ___ / ___ ___ / 20 ___ ___	___ ___	___	❑1 Yes ❑0 No
___ ___	___ ___ / ___ ___ / 20 ___ ___	___ ___	___	❑1 Yes ❑0 No
___ ___	___ ___ / ___ ___ / 20 ___ ___	___ ___	___	❑1 Yes ❑0 No
___ ___	___ ___ / ___ ___ / 20 ___ ___	___ ___	___	❑1 Yes ❑0 No
___ ___	___ ___ / ___ ___ / 20 ___ ___	___ ___	___	❑1 Yes ❑0 No
___ ___	___ ___ / ___ ___ / 20 ___ ___	___ ___	___	❑1 Yes ❑0 No
___ ___	___ ___ / ___ ___ / 20 ___ ___	___ ___	___	❑1 Yes ❑0 No
___ ___	___ ___ / ___ ___ / 20 ___ ___	___ ___	___	❑1 Yes ❑0 No
___ ___	___ ___ / ___ ___ / 20 ___ ___	___ ___	___	❑1 Yes ❑0 No
___ ___	___ ___ / ___ ___ / 20 ___ ___	___ ___	___	❑1 Yes ❑0 No
___ ___	___ ___ / ___ ___ / 20 ___ ___	___ ___	___	❑1 Yes ❑0 No
___ ___	___ ___ / ___ ___ / 20 ___ ___	___ ___	___	❑1 Yes ❑0 No
___ ___	___ ___ / ___ ___ / 20 ___ ___	___ ___	___	❑1 Yes ❑0 No
___ ___	___ ___ / ___ ___ / 20 ___ ___	___ ___	___	❑1 Yes ❑0 No
___ ___	___ ___ / ___ ___ / 20 ___ ___	___ ___	___	❑1 Yes ❑0 No
___ ___	___ ___ / ___ ___ / 20 ___ ___	___ ___	___	❑1 Yes ❑0 No

* 1 = fever
  2 = discomfort/fussiness/irritability/pain
  3 = other

AsthmaNet

AVICA STUDY FAILURE

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

(Coordinator Completed)

1. Has the participant had a febrile seizure? **(1000)** ☐1 Yes ☐0 No

2. Has the participant had a new onset of hepatic, renal or biliary disease that interferes or potentially interferes with pharmacokinetics of the study interventions? **(1010)** ☐1 Yes ☐0 No

3. Has the participant developed jaundice? **(1020)** ☐1 Yes ☐0 No

4. Has the participant developed clinical signs or findings consistent with hepatitis or liver disease? **(1030)** ☐1 Yes ☐0 No

5. Is the participant a study failure? ***If any of the shaded boxes are selected, the participant is an AVICA study failure.*** **(1040)** ☐1 Yes ☐0 No

   ➔ **If *YES*, complete the Termination of AVICA (P4_AVICA_TERM) and AVICA Study Treatment Questionnaire (P4_AVICA_TRTQX) forms and collect AVICA medications.**

6. Date AVICA study failure occurred **(1050)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

Physician Source Documentation

Physician's Signature: _____ **(1060)**

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

Time: __ __ __ __ *(based on a 24-hour clock)* **(1080)**

COMMENTS: (6000)

_____

_____

_____

P4 AVICA FAIL

AsthmaNet

AVICA STUDY FAILURE

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

(Coordinator Completed)

1. Has the participant had a febrile seizure? **(1000)** ☐1 Yes ☐0 No

2. Has the participant had a new onset of hepatic, renal or biliary disease that interferes or potentially interferes with pharmacokinetics of the study interventions? **(1010)** ☐1 Yes ☐0 No

3. Has the participant developed jaundice? **(1020)** ☐1 Yes ☐0 No

4. Has the participant developed clinical signs or findings consistent with hepatitis or liver disease? **(1030)** ☐1 Yes ☐0 No

5. Is the participant a study failure? ***If any of the shaded boxes are selected, the participant is an AVICA study failure.*** **(1040)** ☐1 Yes ☐0 No

   ➔ **If *YES*, complete the Termination of AVICA (P4_AVICA_TERM) and AVICA Study Treatment Questionnaire (P4_AVICA_TRTQX) forms and collect AVICA medications.**

6. Date AVICA study failure occurred **(1050)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

Physician Source Documentation

Physician's Signature: _____ **(1060)**

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

Time: __ __ __ __ *(based on a 24-hour clock)* **(1080)**

COMMENTS: (6000)

_____

_____

_____

P4 AVICA FAIL

AsthmaNet	TERMINATION OF AVICA	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 AVICA 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 INFANT study failure
- ❑$_2$ participant deemed AVICA study failure
- ❑$_3$ parent withdrew consent
- ❑$_4$ no longer interested in participating**
- ❑$_5$ no longer willing to follow protocol**
- ❑$_6$ difficult access to clinic (location, transportation, parking)
- ❑$_7$ participant experienced a serious adverse event*
- ❑$_8$ unable to continue due to personal constraints**
- ❑$_9$ moving out of the area
- ❑$_{10}$ participant lost to follow up
- ❑$_{11}$ unable to make visits during clinic hours
- ❑$_{12}$ 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)**

_____

_____

_____

* P 4 A V I C A T E R M *

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

I verify that all information collected on the AsthmaNet AVICA 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

AVICA 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 Visit 8. If a randomized participant terminates prior to Visit 8, please ask the parent/guardian to complete this form during the termination visit.

Parent/Guardian should complete Q1 – Q5.

1. Did your child use AVICA therapy?
   ➔ If ***NO***, STOP HERE.

(1000) ❑$_1$ Yes ❑$_0$ No

2. How well was your child's fever/pain controlled during the AVICA study?

(1010)
❑$_1$ Not at all
❑$_2$ Hardly at all
❑$_3$ Somewhat
❑$_4$ Fairly
❑$_5$ Very well

3. For the AVICA study, your child was randomized to receive either acetaminophen or ibuprofen. Please check the box that most closely represents your feelings about which of the two treatments your child was receiving.

(1020)
❑$_1$ Acetaminophen
❑$_2$ Ibuprofen
❑$_3$ No idea

4. In general, did your child have difficulty taking 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 / Too busy
❑$_5$ Doesn't like medicine
❑$_6$ Just didn't want to
❑$_7$ Side effects
❑$_8$ Other (specify)

(1040D) _____

5. Prior to enrolling in the INFANT/AVICA study, which medication did you prefer to give to your child?

(1050)
❑$_1$ Acetaminophen
❑$_2$ Ibuprofen
❑$_3$ No preference

Study Coordinator should complete Q6.

6. In your opinion, which of the two treatments was the participant receiving? **(1060)**

- ❑1 Acetaminophen
- ❑2 Ibuprofen
- ❑3 No idea

Clinic Coordinator Completed
COMMENTS: (6000)

_____

_____

_____

AsthmaNet

INFANT ELIGIBILITY CHECKLIST 1

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

(Coordinator Completed)

Informed Consents

1. Has the parent/legal guardian appropriately signed and dated the INFANT 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.

2. Has the parent/legal guardian appropriately signed and dated the AVICA Informed Consent? **(1020)** ☐1 Yes ☐0 No

   2a. If ***YES***, record the date the consent form was signed. **(1030)** __ __ / __ __ / 20 __ __ (MM DD YYYY)
   ➔ Consent should be reviewed and signed on the day Visit 1 is performed.

Study Medicines

3. Does the participant have an intolerance or allergy to fluticasone or montelukast? **(1040)** ☐1 Yes ☐0 No ☐8 Don't know

4. Does the participant have an intolerance or allergy to ibuprofen or acetaminophen? **(1050)** ☐1 Yes ☐0 No ☐8 Don't know

5. Does the participant have an intolerance or allergy to oral corticosteroids (Decadron, Dexamethasone, Orapred, Prelone, Pediapred or prednisone)? **(1060)** ☐1 Yes ☐0 No ☐8 Don't know

6. Is the participant able to take albuterol (such as Proventil and Ventolin)? **(1070)** ☐1 Yes ☐0 No

Medical History Criteria

7. Is the participant 12 to 59 months old? **(1080)** ☐1 Yes ☐0 No

8. Was the participant born before 35 weeks gestation? **(1090)** ☐1 Yes ☐0 No

9. Does the parent report that the participant is up-to-date with immunizations? **(1100)** ☐1 Yes ☐0 No

10.	Has the participant ever had chicken pox or received one dose of the chicken pox vaccine? (Refer to MOP for discussion on immunization records)	**(1110)**	❑1 Yes	❑0 No
11.	Is the participant receiving allergy shots?	**(1120)**	❑1 Yes	❑0 No
	11a. If ***YES***, has the dose been changed in the past 3 months?	**(1130)**	❑1 Yes	❑0 No
12.	Does the participant have any immunodeficiency disorders?	**(1140)**	❑1 Yes	❑0 No
13.	Does the participant have uncontrolled gastroesophageal reflux?	**(1150)**	❑1 Yes	❑0 No
14.	Does the participant have concurrent medical problems other than asthma that are likely to require oral or injectable corticosteroids during the study?	**(1160)**	❑1 Yes	❑0 No
15.	Does the participant have a chronic or active lung disease other than asthma (cystic fibrosis, BPD, etc)?	**(1170)**	❑1 Yes	❑0 No
16.	Does the participant have any co-morbid disorders associated with wheezing (aspiration, tracheomalacia, congenital airway anomalies, or bronchiectasis)?	**(1180)**	❑1 Yes	❑0 No
17.	Does the participant have a chronic medical disorder that could interfere with drug metabolism/excretion (chronic hepatic, biliary, renal disease, or seizure disorder treated with anticonvulsants)?	**(1190)**	❑1 Yes	❑0 No
18.	Does the participant have a chronic medical disorder that may increase the risk of drug-related injury (Osteogenesis imperfecta, Crohn's disease, ulcerative colitis, juvenile rheumatoid arthritis, clotting disorders, factor deficiency, G6PD deficiency, phenylketonuria)?	**(1200)**	❑1 Yes	❑0 No
19.	Does the participant have significant developmental delay/failure to thrive (defined as 5th percentile for height and/or weight or crossing two major percentile lines during the last year for age and sex)?	**(1210)**	❑1 Yes	❑0 No
20.	Does the participant have a significant medical illness other than asthma (refer to P4_EXCLMED)?	**(1220)**	❑1 Yes	❑0 No

Medication History

21.	During the past 6 months, how many oral/systemic corticosteroid courses has the participant had?	**(1230)**	__ __ courses

21a. Is Q21 ≥ 5? **(1240)** ☐1 Yes ☐0 No

22. Has the participant used an oral/systemic corticosteroid for any reason in the past 2 weeks? **(1246)** ☐1 Yes ☐0 No

Other Criteria

23. Does the participant have a primary medical caregiver (nurse practitioner, physician assistant, physician or group medical practice) whom the participant can contact for primary medical care? **(1250)** ☐1 Yes ☐0 No

24. During the past 12 months, how many times has the participant been hospitalized for wheezing or respiratory illnesses? **(1260)** __ __ times

24a. Is Q24 ≥ 3? **(1270)** ☐1 Yes ☐0 No

25. Has the participant ever had a near-fatal asthma exacerbation requiring intubation or assisted ventilation? **(1280)** ☐1 Yes ☐0 No

26. Is the parent able to use the spirotel® e-diary correctly as evidenced by achieving a score of 4 on the spirotel® Performance Checklist (P4_SPIROTEL_PERF)? **(1290)** ☐1 Yes ☐0 No

27. Currently, or within the past month, has the participant been involved in another therapeutic drug trial? **(1300)** ☐1 Yes ☐0 No

28. Does the participant's family have plans to move out of the area before the end of the study? **(1310)** ☐1 Yes ☐0 No

29. Is there any other reason for which this participant should not be included in this study? **(1320)** ☐1 Yes ☐0 No

If ***YES***, describe **(1320D)** _____

_____

30. Is the participant eligible? **(1330)** ☐1 Yes ☐0 No

If any of the shaded boxes are selected, the participant is ineligible.
➔ ***If NO, STOP HERE.***

31. During the past 4 weeks, has the participant been treated with a controller therapy? **(1340)** ☐1 Yes ☐0 No
➔ If ***NO***, skip to P4_ELIG3 and mark P4_ELIG2 missing during data entry.
31a. 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)
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	**(1350-1360)**	❑1 Yes	_ _ inhs/day	Any child on this medication does not qualify
Symbicort (budesonide-fomoterol)	80/4.5 mcg/inhalation 160/4.5 mcg/inhalation	**(1370-1380)**	❑1 Yes	_ _ inhs/day	Any child on this medication does not qualify
Dulera (mometasone-formoterol)	100/5 mcg/inhalation 200/5 mcg/inhalation	**(1390-1400)**	❑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, STOP HERE. Participant can be re-screened 4 weeks after last use.					
Beclomethasone	HFA: 40 mcg/puff	**(1410-1420)**	❑1 Yes	_ _ puffs/day	6 puffs
Beclomethasone	HFA: 80 mcg/puff	**(1430-1440)**	❑1 Yes	_ _ puffs/day	3 puffs
Budesonide	Nebulizer 0.25mg suspension	**(1450-1460)**	❑1 Yes	_ _ nebs/day	4 nebs
Budesonide	Nebulizer 0.5mg suspension	**(1470-1480)**	❑1 Yes	_ _ nebs/day	2 nebs
Budesonide	Nebulizer 1mg suspension	**(1490-1500)**	❑1 Yes	_ _ nebs/day	1 neb
Budesonide	Flexhaler: 90 mcg/inh	**(1510-1520)**	❑1 Yes	_ _ inhs/day	4 inhalations
Budesonide	Flexhaler: 180 mcg/inh	**(1530-1540)**	❑1 Yes	_ _ inhs/day	2 inhalations
Ciclesonide	HFA: 80 mcg/puff	**(1550-1560)**	❑1 Yes	_ _ puffs/day	3 puffs
Ciclesonide	HFA: 160 mcg/puff	**(1570-1580)**	❑1 Yes	_ _ puffs/day	2 puffs

Medication			Taking?	If ***YES***, number of puffs/nebs/ inhalations per day	No more than this number puffs/day (limit)
Flunisolide	HFA: 80 mcg/puff	**(1590-1600)**	❑$_1$ Yes	_ _ puffs/day	3 puffs
Fluticasone	HFA: 44 mcg/puff	**(1610-1620)**	❑$_1$ Yes	_ _ puffs/day	6 puffs
Fluticasone	HFA: 110 mcg/puff	**(1630-1640)**	❑$_1$ Yes	_ _ puffs/day	2 puffs
Fluticasone	HFA: 220 mcg/puff	**(1650-1660)**	❑$_1$ Yes	_ _ puffs/day	1 puff
Fluticasone	DPI: 50 mcg/inh	**(1670-1680)**	❑$_1$ Yes	_ _ inhs/day	4 inhalations
Fluticasone	DPI: 100 mcg/inh	**(1690-1700)**	❑$_1$ Yes	_ _ inhs/day	2 inhalations
Fluticasone	DPI: 250 mcg/inh	**(1710-1720)**	❑$_1$ Yes	_ _ inhs/day	1 inhalation
Mometasone	DPI: 110 mcg/inh	**(1730-1740)**	❑$_1$ Yes	_ _ inhs/day	2 inhalations
Mometasone	DPI: 220 mcg/inh	**(1750-1760)**	❑$_1$ Yes	_ _ inhs/day	1 inhalation
Singulair	4 or 5 mg/tablet	**(1770-1780)**	❑$_1$ Yes	_ _ tablets/day	1 tablet
Singulair	4 mg/packet	**(1790-1800)**	❑$_1$ Yes	_ _ packet/day	1 packet
Triamcinolone	MDI: 75 mcg/puff	**(1810-1820)**	❑$_1$ Yes	_ _ puffs/day	6 puffs

32. Is the participant taking more than 1 controller therapy and the second controller therapy is not a LTRA? **(1830)** ❑$_1$ Yes ❑$_0$ No
    - ➔ If ***YES***, STOP HERE. The participant is ineligible for INFANT.

33. Are any of the doses greater than the limit? **(1840)** ❑$_1$ Yes ❑$_0$ No
    - ➔ If ***YES***, STOP HERE. The participant is ineligible for INFANT.
    - ➔ If ***NO***, proceed to P4_ELIG2 and mark P4_ELIG3 missing during data entry.

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

INFANT ELIGIBILITY CHECKLIST 2

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

(Coordinator Completed)

This form should only be completed for participants who have been treated with a controller therapy in the past 4 weeks (P4_ELIG1 Q30 is answered Yes).

1. Is the participant currently taking ***BOTH*** ICS and LTRA? **(1000)** ❑1 Yes ❑0 No

   1a. If ***YES***, does the participant take LTRA for reasons other than asthma? **(1010)** ❑1 Yes ❑0 No
   - ➔ If ***YES***, the study physician should be consulted.
   - ➔ If ***NO***, the participant is ineligible for INFANT. Skip to Q10.

   1ai. If ***YES***, can the LTRA be discontinued per the study physician? **(1020)** ❑1 Yes ❑0 No
   - ➔ If ***NO***, the participant is ineligible for INFANT. Skip to Q10.

