

CitAD

Study Drug Issue and Return (SD-1)

Purpose: Record whether study drug is issued and/or returned.

When: EN, F3, F6, and F9 visits and as needed.

Completed by: CitAD certified personnel.

Instructions: A SD form is required at each visit even if drug is not issued or returned. If drug is not issued or returned, write the date that the form was completed in item 4. A patient should receive one labeled bottle of study drug at EN, F3, and F6. At each follow-up visit the patient and caregiver are to return all used and unused study drug bottles (even if empty). Record each bottle issued or returned as a separate entry in the appropriate sections. When the drug kit is assigned to the patient, remove the label that is attached to the kit and affix the label in item 8. For each bottle that is issued, take the label that is attached to the bottle and affix the label(s) 11, 12, and 13, as applicable. For information about treatment schedule and titration of dose, refer to the CitAD Handbook.

A. Clinic, patient, and visit identification

1. Clinic ID: _____
2. Patient ID: C _____
3. Patient four-letter code: _____
4. Date study drug issued and/or returned (*If drug is not issued or returned, write the date form completed*):
 _____ - _____ - _____
 day month year
5. Visit ID: _____
 (*if not a scheduled visit, use "n" for visit ID*)
6. Form revision date:
 1 3 - o c t - 1 0
 day month year

B. Study drug issue

7. Drug kit ID: C _____

If not EN visit, skip to item 9.

8. Drug kit label: **At enrollment, affix the drug kit label below.** The label is located on the drug kit box. After receiving the randomization assignment, fill in the items on the label, detach the tear-off portion, and transfer to this form. Enter items into the database. For some reason if the label is not attached to the drug kit box and therefore it is not available to affix on to this form, supply the following information in item 8: drug kit ID, expiration date, and patient ID. These items are then to be data entered into the database.

Affix drug kit label here

9. Is study drug being issued: Yes No
 (1) (2)
10. How was the drug delivered to the patient (*check only one*):
 In-person (1)
 Mail (2)
 Other (*specify*) (3)

14. ←

_____ specify

Affix the study drug label(s) below. Labels are located on the study drug bottles. At time of dispensing study drug to the patient, fill in items on the label, detach tear-off portion, and transfer to this form. Enter items into the database. For some reason if the label is not attached to the study drug bottle and therefore it is not available to affix to this form, supply the following information in item 11: drug kit ID and bottle ID. These items are then to be data entered into the database.

11.

Affix label here

12.

Affix label here

13.

Affix label here

C. Study drug return

14. Were any study drug bottles returned:

Yes No
 (1) (2)

19. ←

	a. Bottle ID	b. Number of capsules remaining
15.	_ _ _	_ _ _ _
16.	_ _ _	_ _ _ _
17.	_ _ _	_ _ _ _
18.	_ _ _	_ _ _ _

D. Administrative information

19. Date form reviewed by coordinator:

_ _ _ _ - _ _ _ _ - _ _ _ _
 day month year

20. Study coordinator ID: _ _ _ _ _

21. Study coordinator signature:

Study physician should review this form before signing below.

22. Date form reviewed by study physician:

_ _ _ _ - _ _ _ _ - _ _ _ _
 day month year

23. Study physician ID: _ _ _ _ _

24. Study physician signature:
