Asthma Clinical Research Network S	SIGNIFICANT ASTHMA EXACERBATION SAE	Patient ID: 1 Patient Initials: Visit Number: Current Date: //
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(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.		he patient experience an increase in cough, chest ness, or wheezing?	□ ₁ Yes	□ ₀ No
	2.	Did tl	he patient experience any of the following conditions?		
02A		2a.	An increase in rescue inhaler use of \geq 8 puffs per 24 hours over baseline rescue inhaler use for a period of 48 hours?	□ ₁ Yes	D ₀ No
02B		2b.	An increase in rescue inhaler use \geq 16 total puffs per 24 hours for a period of 48 hours?	□ ₁ Yes	D 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

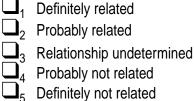
04

3.

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

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

$ \begin{array}{c} \square_1 \\ \square_2 \\ \square_3 \\ \square_4 \\ \square_5 \end{array} $	Definitely related Probably related Relationship undetermined Probably not related Definitely not related



SIGNIFICANT ASTHMA EXACERBATION Patient ID: <u>1</u>_____

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05	5.	Was the significant asthma exacerbation related to the Methacholine Challenge testing? (Check one box only)	 Definitely related Probably related Relationship undetermined Probably not related 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
08A 08A1	8.	What type of care was sought? 8a. Study Investigator? If <i>Yes</i> , indicate type of contact.	$ \begin{array}{c c} & & & \\ $
08B		8b. Primary Care or Other Physician? Name of physician:	\square_1 Yes \square_0 No
08B1		If Yes, indicate type of contact.	$ \begin{array}{c} \square_1 \\ \square_2 \\ \square_3 \end{array} \begin{array}{c} \text{Scheduled clinic visit} \\ \square_3 \end{array} \begin{array}{c} \text{Phone contact} \end{array} $
08C		8c. Emergency Room visit? Name of hospital:	□ ₁ Yes □ ₀ No

SIGNIFICANT ASTHMA EXACERBATION

Patient ID: <u>1</u>_____

Visit	Number:		
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09 09A	9.	Was the patient hospitalized? Name of hospital: If <i>Yes</i> , was intubation and ventilation assistance required?	\square_1 Yes \square_0 No \square_1 Yes \square_0 No
10	10.	Did the asthma exacerbation require treatment with inhaled, oral, or intravenous glucocorticoids? If Yes ,	\square_1 Yes \square_0 No
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? If <i>No</i> , describe	□ 1 Yes □ 0 No
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? <i>If any of the shaded boxes in</i> <i>Questions #9 - #12 are checked, the patient is a treatment failure.</i> If Yes, the patient should continue to participate in the study if participate in the study of participate.	\Box_1 Yes \Box_0 No
		If the patient will not continue participating in the study, please comp Participation form (TERM).	plete the Termination of Study