2. How many months has the participant been treated with a daily controller therapy during the past 6 months? **(1030)** __ months

   2a. Is Q2 > 3? **(1040)** ❑1 Yes ❑0 No

   2ai. If ***YES*** to Q2a, did the participant have any asthma symptoms while taking ICS or LTRA? **(1050)** ❑1 Yes* ❑0 No

3. During the past 12 months, how many wheezing episodes has the participant had (one wheezing episode = 24 hours or more of symptoms)? **(1060)** __ __ episodes

   3a. Is Q3 ≥ 4? **(1070)** ❑1 Yes ❑0 No

4. During the past 12 months, how many asthma exacerbations requiring oral/systemic corticosteroids has the participant had? **(1080)** __ __ exacerbations

   4a. Is Q4 ≥ 2? **(1090)** ❑1 Yes ❑0 No

5. During the past 4 weeks, how many days has the participant had daytime asthma symptoms? **(1100)** __ __ days

   5a. Is Q5 > 8? **(1110)** ❑1 Yes ❑0 No

6. During the past 4 weeks, how many nighttime awakenings has the participant had? **(1120)** __ __ nights

   6a. Is Q6 > 1? **(1130)** ❑1 Yes ❑0 No

7. If ***YES to either Q3a or Q4a***, is the participant taking ICS or LTRA on a daily basis (not intermittently)? **(1140)** ❑1 Yes* ❑0 No

8. If ***YES to either Q5a or Q6a***, did the symptoms appear after the ICS or LTRA was discontinued? **(1150)** ❑1 Yes ❑0 No*

   8a. If **YES to Q8**, is the participant taking ICS or LTRA on a daily basis (not intermittently) **(1160)** ❑1 Yes* ❑0 No

9. Is there any other reason for which this participant should not be included in this study? **(1170)** ❑1 Yes ❑0 No

   If ***YES***, describe **(1170D)**

   _____

   _____

10. Is the participant eligible? **(1180)** ❑1 Yes ❑0 No

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

    ➔ **If *NO, STOP HERE*.**

If any of the starred (*) responses are selected, enroll the participant with Active Run-In Meds. If the participant is currently taking ICS, the Run-In will be with active ICS and placebo LTRA. If the participant is currently taking LTRA, the Run-In will be with active LTRA and placebo ICS.

If none of the starred (*) responses are selected, enroll the participant with placebo ICS and placebo LTRA. Prior to Visit 2, be sure to record the response to Q3a on P4_ELIG2 onto P4_ELIG4 Q9 and the response to Q21 on P4_ELIG1 onto P4_ELIG4 Q10.

11. During the Run-In period, what LTRA will this participant be using? **(1190)** ❑1 Placebo LTRA ❑2 Active LTRA

12. During the Run-In period, what ICS will this participant be using? **(1200)** ❑1 Placebo ICS ❑2 Active ICS

COMMENTS: (6000)

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AsthmaNet

INFANT ELIGIBILITY CHECKLIST 3

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

(Coordinator Completed)

This form should only be completed for participants who have NOT been treated with a controller therapy in the past 4 weeks (P4_ELIG1 Q30 is answered No).

1.	During the past 4 weeks, how many days has the participant had daytime asthma symptoms?	**(1000)**	__ __ days
	1a. Is Q1 > 8?	**(1010)**	❑1 Yes* ❑0 No
2.	During the past 4 weeks, how many nighttime awakenings has the participant had?	**(1020)**	__ __ nights
	2a. Is Q2 ≥ 1?	**(1030)**	❑1 Yes* ❑0 No
3.	During the past 12 months, how many wheezing episodes has the participant had (one wheezing episode = 24 hours or more of symptoms)?	**(1040)**	__ __ episodes
	3a. Is Q3 ≥ 4?	**(1050)**	❑1 Yes* ❑0 No
4.	During the past 6 months, how many asthma exacerbations requiring oral/systemic corticosteroids has the participant had?	**(1060)**	__ __ exacerbations
	4a. Is Q4 ≥ 2?	**(1070)**	❑1 Yes* ❑0 No
5.	Are any of the starred (*) responses selected?	**(1080)**	❑1 Yes ❑0 No
6.	Is there any other reason for which this participant should not be included in this study?	**(1090)**	❑1 Yes ❑0 No
	If ***YES***, describe	**(1090D)**	_____

7.	Is the participant eligible?	**(1100)**	❑1 Yes ❑0 No

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

➔ **If *YES*, enroll the participant with Placebo Run-In Meds and proceed with remaining Visit 1 procedures. Prior to Visit 2, be sure to record the response to Q3a on P4_ELIG3 onto P4_ELIG4 Q9 and the response to Q21 on P4_ELIG1 onto P4_ELIG4 Q10.**

COMMENTS: (6000)

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AsthmaNet

INFANT ELIGIBILITY CHECKLIST 4 (for participants on Placebo Run-In Meds)

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

(Coordinator Completed)

This form should only be completed for participants who were on PLACEBO medication during the Run-in. If the participant was on active medication during the Run-in, mark this form missing during data entry and complete P4_ELIG5.

1. Did the participant have any exacerbations requiring oral/systemic corticosteroids? **(1000)** ❑1 Yes ❑0 No
   ➔ If ***YES***, the participant is ineligible for INFANT. See the MOP for further details.

   1a. If ***YES***, was the participant hospitalized? **(1010)** ❑1 Yes ❑0 No
   ➔ If ***YES***, complete the SERIOUS form.
   ➔ Skip to Q13.

2. Did the participant take any medication for asthma other than albuterol? **(1020)** ❑1 Yes ❑0 No
   ➔ If ***YES***, STOP HERE. The 2 week Run-In should be repeated. See the MOP for further details.

3. Did the participant develop any new medical conditions? **(1030)** ❑1 Yes ❑0 No
   ➔ If ***YES***, the study physician should be consulted.

Q4 – Q8, according to the spirotel® INFANT Eligibility Report:

4. Percent compliance for Diary Completion **(1040)** __ __ __ . __ %

   4a. Is the compliance for Diary Completion ≥ 75%? **(1050)** ❑1 Yes ❑0 No

5. Percent compliance for Brown Daily Inhaler **(1060)** __ __ __ . __ %

   5a. Is the compliance for Brown Daily Inhaler ≥ 75%? **(1070)** ❑1 Yes ❑0 No

6. Percent compliance for Oral Study Medication **(1080)** __ __ __ . __ %

   6a. Is the compliance for Oral Study Medication ≥ 75%? **(1090)** ❑1 Yes ❑0 No

7. Average number of days per week with daytime asthma symptoms **(1100)** __ . __ days

   7a. Did the participant have daily daytime asthma symptoms 7 days per week (Q7 = 7)? **(1110)** ❑1 Yes ❑0 No

   7b. Did the participant have daytime asthma symptoms more than 2 days per week (Q7 > 2)? **(1120)** ❑1 Yes* ❑0 No

P4 ELIG4

8. Number of nighttime awakenings from asthma **(1130)** __ __ awakenings

   8a. Did the participant have > 1 nighttime awakening from asthma (Q8 > 1)? **(1140)** ❑1 Yes ❑0 No

   8b. Did the participant have 1 nighttime awakening from asthma (Q8 = 1) **(1150)** ❑1 Yes* ❑0 No

9. According to P4_ELIG2 or P4_ELIG3 Q3a (whichever form was completed at Visit 1), did the participant have 4 or more wheezing episodes (1 wheezing episode = 24 hours or more of symptoms) in the 12 months prior to enrollment? **(1160)** ❑1 Yes* ❑0 No

10. According to P4_ELIG1 Q21, did the participant have 2 or more exacerbations requiring oral/systemic corticosteroids in the 6 months prior to enrollment? **(1170)** ❑1 Yes* ❑0 No

11. Are any of the starred (*) responses selected? **(1180)** ❑1 Yes ❑0 No
    ➔ If ***NO*** and no gray boxes were checked, the participant is still eligible. The Run-In should be extended for another 2 weeks. See the MOP for further details.

12. Is there any other reason for which this participant should not be included in this study? **(1190)** ❑1 Yes ❑0 No

    If ***YES***, describe **(1190D)** _____

    _____

13. Is the participant eligible? **(1200)** ❑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)**

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AsthmaNet

INFANT ELIGIBILITY CHECKLIST 5 (for participants on Active Run-In Meds)

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

(Coordinator Completed)

This form should only be completed for participants who were on ACTIVE medication during the Run-In. If the participant was on placebo medication, mark this form missing during data entry and complete P4_ELIG4.

1. Did the participant have any exacerbations requiring oral/systemic corticosteroids? **(1000)** ❑1 Yes ❑0 No
   ➔ If ***YES***, the participant is ineligible for INFANT. See the MOP for further details.

   1a. If ***YES***, was the participant hospitalized? **(1010)** ❑1 Yes ❑0 No
   ➔ If ***YES***, complete the SERIOUS form.
   ➔ Skip to Q10.

2. Did the participant take any additional medication for asthma (other than albuterol), including an increase in medication dose or frequency? **(1020)** ❑1 Yes ❑0 No
   ➔ If ***YES***, the study physician should be consulted.

3. Did the participant develop any new medical conditions? **(1030)** ❑1 Yes ❑0 No
   ➔ If ***YES***, the study physician should be consulted.

Q4 – Q8, according to the spirotel® INFANT Eligibility Report:

4. Percent compliance for Diary Completion **(1040)** __ __ __ . __ %

   4a. Is the compliance for Diary Completion ≥ 75%? **(1050)** ❑1 Yes ❑0 No

5. Percent compliance for Brown Daily Inhaler **(1060)** __ __ __ . __ %

   5a. Is the compliance for Brown Daily Inhaler ≥ 75%? **(1070)** ❑1 Yes ❑0 No

6. Percent compliance for Oral Study Medication **(1080)** __ __ __ . __ %

   6a. Is the compliance for Oral Study Medication ≥ 75%? **(1090)** ❑1 Yes ❑0 No

7. Average number of days per week with daytime asthma symptoms **(1100)** __ . __ days

   7a. Did the participant have daytime asthma symptoms >2 days per week? **(1110)** ❑1 Yes ❑0 No
   ➔ If ***NO***, skip to Q8.

P4 ELIG5

7b. Did the participant have daytime asthma symptoms 7 days per week? **(1120)** ❑1 Yes ❑0 No

- ➔ If ***YES***, the participant is ineligible for INFANT. Skip to Q10.
- ➔ If ***NO***, STOP HERE. Run-In should be extended for 2 weeks. See the MOP for further details.

8. Number of nighttime awakenings from asthma **(1130)** __ __ awakenings

8a. Did the participant have > 1 nighttime awakening from asthma? **(1140)** ❑1 Yes ❑0 No

- ➔ If ***YES***, STOP HERE. Run-In should be extended for 2 weeks. See the MOP for further details.

9. Is there any other reason for which this participant should not be included in this study? **(1150)** ❑1 Yes ❑0 No

If ***YES***, describe **(1150D)** _____

_____

10. Is the participant eligible? **(1160)** ❑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)

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AsthmaNet

INFANT COMPLIANCE CHECKLIST

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

(Coordinator Completed)

Information for Q1 – Q7 is obtained from the spirotel® Participant Compliance Report (P4_COMPLY_RPT).

