

Site Number: _____

Screening ID: _____ - ____

Participant Letters: _____

For this study, only events Grade 2 and greater will be reported to the Coordinating Center. The Study Coordinator should complete this form to report:

- A new adverse event, or
- A **change in intensity, frequency, or duration of a previously reported adverse event.**

If updating a previously reported adverse event, make the necessary changes to the original report and send copies of the updated pages to the Coordinating Center. Include a copy of the first page for updates so that changes can be linked to the original Adverse Event ID Number.

An *adverse event* is described as any unfavorable or unintended clinical event, sign, symptom, or disease, or any event that has *changed* adversely in nature, intensity, or frequency. Unless this event is a *serious adverse event*, this form should be completed at the next scheduled follow-up visit.

A. REPORT INFORMATION

Adverse Event ID Number: # # # #

1. Date of report:

____ / ____ / ____
DAY MONTH YEAR

2. Last attended study visit (*check one*):

- | | | | |
|---------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|
| <input type="checkbox"/> -1 Screening | <input type="checkbox"/> 8 Visit 8 | <input type="checkbox"/> 17 Visit 17 | <input type="checkbox"/> 26 Visit 26 |
| <input type="checkbox"/> 0 Baseline | <input type="checkbox"/> 9 Visit 9 | <input type="checkbox"/> 18 Visit 18 | <input type="checkbox"/> 27 Visit 27 |
| <input type="checkbox"/> 1 Visit 1 | <input type="checkbox"/> 10 Visit 10 | <input type="checkbox"/> 19 Visit 19 | <input type="checkbox"/> 28 Visit 28 |
| <input type="checkbox"/> 2 Visit 2 | <input type="checkbox"/> 11 Visit 11 | <input type="checkbox"/> 20 Visit 20 | <input type="checkbox"/> 29 Visit 29 |
| <input type="checkbox"/> 3 Visit 3 | <input type="checkbox"/> 12 Visit 12 | <input type="checkbox"/> 21 Visit 21 | <input type="checkbox"/> 30 Visit 30 |
| <input type="checkbox"/> 4 Visit 4 | <input type="checkbox"/> 13 Visit 13 | <input type="checkbox"/> 22 Visit 22 | <input type="checkbox"/> 31 Visit 31 |
| <input type="checkbox"/> 5 Visit 5 | <input type="checkbox"/> 14 Visit 14 | <input type="checkbox"/> 23 Visit 23 | |
| <input type="checkbox"/> 6 Visit 6 | <input type="checkbox"/> 15 Visit 15 | <input type="checkbox"/> 24 Visit 24 | |
| <input type="checkbox"/> 7 Visit 7 | <input type="checkbox"/> 16 Visit 16 | <input type="checkbox"/> 25 Visit 25 | |

3. How many separate adverse events are being reported at this time? _____

IF MORE THAN ONE, each adverse event requires the completion of a separate Adverse Event Report Form

B. GENERAL EVENT INFORMATION

1. Date of onset of adverse event:

____ / ____ / ____
DAY MONTH YEAR

2. Event Type (*check one*):

- ☐ 1 Fever
- ☐ 2 Cough
- ☐ 3 Shortness of Breath
- ☐ 4 Hypotension
- ☐ 5 Hypertension
- ☐ 6 Tachycardia
- ☐ 7 Rash
- ☐ 8 Pruritus
- ☐ 9 Vomiting
- ☐ 10 Nausea
- ☐ 11 Headache
- ☐ 12 Diarrhea
- ☐ 13 Abdominal Pain
- ☐ 14 Allergic reaction or episode

Infection

- ☐ 15 Viral infection
- ☐ 16 Bacterial infection
- ☐ 17 Fungal infection
- ☐ 18 Protozoal infection
- ☐ 19 Infection of unknown cause

Laboratory Abnormality

- ☐ 20 Leukopenia
- ☐ 21 Neutropenia
- ☐ 22 Thrombocytopenia
- ☐ 23 Lymphopenia
- ☐ 24 Other laboratory abnormality

On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates.
Write "*" if the desired information is permanently unavailable (i.e. will not be known in any future updates).

Site: _____ Screening ID: _____ - _____ Letters: _____ Adverse Event ID Number: _____

B. GENERAL EVENT INFORMATION (Continued)

2. Event Type (*check one*): (continued)

Accident

- ☐ 25 Accident requiring medical assistance, but no ER visit or hospital admission
☐ 26 Accident requiring ER visit, but no hospital admission
☐ 27 Accident requiring admission to hospital

Pregnancy

- ☐ 28 Pregnancy (Complete Forms CTL14 and CTL14R)

Diabetes Related

- ☐ 29 Ketoacidosis with ER visit, but no hospital admission
☐ 30 Ketoacidosis requiring admission to hospital
☐ 31 Hypoglycemia with assistance, but without seizure or coma
☐ 32 Hypoglycemia resulting in seizure and/or coma

Other

- ☐ 99 Other, a. Specify: _____

3. Did the event occur during the infusion of study medication?

Y N

4. If event is severe hypoglycemia, record glucose level during the event:
 (If blood glucose value is unknown for a severe hypoglycemic event,
 record "*" for this question)

_____.____

a. Units:

- ☐ 1 mg/dl
☐ 2 mmol/L

C. EVENT DESCRIPTION

1. Describe the event:

(If an infection, describe
 organism, sensitivity,
 treatment, etc.)

2. What was the outcome of the adverse event? (*check one*)

- ☐ 1 Recovered, no residual effect
☐ 2 Residual effect, no treatment
☐ 3 Residual effect, being treated
☐ 4 Persistent, no treatment
☐ 5 Persistent, being treated
☐ 6 Death

- ☐ 99 Other, a. Specify: _____

3. Has the adverse event resolved?

Y N

If YES,

a. Date resolved:

____/____/____
 DAY MONTH YEAR

4. Intensity of reported event (*check one*): **NOTE:** Use NCI Common Terminology Criteria for Adverse Events (CTCAE) to grade intensity or TrialNet guidelines

- ☐ 2 Grade 2 ☐ 3 Grade 3 ☐ 4 Grade 4 ☐ 5 Grade 5

- Grade 2:** A moderate adverse event. The symptom impairs the participant's usual function, but presents no danger to the participant, or resolves with intervention.
Grade 3: A severe adverse event resulting in hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect.
Grade 4: A life-threatening or disabling adverse event.
Grade 5: A fatal adverse event.

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Site: _____ Screening ID: _____ - _____ Letters: _____ Adverse Event ID Number: _____

D. RELATIONSHIP, ACTION TAKEN, AND INTENSITY

1. Relationship to study medication (*check one*):

☐ 1 Not related ☐ 2 Unlikely ☐ 3 Possible ☐ 4 Probable ☐ 5 Definite

Not related: No relationship (0% chance) that AE is related to study medication
Unlikely: Relationship is possible, but not likely (1 – 19% chance) that AE is related to study medication
Possible: Reasonable likelihood that the study medication caused the adverse event with a chance (20-50%) the AE is related that cannot be excluded
Probable: Relationship is quite likely (51 – 99% chance) that the AE is related to the study medication
Definite: Unquestionable relationship (100% chance) that the AE is related to the study medication

2. Was the event related to a study procedure?

Y N

If YES,

a. Describe:

3. Actions taken for the adverse event:

a. Study infusions interrupted or discontinued?

Y N

e. None?

Y N

b. Concomitant medication prescribed?

Y N

f. Requested testing of viral specimens?

Y N

c. Outpatient procedure?

Y N

g. Other?

Y N

d. Non-drug treatment?

Y N

If OTHER,

1) Specify:

If concomitant medication was prescribed, complete the Concomitant Medications Form (CTL10)

4. Did treatment require any of the following?

a. Visit to study site?

