

MULTICENTER AIDS COHORT STUDY

NEW ENROLLMENT

MEDICAL RECORD ABSTRACTION GUIDELINES

(MRA GUIDELINES)

General Instructions:

1. The **Medical Record Abstraction (MRA) Form** MUST BE filled out for all HIV positive men on HAART and all HIV positive men not on HAART who **have** medical records.
2. THE DATA FROM THIS FORM SHOULD BE ENTERED AT EACH SITE ONLY FOR MEN WHO ARE ENROLLED IN THE MACS. CAMACS will provide a codebook and input file for data entry purposes. **MRA Forms** from men who were screened but not eligible should not be sent to CAMACS.
3. The front page tear sheet should be torn off once abstraction has been completed. The front page should not be data entered or stored in the patient file with the **MRA Form**. The function of the front page is to facilitate abstraction by providing patient information so abstractionists can more easily identify pertinent patient files.
4. On the front page tear sheet should be the date that the participant first self-reported taking a HAART regimen. Abstractionists should begin searching medical records 6-months prior to this self-reported date to ensure that the form captures the first time the participant began taking HAART. If the abstractionist finds that the man was taking HAART in the records dated 6-months prior to this self-reported start date, the abstractionist should request records 1 year prior to the participant's self-reported date. Abstractionists should keep going back until they find the most likely HAART start date in the medical records.
5. There are 2 sections of this form, a section that is required to be completed (*Section A*) and a section that is not required for enrollment, but is supplemental information (*Section B*). For a participant to be eligible for enrollment into the MACS, *Section A* must be completed.
6. Throughout this form, a regimen refers to medications that a participant took simultaneously.
7. Follow the skip patterns as they appear on the form.
8. A screening ID should be entered for every **MRA Form**.
9. Abstractionists should not fill out the MACSID during abstraction. The MACSID will be assigned only for men who are deemed eligible for enrollment into the MACS at the end of the entire screening process. This field will remain blank for all men who complete the screening process but are not eligible for enrollment.
10. If only the month and year are available through the medical records, abstractionists should code the day as "15".

SECTION A: Required Abstraction

As indicated in the general instructions, this entire section must be completed for a participant to be eligible for enrollment into the MACS. If any of the required information is unavailable or cannot be located in the medical records, the man is ineligible for enrollment. There are several exceptions to this:

- 1) In *Question A.2.B*, the stop date and prescribed dosage are not required for a participant to be eligible
- 2) While *A.4.B* asks for CD4, CD8, and CD3 counts and percentages, only the CD4 numbers are required.
- 3) Only *Q.A.1* and *Q.A.5* are for seropositives not on HAART

Question A.1:

To decide whether the medical records indicate if a person has ever used HAART, abstractionists should use the tools provided in *Appendix A* of the **MRA Form** (pages 10,11). These tools outline the different possible combinations that define a HAART regimen as well as providing a checklist with which to total the number of medications from each class of antiviral drugs for any given regimen. The checklist is regimen specific in that it was created to be used to categorize a specific regimen as HAART or not HAART. A separate, blank checklist should be completed for each regimen that can be found in the medical records. Abstractionist should not fill in one checklist for all drugs in the patient's history, but rather should fill out multiple checklists, one for each regimen that can be defined through the patient's medical records. Abstractionists should be very careful to make sure that the drugs indicated on any given checklist were all taken by the patient at the same time.

HAART is defined as one of the four specific regimen types outlined in *Appendix A: Definition of HAART*. Abstractionists should consult with their principal investigator, project director or designated point person if they have any questions at all about whether or not a regimen can be categorized as a HAART regimen. If sites come across any regimen that does not fit into the specifically outlined HAART definitions, but they think it is a HAART regimen, contact the CAMACS Coordinator (Janet Schollenberger) at 410-955-4320.

If a participant was ever on a HAART regimen (even if only for a day or two), he should be categorized as having been on HAART. For example, if a participant started a HAART regimen on 06/01/99 but could only tolerate it for one week, stopped and did not start on HAART again until 03/15/00 (when he began taking HAART regularly), then he should be put in the HAART category, and his start date should be recorded as "06/01/99."

If it is decided through the process outlined above that the participant never used HAART, the abstractionist should **SKIP TO Q5**.

If a man is involved in a clinical trial or research study, this person should only be classified as using HAART if the drugs in that study can be documented in a way that verifies the man was on HAART. For example, if the man definitely received AZT, 3TC, and an unknown PI (blinded to the PI), the abstractor should list AZT, 3TC and "Unknown PI" and use the 3-digit code "999."

Question A.2.A:

This question asks when HAART was first prescribed. Abstractionists should look through records for the first date at which a physician prescribed a HAART regimen for the participant. Individual start dates of each drug in the regimen may be different. The date HAART was first prescribed should be the first date that all the medications comprising the HAART regimen were prescribed to be taken concurrently.

Question A.2.B:

Abstractionists should list only the medications which comprised the participant's first documented HAART regimen here, as well as the corresponding drug code, the start date, stop date and the prescribed dosage. All medications for that particular regimen should be listed. *Question A.2.B* is used to define the individual dates that the participant actually was prescribed the different medications within the HAART regimen. Drug codes can be found in **Appendix B: Drug List**. If a drug is reported that is not listed on the Drug List, sites should call the CAMACS Coordinator (Janet Schollenberger) at 410-955-4320 to get a 3-digit drug code assigned to the drug. If additional spaces are needed (i.e. a participant has more than 5 medications comprising his first HAART regimen), xerox the chart in *A.2.B*, fill in additional medications, and attach to the **MRA Form**.