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

Diary Completion

2. Number of days where PM scheduled session is complete **(1010)** __ __ __ days

3. Percent compliance **(1020)** __ __ __ . __ %

Brown Daily Inhaler

4. Number of puffs that were taken from the brown daily inhaler **(1030)** __ __ __ puffs

5. Percent compliance **(1040)** __ __ __ . __ %

Oral Medication

6. Number of days where oral study medication was taken **(1050)** __ __ __ days

7. Percent compliance **(1060)** __ __ __ . __ %

COMMENTS: (6000)

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AsthmaNet

INFANT STUDY FAILURE

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

(Coordinator Completed)

1. Has the participant required 4 courses of prednisolone since randomization? **(1000)** ☐1 Yes ☐0 No

2. Has the participant been hospitalized for more than 24 hours due to an asthma exacerbation? **(1010)** ☐1 Yes ☐0 No

3. Has the participant moved forward to the next treatment arm due to recurrent exacerbations (protocol-defined) two times during the course of the study? **(1020)** ☐1 Yes ☐0 No

4. Is the participant a study failure? **If any of the shaded boxes are selected, the participant is an INFANT study failure.** **(1030)** ☐1 Yes ☐0 No

   ➔ **If YES, complete the Termination of INFANT (P4_INFANT_TERM), Termination of AVICA (P4_AVICA_TERM), INFANT Study Treatment Questionnaire (P4_INFANT_TRTQX), and AVICA Study Treatment Questionnaire (P4_AVICA_TRTQX) forms and collect study medications.**

5. Date INFANT study failure occurred. **(1040)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

Physician Source Documentation

Physician's Signature: _____ **(1050)**

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

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

COMMENTS: **(6000)**

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P4 INFANT FAIL

AsthmaNet

TERMINATION OF INFANT

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 INFANT 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 INFANT 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)**

_____

_____

_____

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

I verify that all information collected on the AsthmaNet INFANT 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

INFANT TREATMENT ARM FAILURE

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

(Coordinator Completed)

1. Has the participant received his/her second course of an oral/systemic corticosteroid for an asthma exacerbation within any of the three treatment periods (V2 - V4, V4 – V6, V6 – V8)? **(1000)** ❑$_1$ Yes ❑$_0$ No

   ➔ **If *NO*, STOP HERE. Do not enter this form into the database.**

   ➔ **If *YES*, the participant is a treatment arm failure and the participant should be scheduled to begin the next treatment period.**

2. Date treatment arm failure occurred **(1010)** __ __ / __ __ / 20 __ __
   MM DD YYYY

Physician Source Documentation

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

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

Time: __ __ __ __ *(based on a 24-hour clock)* **(1040)**

COMMENTS: (6000)

_____

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P4 INFANT TRTFAIL

AsthmaNet

INFANT 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 Visits 4, 6 and 8. If a randomized participant terminates prior to Visits 4, 6 or 8, please ask the parent/guardian to complete this form during the termination visit.

Parent/Guardian should complete Pages 1-4.

1. During this treatment period, how well did you think the study medications received during the INFANT study controlled the participant's asthma symptoms?

(1000)
- ❑$_1$ Not at all
- ❑$_2$ Hardly at all
- ❑$_3$ Somewhat
- ❑$_4$ Fairly
- ❑$_5$ Very well

The following questions refer to the <u>brown Daily Inhaler</u> that the participant used every morning and evening.

2. During this treatment period, the participant was randomized to receive either an active (i.e., real) brown Daily Inhaler or an inactive (i.e., look-alike) brown Daily Inhaler. Please check the box that most closely represents your feelings about the **brown Daily Inhaler**.

(1010)
- ❑$_1$ Definitely placebo
- ❑$_2$ Probably placebo
- ❑$_3$ I don't know, but my guess would be:

(1020)
- ❑$_1$ Placebo
- ❑$_2$ Active drug

- ❑$_4$ Probably active drug
- ❑$_5$ Definitely active drug

3. During this treatment period, what best describes how the participant took the **brown Daily Inhaler**?

(1030)
- ❑$_1$ More regularly at the beginning
- ❑$_2$ More regularly at the end
- ❑$_3$ The same throughout the study

4. Did the participant object to taking the **brown Daily Inhaler**?
➔ ***If you answered 'No', SKIP to Q5.***

(1040) ❑$_1$ Yes ❑$_0$ No

4a. If ***YES***, what was the primary reason the participant didn't like taking the **brown Daily Inhaler**?

(1050)
- ❑1 Tasted bad
- ❑2 Smelled bad
- ❑3 Inconvenient
- ❑4 Forgot / Too busy
- ❑5 Doesn't like medicine
- ❑6 Just didn't want to
- ❑7 Side effects
- ❑8 Other (specify)

(1050D) _____

The following questions refer to the <u>white Rescue Inhaler</u> that the participant used along with the red Albuterol Inhaler for asthma symptoms.

5. During this treatment period, the participant was randomized to receive either an active (i.e., real) white Rescue Inhaler or an inactive (i.e., look-alike) white Rescue Inhaler. Please check the box that most closely represents your feelings about the **white Rescue Inhaler**.

(1060)
- ❑1 Definitely placebo
- ❑2 Probably placebo
- ❑3 I don't know, but my guess would be:

(1070)
- ❑1 Placebo
- ❑2 Active drug

- ❑4 Probably active drug
- ❑5 Definitely active drug

6. During this treatment period, what best describes how the participant took the **white Rescue Inhaler**?

(1080)
- ❑1 More regularly at the beginning
- ❑2 More regularly at the end
- ❑3 The same throughout the study

7. Did the participant object to taking the **white Rescue Inhaler**?

(1090) ❑1 Yes ❑0 No

➔ ***If you answered 'No', SKIP to Q8.***

7a. If ***YES***, what was the primary reason the participant didn't like taking the **white Rescue Inhaler**?

(1100)
- ❑1 Tasted bad
- ❑2 Smelled bad
- ❑3 Inconvenient
- ❑4 Forgot / Too busy
- ❑5 Doesn't like medicine
- ❑6 Just didn't want to
- ❑7 Side effects
- ❑8 Other (specify)

(1100D) _____

8. Before participation in the INFANT study, how often did the participant use a spacer to take inhaler medications?

(1110)
- ❑1 Always
- ❑2 Sometimes
- ❑3 Occasionally
- ❑4 Never
- ❑5 Not applicable-inhaler medications not used before INFANT

9. Please rate the difficulty of using 2 rescue inhalers during the INFANT study.

(1120)
- ❑1 Easy
- ❑2 Okay
- ❑3 Inconvenient
- ❑4 Hard
- ❑5 Not applicable

The following questions refer to the <u>oral study medication</u> that the participant used every evening.

10. During this treatment period, the participant was randomized to receive either an active (i.e., real) oral study medication or an inactive (i.e., look-alike) oral study medication. Please check the box that most closely represents your feelings about the **study tablets/granules**.

(1130)
- ❑1 Definitely placebo
- ❑2 Probably placebo
- ❑3 I don't know, but my guess would be:

(1140)
- ❑1 Placebo
- ❑2 Active drug

- ❑4 Probably active drug
- ❑5 Definitely active drug

11. During this treatment period, what best describes how the participant took the **oral study medication**?

(1150)
- ❑1 More regularly at the beginning
- ❑2 More regularly at the end
- ❑3 The same throughout the study

12. Did the participant object to taking the **oral study medication**?
➔ ***If you answered 'No', STOP HERE.***

(1160) ❑1 Yes ❑0 No

12a. If ***YES***, what was the primary reason the participant didn't like taking the **oral study medication**?

(1170)

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

(1170D) _____

Study Coordinator should complete Q13 - 15.

13. In your opinion, what was contained in the **brown Daily Inhaler** for this participant? **(1180)**
- ❑1 Inhaled corticosteroid
- ❑2 Placebo
- ❑3 No idea

14. In your opinion, what was contained in the **white Rescue Inhaler** for this participant? **(1190)**
- ❑1 Inhaled corticosteroid
- ❑2 Placebo
- ❑3 No idea

15. In your opinion, what was contained in the **oral study medication** for this participant? **(1200)**
- ❑1 LTRA
- ❑2 Placebo
- ❑3 No idea

Clinic Coordinator Completed

COMMENTS: (6000)

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AsthmaNet

INFANT LABORATORY RESULTS

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

(Coordinator Completed)

If unable to collect blood and/or urine at Visit 2, samples can be collected at a later visit. Only collect each sample once.

BLOOD TESTS and SPECIMEN COLLECTIONS

1. Were you able to collect a blood sample from the participant today? **(1000)** ❑1 Yes ❑0 No
   ➔ If **NO**, skip to Q8.

Local Laboratory Results

2. Total WBC **(1010)** __ __ __ __ __ /cu.mm

3. Eosinophils **(1020)** __ __ . __ %

External Laboratory Samples

4. Were you able to collect a sample for allergen-specific IgE, total IgE and ECP? **(1030)** ❑1 Yes ❑0 No

5. Were you able to collect a sample for genetic analysis? **(1040)** ❑1 Yes ❑0 No

6. Were you able to collect a sample for metabolomics and proteomics? **(1050)** ❑1 Yes ❑0 No

7. Were you able to collect a sample for glutathione and metabolites? **(1060)** ❑1 Yes ❑0 No

Urine Laboratory Sample

8. Were you able to collect a urine sample from the participant today? **(1070)** ❑1 Yes ❑0 No

NASAL SAMPLING

9. Were you able to collect a nasal sample from the participant today? **(1080)** ❑1 Yes ❑0 No

   9a. If ***YES***, which collection technique was used? **(1090)** ❑1 Nasal Blow
   ❑2 Nasal Swab

COMMENTS: (6000)

_____

AsthmaNet

PHONE/VISIT SYMPTOM ASSESSMENT

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

(Coordinator Completed)

1. Since the last visit or phone contact, has your child been to a doctor for breathing problems? **(1000)** ❑1 Yes ❑0 No

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

2. Since the last visit or phone contact, has your child been to an ER/urgent care facility for breathing problems? **(1020)** ❑1 Yes ❑0 No
   ➔ If **YES**, assess whether the participant is a study failure.

3. Since the last visit or phone contact, has your child been hospitalized for breathing problems? **(1030)** ❑1 Yes ❑0 No
   ➔ If **YES**, assess whether the participant is a study failure.

4. During the past 2 weeks, did your child have wheezing or cough? **(1040)** ❑1 Yes ❑0 No

   4a. If ***YES***, how many days? **(1050)** __ __ days

   4b. Is Q4a > 5? **(1060)** ❑1 Yes ❑0 No
   ➔ If **YES**, and cough was moderate-severe, study physician should be consulted as to whether prednisolone therapy should be started.

5. During the past 2 weeks, did your child awaken from sleep due to asthma symptoms? **(1070)** ❑1 Yes ❑0 No

   5a. If ***YES***, how many nights? **(1080)** __ __ nights

   5b. Is Q5a > 1? **(1090)** ❑1 Yes ❑0 No
   ➔ If **YES**, and there were at least 2 consecutive nights, study physician should be consulted.

6. During the past 2 weeks, did your child take any albuterol (excluding pre-exercise)? **(1100)** ❑1 Yes ❑0 No

   6a. If **YES**, how many days? **(1110)** __ __ days

7. Has your child been using the white Rescue inhaler each time the red Albuterol inhaler is used? **(1120)** ❑1 Yes ❑0 No ❑9 N/A
   ➔ If **NO**, please review adherence with parent.

8. Have you been completing the spirotel® Diary daily? **(1130)** ❑1 Yes ❑0 No
   ➔ If **NO**, please review adherence with parent.

