

Sae

Physician Date:

(mm-dd-yyyy)

Physician Cert#:

1. Type of report:

- Initial report
- Follow up report

2. Enter code, date, adverse event(s), and event grade(s) using criteria in Appendix A. Code the primary event on line 1.

[Attachment: "CTCAE_4.03_2010-06-14_QuickReference_5x7.pdf"]

Adverse Event 1

Code:

Date:

(mm-dd-yyyy)

Adverse Event:

Grade:

Adverse Event 2

Code:

Date:

(mm-dd-yyyy)

Adverse Event:

Grade:

Adverse Event 3

Code:

Date:

(mm-dd-yyyy)

Adverse Event:

Grade:

Adverse Event 4

Code:

Date:

(mm-dd-yyyy)

Adverse Event:

Grade:

Adverse Event 5

Code:

Date:

(mm-dd-yyyy)

Adverse Event:

Grade:

3. Did the participant get admitted to the hospital because of this event?

- Yes
- No

3a. Date of Admission

(mm-dd-yyyy)

3b. Date of Discharge

(mm-dd-yyyy)

4. Description of event. Include pre-existing medical conditions and concomitant medications:

5. Action Taken:

6. Attribution for event (check only one)

- Unrelated
 - Probably not related / remotely related
 - Possibly Related
 - Probably Related
 - Definitely Related
 - No answer
-

7. Type of Event:

- Expected
 - Unexpected
 - No answer
-

8. Assessment of Adverse Event Outcome (at the time of last observation):

Event outcome: (if ongoing, Adverse Event follow-up must be completed)

- Ongoing
 - Resolved
 - Death
 - No answer
-

If resolved, enter date and how below.

Date:

_____ (mm-dd-yyyy)

Resolved how?

- Resolved with sequelae
 - Resolved without sequelae
 - No answer
-

If with sequelae, specify:

If Death (Appendix B must be completed)

9. Relevant tests/lab data, discharge summaries, including dates (enter PDF file name of scanned copies of all associated reports):

Appendix B-Death Information

1. Date of Death

_____ (mm-dd-yyyy)

2. Location

- In hospital
- At home
- Unknown
- Other
- No answer

If other, specify:

3. Cause of Death (check all that apply)

- CVA
- Emboli/thrombi
- Hemolytic/aplastic anemia
- Hepatic Failure
- Infection
- Cardiac Failure
- Multi-system organ failure
- Pulmonary hypertension, clinical
- Renal Failure
- Respiratory Failure
- Splenic Sequestration
- Trauma
- Unknown
- Other

If other, specify:
