

Guidelines for Completing Visit 35.6/76 Drug Form 1 (MACS Questionnaire)

General Instructions:

1. A **Drug Form 1** should be completed for each drug a participant lists in **Section 4, Q.21.B(1)**.

Coding Example:

X is in a ddl, d4T, nelfinavir and efavirenz trial. He knows he is taking ddl and d4T, but does not know whether he is taking nelfinavir, efavirenz or a placebo.

Complete 4 drug forms. For ddl and d4T, bubble "NO" for placebo (Q1B). For nelfinavir and efavirenz, mark "YES" for placebo (Q1B) and complete only Q1 on the Drug Form 1.

See S4 guidelines, Question 21, for other specific examples

2. Drugs listed in combination (i.e. AZT/ddC) should only be used when part of a blinded research study. These specific studies were common during the combination therapy era, but are unlikely to appear in the current era of HAART therapy. A blinded study is one in which the participant may have taken a placebo or is unaware of the actual treatment. Otherwise, each medication should be coded separately and a separate drug form completed for each.
3. **If a participant is taking a medication as part of a research study but then continues that medication after the trial ends during the same visit period, complete two drug forms.** One form will correspond to the portion of the visit when the participant was enrolled in the trial. The second drug form will correspond to the portion of the visit continuing the medication usage but not part of the trial.
4. If a participant is taking a medication as part of a research study but is not blinded to the treatment, complete the entire drug form 1, do not stop after Q1.E.

5. The listing of medications on **Drug Form 1** is not complete. However, each drug still retains a unique code. Refer to the current drug list. Mark "*Other*" and use the specify box for medications not listed on **Drug Form 1**. Be sure to check **Drug List 2** for participant's responses not on **Drug List 1**. Notify CAMACS of any frequently used medications that do not have unique codes.
6. All questions refer to the period since the participant's last visit.
7. Note that all known protease inhibitors have now been given unique codes.

Question 1:

If the medication is not being taken as part of a research study, skip *B - E*.
If the medication is part of a blinded research study, stop after Q1.

Do not answer Q.2-Q.12 if the participant is taking this drug as part of a blinded research study and therefore does not know whether he is taking a placebo or the actual drug.

Q1.D - If the participant answers "yes" to this question, there are two options:

- 1) If the participant is **BLINDED** to the treatment, he should **STOP** at this point (i.e if Q1.B is "Yes");
- 2) If the participant is **UNBLINDED** to the treatment, **SKIP TO Q4.**

Q1.E - This question should only be answered if the participant took the medication as part of a research study since last visit but is not currently taking the medication as part of the research study. If the participant cannot remember the exact month, probe for the season.

Summer	= July
Fall	= October
Winter	= January
Spring	= April

Question 2:

Do not leave blank unless the medication is part of a blinded research study. If the medication is not being taken as part of a research study there is no need for the interviewer to read the bracketed portion of this question.

Question 3:

If the participant cannot remember the exact month, probe for the season as follows:

Summer = July
Fall = October
Winter = January
Spring = April

Question 4:

This is the number of times per day prescribed by the physician.

Question 5:

This is the number of pills per dose prescribed by the physician.

Question 6:

This question refers to whether or not the participant started the medication since his last visit.

Question 7:

This question should only be answered if the participant started the medication since his last visit (Q4 = yes). If the participant cannot remember the exact month, probe for the season as follows:

Summer = July
Fall = October
Winter = January
Spring = Fall

Question 8:

Mark only one response.

Question 9:

Mark all the side effects that the participant has experienced on this medication. If the participant says that he does not know exactly which medication causes which side effects (or if he suspects the side effects are a result of medication interaction), mark the side effect for each of the drugs, which the participant believes could be contributing to this particular side effect. "None of the above" should only be answered "yes" if all the possible responses above it are "no" (blank).

Question 10:

The participant should not be considered to have stopped his medications during the time he is not taking the medications due to an alternating drug regimen.

Question 11:

This question should only be answered if the participant is not alternating drugs and has stopped his medication usage since the last visit.

Each item should be read to the participant. If an item above the line is marked, but was not marked in Q7, please confirm the participant's answer and modify Q7 appropriately. If participant responds with reasons not listed on the form, mark "*Other*" and record in participant's words the reason(s) in the specify box.

Question 12:

This question is designed to assess adherence to a prescribed medication schedule.