9. Has your child been using the brown Daily inhaler every morning and evening? **(1140)** ❑$_1$ Yes ❑$_0$ No
   ➔ If **NO**, please review adherence with parent.

10. Has your child been taking the oral study medication once daily? **(1150)** ❑$_1$ Yes ❑$_0$ No
    ➔ If **NO**, please review adherence with parent.

11. Since the last visit or phone contact, has your child used AVICA medication? **(1160)** ❑$_1$ Yes ❑$_0$ No
    ➔ If **YES**, instruct the parent to record the AVICA use on the AVICA Medication diary.

12. Since the last visit or phone contact, has your child used prednisolone? **(1170)** ❑$_1$ Yes ❑$_0$ No

    12a. If **YES**, how many times was prednisolone used since starting the current treatment sequence (since visits 2, 4, 6)? **(1180)** __ times
    ➔ If Q12a > 1 the participant is an INFANT treatment arm failure. Complete the P4_INFANT_TRTFAIL form.

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

INFANT PREDNISOLONE MEDICATION

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

(Coordinator Completed)

Complete this form each time an INFANT 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 INFANT protocol specifications are to prescribe oral steroids if: **(1010)**
   - ❑1 Symptoms did not improve after 3 ICS/SABA treatments administered every 20 minutes
   - ❑2 > 6 rescue treatments were needed for > 24 hours
   - ❑3 Moderate-severe cough or wheeze occurred for at least 5 of the preceding 7 days
   - ❑4 Specified thresholds of rescue ICS/SABA uses were reached
   - ❑5 There was an unscheduled visit for acute asthma care requiring repeated doses of SABA
   - ❑6 Hospitalization was needed for asthma
   - ❑7 Physician discretion **(If Physician discretion, please explain in the comments section below)**

3. Is the start of this prednisolone course on the same day as Visit 4 or 6? **(1020)** ❑1 Yes ❑0 No
   ➔ **If *YES*, the visit should be postponed for 4 to 7 days. Study medications from the current treatment period should be continued.**

* P 4 P R E D *

4. Is this the second prednisolone course within a treatment sequence (i.e. Visits 2-4, Visits 4-6, or Visits 6-8)? **(1030)** ❑$_1$ Yes ❑$_0$ No
   ➔ **If *YES*, the participant is an INFANT treatment arm failure. Complete the P4_INFANT_TRTFAIL form.**

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

6. 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

TERMINATION OF INFANT 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.

(1000)
- ❑1 inability to demonstrate adherence with spirotel®
- ❑2 inability to demonstrate adherence with study medications
- ❑3 too few asthma symptoms during Run-In
- ❑4 too many asthma symptoms during Run-In
- ❑5 asthma exacerbation during Run-In
- ❑6 participant required an asthma medication other than study medications since Visit 1
- ❑7 parent withdrew consent
- ❑8 participant lost to follow up
- ❑9 participant experienced a serious adverse event*
- ❑10 physician initiated termination of study participation**
- ❑11 other**

*** Please complete the Serious Adverse Event Reporting (SERIOUS) form.**
****Additional explanation required: (1000D)**

_____

_____

_____

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

I verify that all information collected on the AsthmaNet INFANT 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.

_____ **(1010)** __ __ / __ __ / 20 __ __ **(1020)**
Coordinator Signature MM DD YY

_____ **(1030)** __ __ / __ __ / 20 __ __ **(1040)**
Project Investigator Signature MM DD YY

COMMENTS: (6000)

_____

P4 TERMR

AsthmaNet

CLINICAL ADVERSE EVENTS

(Coordinator completed)

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

Part. Initials: __ __ __

Visit: __ __ __

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

❑0 None

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

AsthmaNet

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.***

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

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)

_____

_____

_____

Scheduled Assessment (6 PM – Noon the following day)

Q1. Did your child have any asthma symptoms today? __ (3=Yes, 0=No)

➔ If **No**, spirotel® will skip the user to Q9

Q2. Did your child awaken at night with difficulty breathing? __ (3=Yes, 0=No)

Q3. How severe was your child's cough today? __ (0, 1, 2, 3)

Q4. How severe was your child's wheezing today? __ (0, 1, 2, 3)

Q5. How severe was your child's trouble breathing today? __ (0, 1, 2, 3)

Q6. How much did your child's asthma symptoms interfere with your child's activities today? __ (0, 1, 2, 3)

Q7. Number of puffs from your red Albuterol Inhaler taken for asthma symptoms in the past 24 hours __ __ (numeric 0-16)

Q8. Number of puffs from your white Rescue Inhaler taken for asthma symptoms in the past 24 hours __ __ (numeric 0-16)

Q9. Number of inhalations taken from your brown daily inhaler in the past 24 hours __ (numeric 0-4)

Q10. Oral study medication taken at bedtime? __ (3=Yes, 0=No)

Prompts and Alerts

1. Applies when a scheduled session is started after 12:00 AM:
   Line 1: Questions refer
   Line 2: to yesterday
2. If Q7 >=8 or Q8 >=8, then present alert:
   Line 1: Rescue Use High
   Line 2: Call Clinic ASAP
3. If Q3 = 3, Q4 = 3, Q5 = 3, or Q6 = 3, then present alert:
   Line 1: Symptom Severe
   Line 2: Call Clinic ASAP
4. If Q3 >= 2 or Q4 >= 2 for 5 spirotel sessions in any 7 calendar day segment where return visit number >= 3, then present alert:
   Line 1: 7 Day Symp High
   Line 2: Call Clinic ASAP
5. If sum of Q7 >= 90 or sum of Q8 >= 90 for any 30 consecutive calendar days where return visit number >= 3, then present alert:
   Line 1: 30DayRescueHigh
   Line 2: Call Clinic ASAP

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

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

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

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

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

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

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

AsthmaNet

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

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

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

FREQUENTLY USED ASTHMA & ALLERGY DRUG CODES

AsthmaNet

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

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