

**SIGNIFICANT ASTHMA
EXACERBATION**

Subject ID: 2
 Subject Initials: _____
 Visit Number: _____
 Current Date: _____ / _____ / _____
month day year
 Interviewer ID: _____

(Clinic Coordinator completed)

This form must be completed each time a subject experiences an asthma exacerbation according to the definition below.

SAE_01 1. Did the subject experience an increase in cough, chest tightness, or wheezing? ₁ Yes ₀ No

2. Did the subject experience any of the following conditions?

SAE_02a 2a. An increase in rescue inhaler use of ≥ 8 puffs per 24 hours over baseline rescue inhaler use for a period of 48 hours? ₁ Yes ₀ No

SAE_02b 2b. Use of rescue inhaler ≥ 16 total puffs per 24 hours for a period of 48 hours? ₁ Yes ₀ No

SAE_02c 2c. A fall in pre-bronchodilator PEFR to $\leq 65\%$ of baseline (baseline defined as average AM or PM pre-bronchodilator PEFR recorded during study week 4, just prior to steroid withdrawal)? ₁ Yes ₀ No

If you did not answer YES to Question #1 AND at least one item in Question #2, the subject did not experience a significant asthma exacerbation as defined in the Manual of Operations. DO NOT COMPLETE THIS FORM.

If the subject has experienced a significant asthma exacerbation but has not yet completed the RUN-IN period, STOP. The subject is ineligible for the study.

SAE_03 3. Date of significant asthma exacerbation _____ / _____ / _____
month day year

SAE_04 4. Was the significant asthma exacerbation related to the routine pulmonary function testing? *(Check one box only)*

₁ Definitely related
₂ Probably related
₃ Relationship undetermined
₄ Probably not related
₅ Definitely not related

SAE_05 5. Was the significant asthma exacerbation related to the Beta-agonist Reversibility testing? *(Check one box only)*

₁ Definitely related
₂ Probably related
₃ Relationship undetermined
₄ Probably not related
₅ Definitely not related

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- SAE_06** 6. Was the significant asthma exacerbation related to the Methacholine Challenge testing? *(Check one box only)*
- ₁ Definitely related
₂ Probably related
₃ Relationship undetermined
₄ Probably not related
₅ Definitely not related
- SAE_07** 7. Was the asthma exacerbation resolved by increasing PRN use of the rescue inhaler?
- ₁ Yes ₀ No
- SAE_08** 8. Did the subject seek care for the asthma exacerbation?
If **No**, skip to Question #10.
- ₁ Yes ₀ No
9. What type of care was sought?
- SAE_09a** 9a. Study Investigator?
- ₁ Yes ₀ No
- SAE_09a1** If **Yes**, indicate type of contact.
- ₁ Scheduled clinic visit
₂ Unscheduled clinic visit
₃ Phone contact
- SAE_09b** 9b. Primary Care or Other Physician?
Name of physician: _____
- ₁ Yes ₀ No
- SAE_09b1** If **Yes**, indicate type of contact.
- ₁ Scheduled clinic visit
₂ Unscheduled clinic visit
₃ Phone contact
- SAE_09c** 9c. Emergency Room visit?
Name of hospital: _____
- ₁ Yes ₀ No

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SAE_10

10. Was the subject hospitalized?

₁ Yes ₀ No

Name of hospital: _____

If Yes, please complete the Serious Adverse Event Reporting Form (SERIOUS).

SAE_10a

If **Yes**, was intubation and ventilation assistance required?

₁ Yes ₀ No

SAE_11

11. Did the asthma exacerbation require treatment with inhaled, oral, or intravenous glucocorticoids?

₁ Yes ₀ No

If **Yes**,

SAE_11a

11a. Start date of glucocorticoid:

____ / ____ / ____
month day year

SAE_11b

11b. Stop date of glucocorticoid:

____ / ____ / ____
month day year

SAE_12

12. Was the asthma exacerbation treated as outlined in the Manual of Operations?

₁ Yes ₀ No

If **No**, describe _____

