



Telephone Contact (TC-1)

Purpose: Record the information obtained during the telephone contact.
When: At T1, T2, T4, and T7, or any unscheduled telephone contacts.
Completed by: CitAD certified personnel.
Information obtained from: Patient and/or caregiver.
Instructions: Items should be answered based on the interviewer's assessment of information provided by the patient and/or caregiver. Any serious adverse events should be recorded on the Safety Report (SR) form.

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: _____
Enter "n" for unscheduled contacts.

6. Form revision date:
 1 1 - a u - 0 9
 day month year

10. Physician recommended dose for the patient until next visit or contact (*check only one*):

- Not on study drug (1)
- 10 mg (2)
- 20 mg (3)
- 30 mg (4)

11. Is this a scheduled telephone contact (i.e., T1, T2, T4, or T7):

(Yes) (No)
(1) (2)

22. _____

B. Medical history

7. Is the patient experiencing any side effects:
(Yes) (No)
(1) (2)

If yes, specify:

8. Current dose (*check only one*):

- Not on study drug (1)
- 10 mg (2)
- 20 mg (3)
- 30 mg (4)

9. Does the physician recommend a dose change based on information gathered on this call:
(Yes) (No)
(1) (2)

C. Agitation/Aggression subitems on NPI

12. Does the patient have periods when he/she refuses to cooperate or won't let people help him/her? Is he/she hard to handle:

Yes (1) No (2)
22.

13. Does the patient get upset with those trying to care for him/her or resist activities such as bathing or changing clothes:

Yes (1) No (2)

14. Is the patient stubborn, having to have things his/her way:

Yes (1) No (2)

15. Is the patient uncooperative, resistive to help from others:

Yes (1) No (2)

16. Does the patient have any other behaviors that make him hard to handle:

Yes (1) No (2)

17. Does the patient shout or curse angrily:

Yes (1) No (2)

18. Does the patient slam doors, kick furniture, or throw things:

Yes (1) No (2)

19. Does the patient attempt to hurt or hit others:

Yes (1) No (2)

20. Does the patient have any other aggressive or agitated behaviors:

Yes (1) No (2)

If all items from 14 to 21 are marked "no", re-evaluate the answer in item 13.

21. Determine the frequency and severity of the agitation/aggression:

a. Frequency (*check only one*):

- Occasionally - less than once per week (1)
- Often - about once per week (2)
- Frequently - several times per week but less than every day (3)
- Very frequently - once or more per day (4)

b. Severity (*check only one*):

- Mild - behavior is disruptive but can be managed with redirection or reassurance (1)
- Moderate - behaviors disruptive and difficult to redirect or control (2)
- Marked - agitation is very disruptive and a major source of difficulty; there may be a threat of personal harm. Medications are often required (3)

c. Caregiver distress

How emotionally distressing do you find this behavior (*check only one*):

- Not at all (1)
- Minimally (2)
- Mildly (3)
- Moderately (4)
- Severely (5)
- Very severely or extremely (6)

D. Respondent

22. Caregiver four-letter code: _____

23. The information on this form was obtained (*check only one*):

- Exclusively from the patient (1)
- Primarily from the patient (2)
- Equally from the patient and the caregiver (3)
- Primarily from a caregiver (4)
- Exclusively from a caregiver (5)
- Other (6)

_____ specify

E. Administrative information

Personnel who conducted telephone contact

24. Date form reviewed by examiner:

____ - ____ - ____
 day month year

25. Examiner ID: ____ - ____ - ____

26. Examiner personnel signature:

Study coordinator review

27. Date form reviewed by study coordinator:

____ - ____ - ____
 day month year

28. Study coordinator ID: ____ - ____ - ____

29. Study coordinator signature:
