Reference #: _____

CitAD

Death Report
(DR-1)

Purpose: Notify the CC of a patient's death occurring within and a month after the 9-week study period and provide information on the clinical assessment of the death.

When: **Within two working days** of the clinic site being notified of the patient's death.

Completed by: CitAD certified personnel.

Information obtained from: Caregiver and other sources.

Instructions: Contact the CC immediately upon learning of the death even if all details of death are unknown at that time. Complete the form within two working days of learning of the death. Fax DR form to CC at (443) 287-5797. Contact the CC to confirm receipt of fax.

For updates, complete a new DR form. Do not update by crossing out items from previous death reports. Complete sections A, B, and D, and for section C, complete only updated items. Fill out the current date in item 4 (do not use date of initial DR form). Indicate that the form is an update to a previous Death Report in section B. Fax Death Report updates to CC. Follow local guidelines regarding reporting deaths to your IRB or local review board.

A. Clinic, patient, and visit identification

1. Clinic ID: ____ ____ ____ ____

2. Patient ID: C ____ ____ ____ ____

3. Patient four-letter code: ____ ____ ____ ____

4. Date form completed:

____ ____–____ ____ ____–____ ____
day month year

5. Visit ID: n ____

6. Form revision date:

1 1 – a u g – 0 9
day month year

B. Death Report information

7. Type of Death Report:

Initial Death Report . . . . . (1)

11.

Update to a previous Death Report . . . . . (2)

8. Date of initial Death Report:

____ ____–____ ____ ____–____ ____
day month year

9. Number of updates including this report: ____ ____

10. Item(s) being updated:

_____
specify

11. Is additional information expected:

Yes (1) No (2)

C. Death information

12. Date of death:

____ ____–____ ____ ____–____ ____
day month year

13. Date of Safety Report (SR) form completed:

____ ____–____ ____ ____–____ ____
day month year

14. Date of the most recent dose of study medication:

____ ____–____ ____ ____–____ ____
day month year

15. Relationship of death to study treatment *(check only one):*

Not related . . . . . (1)
Possible . . . . . (2)
Probable . . . . . (3)
Definite . . . . . (4)

16. Source of death notification *(check all that apply):*

- **a.** Medical record . . . . . (1)
- **b.** Medical examiner . . . . . (1)
- **c.** Coroner . . . . . (1)
- **d.** Funeral parlor/home . . . . . (1)
- **e.** Patient's family . . . . . (1)
- **f.** Caregiver . . . . . (1)
- **g.** Friend . . . . . (1)
- **h.** Health care provider . . . . . (1)
- **i.** Newspaper . . . . . (1)
- **j.** Death index . . . . . (1)
- **k.** Other . . . . . (1)

_____
specify

17. Place of death *(check only one):*

- Hospital/hospice . . . . . (1)
- Home . . . . . (2)
- Unknown . . . . . (3)
- Other . . . . . (4)

_____
specify

18. Location of place of death:

_____
state/country

19. Cause of death:

_____
_____
_____
_____

20. Contributing cause(s) of death:

_____
_____
_____
_____

D. Administrative information

21. Date form reviewed by study coordinator:

____ ____–____ ____ ____–____ ____
day month year

22. Study coordinator ID: ____ ____ ____

23. Study coordinator signature:

_____

Study physician should review this form before signing below.

24. Date form reviewed by study physician:

____ ____–____ ____ ____–____ ____
day month year

25. Study physician ID: ____ ____ ____

26. Study physician signature:

_____

E. Coordinating Center use

27. Death report number: ____ ____ ____

28. Date report received:

____ ____–____ ____ ____–____ ____
day month year