

Instructions for Completing the Pill Count Form

Pill Count Form Header:

Since there will be more than 1 study drug blister pack given to the participant on several occasions during treatment, the following guidelines should be used when documenting the information on the CRF and entering the data in the DMS.

Week

The week number that should be written on the CRF and entered into the DMS should be the Week number of the visit when the blister packs are being reviewed and compared to the Pill Count Form (PLC). The Sequence number will be different in cases where pill compliance is being assessed for more than one week.

EXAMPLE: On Week 4 (5/13/00) you compare the participant's self-report with the blister packs for the two previous weeks (compliance from week 2-3 and week 3-4). The PLC forms should be labeled Week 4, Sequence 01 and Week 4, Sequence 02 for this example.

Date

The date on the PLC form should be the date that the form is completed.

Week	Date on CRF	Review PILLS TAKEN from calendar weeks:	Week # entered into the DMS:
0	N/A	N/A	N/A
1	Wk 1 visit date	0-1	1
2	Wk 2 visit date	1-2	2
4	Wk 4 visit date	2-3 and 3-4	Wk 4, Seq 01, 02
6	Wk 6 visit date	4-5 and 5-6	Wk 6, Seq 01, 02
8	Wk 8 visit date	6-7 and 7-8	Wk 8, Seq 01, 02
10	Wk 10 visit date	8-9 and 9-10	Wk 10, Seq 01, 02
12	Wk 12 visit date	10-11 and 11-12	Wk 12, Seq 01, 02
16	Wk 16 visit date	12-13, 13-14, 14-15, and 15-16	Wk 16, Seq 01, 02, 03, 04

Documenting Pill Taking Behavior:

Extra Pills

Since the Pill Count Form is not completed until the participant returns with the blisterpack, there is no need to record the extra pills in the pack as PILLS PRESCRIBED until the participant returns for the next visit and the RA reviews whether the extra pills were taken. If the person returns and the extra pills were taken, document the extra pills as prescribed and taken and record the relevant dates.

Missed Visits

If a participant attends a visit and receives medication but does not return for the next scheduled visit, use the following data entry guidelines.

EXAMPLE: On Week 2 the PILLS PRESCRIBED on Week 1 is compared to PILLS TAKEN and documented on the PLC. Two blister packs will be given to the participant since the next scheduled visit is Week 4.

EXAMPLE 4: Participant is given 1 pill pack (10 days worth) but the time frame between visits is 14 days.

Participant forgets to take pills on days 9 and 10. On days 12 and 14, the participant goes back and takes the pills that were left (not taken on days 9 and 10).

Days 9 & 10: Nalt PP: 2 Acam PP: 6
 Nalt PT: 0 Acam PT: 0

Days 12 & 14: Nalt PP: 0 Acam PP: 0
 Nalt PT: 2 Acam PT: 6

Staff did not technically prescribe the pills for days 11-14 so these should not be documented as such. And you cannot document the PP on days 12 & 14 because it will look as though you prescribed more pills than were in the pill pack. This will show that the participant was noncompliant on days 9 & 10 but that they were compliant on days 12 and 14.

Days 11 & 13: Nalt PP: 0 Acam PP: 0
 Nalt PT: 0 Acam PT: 0

This will not show noncompliance because the participant was not prescribed medications for these days.

Frequently Asked Questions

1) PLC "returned" vs. "not returned" - Are all days checked as returned if the pack is returned or only the actual day that the pack was returned on?

You only have to check "returned" or "not returned" once. If you've checked returned/not returned for each day, you get two gold stars. If the pack is returned after the visit, then you must go back into DMS and change "not returned" to "returned".

2) If there is a dose reduction, should that dose reduction be documented once or should it be documented on all forms for that week? For example, at week 12, there are four blister packs given to the patients. At week 16 four PLC forms are completed. At week 12 there was a dose reduction. Should the reduction be noted only on the PLC form that includes the week 12 time frame or should it be included on all four forms?

The dose reduction should be noted only on the form that includes the date that the reduction occurred.

3) If the medication is not returned how should this be documented?

If the blisterpack was never returned by the patient or was noted to be lost, a comment would suffice on the return section of the medication dispensation log rather than leaving it blank.

4) If the patient does not return the blister pack but says s/he took the medication how should this be documented?

There is a place on the form to record "patient self-report." The pills should be recorded as prescribed and taken. If the blister pack is returned at a later visit the blister pack can then be compared to the form and the form can be amended if need be.