Y N

d. In-patient rehabilitation?

Y N

b. Visit to emergency room?

Y N

e. Admission to hospital?

Y N

c. Out-patient rehabilitation?

Y N

f. Admission to skilled nursing facility?

Y N

If treatment involved admission to hospital, skilled nursing facility, or in-patient rehabilitation:

g. Record length of stay:

Days

5. Did treatment of the adverse event require unmasking of the participant's treatment group assignment?

Y N

If YES, a. Describe the circumstances:

Site: _____ Screening ID: _____ - _____ Letters: _____ Adverse Event ID Number: _____

E. CONCLUSION

1. Include any additional comments (*e.g. note whether or not the participant has experienced this problem before, any follow-up plans, etc.*):

2. Was this a serious adverse event?

Y N

If YES, complete the following section (Section F)

If NO, DO **NOT** complete **Section F**

Site: _____ Screening ID: _____ - _____ Letters: _____ Adverse Event ID Number: _____

F. SERIOUS EVENT DESCRIPTION (This section only needs to be completed for Serious Adverse Events)

A **Serious Adverse Event** is defined as occurrence of one or more of the following:

- An event that is of intensity **Grade 3, 4, or 5**
- An overdose
- Any other condition that in the opinion of appropriate medical personnel will result in one of the above outcomes if left untreated
- Death
- Any life threatening condition
- Inpatient hospitalization or prolongation of current hospitalization
- Significant disability or incapacity
- Congenital anomaly/birth defect (*only if the offspring was exposed to the study medication in utero*)

All **Serious Adverse Events** must be reported to the Coordinating Center within **24 hours**.

All **Serious Adverse Events** also require the completion of the **TrialNet MedWatch Form**, which must be faxed to the Coordinating Center at **(866) 804-6058** or **(301) 468-1676** within **24 hours** of clinic notification.

1. Did the adverse event result in any of the following?

a. Require or prolong hospitalization?

Y N

c. Permanent or severe disability?

Y N

b. Death?

Y N

IF ADVERSE EVENT RESULTED IN DEATH:

1) Date of death:

____ / ____ / ____
DAY MONTH YEAR

2) Probable cause of death:

An adverse event resulting in death requires completion of the Mortality Event Form (CTL13M)

2. Was the serious adverse experience:

a. Congenital anomaly?

Y N

d. Due to overdose of study medication?

Y N

b. Cancer?

Y N

e. Condition that could have resulted in one of the previous outcomes if left untreated?

Y N

c. Life-threatening?

Y N

3. Describe the adverse event in detail (*include information leading up to the event, procedures or tests completed, date stopped study medication, etc.*):

4. Was this an "unexpected" adverse event?

Y N

An **unexpected adverse event** is defined as one for which the specificity or severity of which is **not consistent** with the current Investigator's Brochure. For a complete list of expected adverse events for abatacept see the Manual of Operations.

5. Date the TrialNet MedWatch Form was faxed to the Coordinating Center:

____ / ____ / ____
DAY MONTH YEAR

a. Time the TrialNet MedWatch Form was faxed (24-hour clock):

____:____ (24 hour clock)

REPORTING OF ADVERSE EVENTS

Complete this form with as much information as is currently known regarding the adverse event. If information for a question is currently unavailable but will be known, answer with a "?". If information is permanently unknown, and the answer to the question will be unknown in all future updates, answer with an "*". No questions should be left blank.

Initials (first, middle, last) of person completing this form:

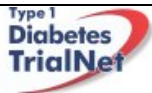
F M L

Date form completed:

____ / ____ / ____
DAY MONTH YEAR

Signature of Principal Investigator:

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CTLA-4 Ig Study
ADVERSE EVENT REPORT FORM

Form CTL13

01 JAN 2008

Version 1.0

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Top Copy – Send to TrialNet Coordinating Center

Bottom Copy – Retain at site