For the start date, abstractionists should try to locate the date in the medical record that represents the date the specific medication was prescribed. **NOTE** that this date may be earlier than the date the entire regimen was first prescribed. If no changes in medication following the initial prescription are found in the medical records, leave the stop date blank.

While prescribed dosage is not required information for a participant to be eligible, abstractionists should try to find and abstract this information from the medical records. Under prescribed dosage, abstractionists should record the target (full) dose in mg's (e.g. if starting dose of ritonavir is 300mg and increased to full dose of 600mg bid, over 14 days B record the full dose). Abstractors should use the following notation to denote frequency of dosing:

qod = every 48 hours, or every other day
qd = every 24 hours, or every day
bid = every 12 hours, or 2 times/day
tid = every 8 hours, or 3 times/day
qid = every 6 hours, or 4 times/day.

Example: If a prescription is written: "Norvir 100mg; take 6 caps bid," the abstractor should record as noted but do the conversion later and record this as 600mg bid. If the prescription read "100mg; take 4 caps bid," then this should be noted on the form but recorded as 400mg bid.

Example: The oral solution for Norvir comes as 80mg/mL, so a full dose of 600mg = 7.5mL bid. While this will be seen infrequently in the medical records, the abstractor should note the 7.5mL bid but then convert to mg's, and the dose should be recorded as 600mg bid.

Medications that contain multiple medications in one pill (such as Combivir and Trizivir), should be coded by the name and 3-digit code of the combination pill. Therefore, if a participant reports Combivir, the name "Combivir" should be written in the space for the drug's name, and the 3-digit code "227" should be written in for the drug code. For the combination medications, the dosage amount (e.g. mg's) will not be able to be recorded. In this case, code the prescribed dosage as number of pills and frequency (e.g., "Trizivir one bid"). The checklist in **Appendix A** contains combination-type pills with instructions for defining HAART if a participant is on one of these medications.

Question A.3:

If a participant used any of the antiviral medications listed in **Appendix B: Drug List** before his first HAART regimen, mark "YES." The exact drug information will be recorded in *Question B.1*, if it is available. If abstractionists cannot locate records that would document whether or not the participant took antiretroviral medications prior to initiating HAART, mark "UNKNOWN."

Question A.4:

For this question, abstractionists should identify the blood draw at the time of HAART initiation (blood drawn same day that regimen was prescribed). If a same-day blood draw is not available, sites should record results from the most recent blood draw prior to HAART initiation in *A.4.A*. The blood draw listed in *A.4.A* must be within 4 months of the date that HAART was first prescribed. For example, HAART was first prescribed on 01/15/2000. Blood draws are noted in the medical records on 11/28/1999 and 01/05/2000. The lab results from 01/05/2000 should be entered in *A.4*.

Question QA.4.A(2):

If the results of the assay are below the limit of the assay's detection (may be called "undetectable"), sites should mark "YES" to *Question A.4.A(2)* and list the assay kit's lower limit of detection in *A.4.A(3)*.

Question A.4.B:

The blood draw listed in *A.4.B* must be within 4 months of the date that HAART was first prescribed. For this question, only the CD4 information is required, though if the CD8 and CD3 information is available, that should be recorded in the spaces provided as well.

Question A.5:

Review the dates of the self-reported AIDS diagnoses on the **Screening Form**. If an AIDS-defining illness is found in the medical records, mark "YES" to *Question A.5.A*. If the AIDS diagnosis was prior to HAART initiation, stop here and do not continue further with the medical record abstraction. If the AIDS diagnosis was after the HAART initiation, record the diagnosis date, disease, disease code and method of diagnosis in *A.5.C* using *Appendix C*.

SECTION B: Supplemental Abstraction

While none of this section is required for eligibility, abstractionists should record here any supplemental information they are able to obtain from the participant's medical records.

Question B.1:

This question should only be filled out if the abstractor is able to document that a participant took ARTs prior to initiating HAART. Only list the ARTs that were used prior to HAART initiation in the spaces provided, along with the 3-digit drug code, start date, stop date and prescribed dosage. Dosing information should follow the guidelines detailed in *Question A.2.B*. Specific drugs used as part of the initial HAART regimen should be reported in *A.2.B* even if started prior to the HAART regimen.

Question B.2:

If an additional HIV RNA and/or T-cell result is available prior to HAART initiation, include this information in *Question B.2*. Only include results that are from blood draws within 4 months of the HAART initiation. Data should be included per instruction for *Question A.4*.

Question B.3:

This question should be filled out only if the abstractor can find information on additional ART regimens that a participant was on after his first HAART regimen. This would include both HAART and non-HAART regimens. *Question B.3* should be filled out based on the antiretroviral regimens, or the antiretroviral drugs that a participant took concurrently. Each regimen should be listed in a different section of *B.3*. If additional spaces are needed, xerox this page as needed.

Question B.4:

Question B.4 should be used to document additional HIV RNA and T-cell results post HAART. Start with results closest to HAART. Do not include results more frequently than quarterly (i.e., every 3 months). If additional spaces are needed, copy either *Part A* or *Part B* as needed.