Asthma Clinical Research Network BAGS
NIH/NHLBI

SIGNIFICANT ASTHMA EXACERBATION

SAE

Patient ID: 1 ___ ___ ___ ___
Patient Initials: ___ ___ ___
Visit Number: ___ ___
Current Date: ___ ___ / _____ / ___ ___
month day year
Interviewer ID: ___ ___ ___ ___

(Clinic Coordinator completed)

This form is to be filled out each time a patient experiences an asthma exacerbation according to the definition below.

01 1. Did the patient experience an increase in cough, chest tightness, or wheezing? ❑1 Yes ❑0 No

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

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

02B 2b. An increase in rescue inhaler use ≥ 16 total puffs per 24 hours for a period of 48 hours? ❑1 Yes ❑0 No

02C 2c. A fall in PEFR to 65% of reference? ❑1 Yes ❑0 No

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

If the patient has experienced a significant asthma exacerbation but has not yet completed the RUN-IN period, STOP. The patient is ineligible for the study. Please complete the Termination of Study Participation form (TERM).

03 3. 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

04 4. 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

05 5. 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

06 6. Was the asthma exacerbation resolved by increasing PRN use of the rescue inhaler?

❑1 Yes ❑0 No

07 7. Did the patient seek care for the asthma exacerbation? If ***No***, skip to Question #9.

❑1 Yes ❑0 No

8. What type of care was sought?

08A 8a. Study Investigator?

❑1 Yes ❑0 No

08A1 If ***Yes***, indicate type of contact.

- ❑1 Scheduled clinic visit
- ❑2 Unscheduled clinic visit
- ❑3 Phone contact

08B 8b. Primary Care or Other Physician?

❑1 Yes ❑0 No

Name of physician: _____

08B1 If ***Yes***, indicate type of contact.

- ❑1 Scheduled clinic visit
- ❑2 Unscheduled clinic visit
- ❑3 Phone contact

08C 8c. Emergency Room visit?

❑1 Yes ❑0 No

Name of hospital: _____

09 9. Was the patient hospitalized? ☐1 Yes ☐0 No
Name of hospital: _____

09A If ***Yes***, was intubation and ventilation assistance required? ☐1 Yes ☐0 No

10 10. Did the asthma exacerbation require treatment with inhaled, oral, or intravenous glucocorticoids? ☐1 Yes ☐0 No

If ***Yes***,

10A 10a. Start date of glucocorticoid: ___ ___ / ___ ___ / ___ ___
month day year

10B 10b. Stop date of glucocorticoid: *(actual or proposed)* ___ ___ / ___ ___ / ___ ___
month day year

11 11. Was the asthma exacerbation treated as outlined in the Manual of Operations? ☐1 Yes ☐0 No
If ***No***, describe _____
_____
_____

12 12. Was the patient deemed a treatment failure due to a previous asthma exacerbation? ☐1 Yes ☐0 No

13 13. Is the patient a treatment failure? ***If any of the shaded boxes in Questions #9 - #12 are checked, the patient is a treatment failure.*** ☐1 Yes ☐0 No

☞ If Yes, the patient should continue to participate in the study if possible.

If the patient will not continue participating in the study, please complete the Termination of Study Participation form (TERM).