Asthma Clinical Research Network CIMA
NIH/NHLBI

CLINICAL ADVERSE EVENTS

Subject ID: 2 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Current Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Interviewer ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

CAE_01 1. Description of Adverse Event (ICD9 Code) ___ ___ ___ . ___ ___

Describe: _____

CAE_02 2. Date Adverse Event started ___ ___ / ___ ___ / ___ ___ (month / day / year)

CAE_03 3. Type of Adverse Event

- ❑1 Intermittent
- ❑2 Continuous

CAE_04 4. Adverse Event severity

No interruption of normal activities, protocol medications, or procedures	❑1 Mild
Brief interruption of normal activities, protocol medications, or procedures	❑2 Moderate
Significant interruption in activities and/or unlikely to continue with study	❑3 Severe

CAE_05 5. Was this Adverse Event considered serious (resulting in hospitalization, extension of hospital stay, or death)? ❑1 Yes ❑0 No

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

If No, skip to Question # 7

6. Why was the event serious?

CAE_06a	6a.	Fatal Event?	❑1 Yes	❑0 No
CAE_06b	6b.	Life-threatening event?	❑1 Yes	❑0 No
CAE_06c	6c.	Inpatient hospitalization required?	❑1 Yes	❑0 No
CAE_06d	6d.	Hospitalization prolonged?	❑1 Yes	❑0 No
CAE_06e	6e.	Disabling or incapacitating?	❑1 Yes	❑0 No
CAE_06f	6f.	Overdose?	❑1 Yes	❑0 No
CAE_06g	6g.	Cancer?	❑1 Yes	❑0 No
CAE_06h	6h.	Congenital anomaly?	❑1 Yes	❑0 No
CAE_06i	6i.	Serious laboratory abnormality with clinical symptoms?	❑1 Yes	❑0 No

CAE_07 7. Likelihood of relationship to test drug

- ❑1 None
- ❑2 Unlikely (Remote)
- ❑3 Possible
- ❑4 Probable
- ❑5 Highly Probable

CAE_08 8. Were any study medications altered?

- ❑1 Discontinued
- ❑2 Reduced
- ❑3 Interrupted, but resumed at current dose
- ❑4 Unchanged
- ❑5 Increased

9. What, in your opinion, caused the event?

CAE_09a 9a. Toxicity of study drug? ❑1 Yes ❑0 No

CAE_09b 9b. Withdrawal of study drugs? ❑1 Yes ❑0 No

CAE_09c 9c. Concurrent medication? ❑1 Yes ❑0 No
If ***Yes***, describe _____

CAE_09d 9d. Concurrent disorder? ❑1 Yes ❑0 No
If ***Yes***, describe _____

CAE_09e 9e. Other event? ❑1 Yes ❑0 No
If ***Yes***, describe _____

CAE_10 10. Did the subject require medication treatment, other than the study medication, for this Clinical Adverse Event? ❑1 Yes ❑0 No

CAE_10a If ***Yes***, did the Clinical Adverse Event require treatment with inhaled, oral, or intravenous glucocorticoids? ❑1 Yes ❑0 No

If ***Yes***,

CAE_10b Start date of glucocorticoid ___ ___ / ___ ___ / ___ ___
month day year

CAE_10c Stop date of glucocorticoid ___ ___ / ___ ___ / ___ ___
month day year

CAE_11 11. Did the subject require hospitalization for this Clinical Adverse Event? ❑1 Yes ❑0 No
If Yes, please complete the Serious Adverse Event Reporting Form (SERIOUS).

CAE_12 12. Did the subject require any other type of treatment for this Clinical Adverse Event? ❑1 Yes ❑0 No

CAE_13 13. Adverse Event status

- ❑1 Ongoing
- ❑2 Completely Recovered
- ❑3 Recovered, but with lasting effects
- ❑4 Death

CAE_14 14. Adverse Event status date ___ ___ / ___ ___ / ___ ___
month day year

CAE_14a If event was resolved in less than 24 hours, provide duration: ___ ___ hours