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## MTN-003 (VOICE) Data Communiqué #4

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February 16, 2012

This communiqué is official study documentation for MTN-003. It is considered part of the MTN-003 Study-Specific Procedures (SSP) Manual. Please circulate this communiqué among relevant staff for their review, and print and file a copy in Section 15 of each MTN-003 SSP Manual maintained at your site.

### UPDATES

#### 1. SCHARP Staffing Update

Karen Patterson is out on leave until mid-April 2012. Until further notice, please contact Missy Cianciola (missy@[scharp.org](mailto:missy@scharp.org)) regarding questions related to data collection or data management in MTN-003.

### CLARIFICATIONS

#### 1. PUEV Completion for Oral Truvada/Oral Placebo Participants: List #2 Clarification

In late January 2012, SCHARP distributed two sets of PTID lists for each site related to scheduling and completion of PUEVs for participants on the oral Truvada/oral placebo study arm. Note that for List #2 (List of Oral Truvada/Placebo Participants whose Month 15 Visit Target Date is on or after 01 Jun 2012); the dates provided in the 3<sup>rd</sup> column are not indicating when the PUEV should occur. To use this list, conduct the PUEV at the Month 13 visit for each PTID listed.

For example, for a participant whose Month 15 target visit date is listed as 26 June 2012 on the list, conduct her PUEV at her Month 13 study visit, not on 26 June 2012.

#### 2. Missed PUEVs

If a participant misses her PUEV visit (for example, per List #1 she is to have her PUEV at Month 18), complete a Missed Visit form for the visit and complete the PUEV the very next time the participant comes to the clinic. For this example, complete the PUEV at Month 19. This guidance is also provided in SSP Section 6.14.1.

#### 3. Study Exit/Termination Visit CRF Requirements for Confirmed HIV Seroconverters

Note that confirmed HIV seroconverters (participants with a HTR-1 CRF with a final HIV status of “positive”) do not need to complete a Study Exit/Termination visit (as the main goal of the study exit visit is to identify delayed HIV seroconversions). These participants should be terminated once the PUEV is completed by completing the following CRFs:

- Study Exit Visit (mark item 1 “no”, specify in 1a visit not required)
- End of Study Inventory
- Termination (use date of PUEV as termination date).

#### 4. Procedures for Participants who Have a Positive HIV Rapid Test Result at the Study Exit/Termination Visit

If a participant has a positive rapid HIV test result at her study exit/termination visit, do not terminate her at that time. Complete and fax all required Study Exit/Termination visit CRFs except for the Termination CRF.

Schedule her to come back for an interim visit (assign visit code 89.1). At this interim visit, collect Sample 2 as well as samples for HIV RNA viral load, CD4+ testing, and plasma archive. Complete the following CRFs. Assign visit code 89.1 to all new CRFs completed.

- Interim Visit (item 1 = other – to collect Sample 2; item 2 = other, SS-1; item 3 = not done; item 4 = no vaccination - not indicated)
- Specimen Storage (item 1= plasma, will be collected/stored, mark all other items as “not required” or “n/a”)
- Seroconverter Lab Results (once HIV RNA viral load and CD4+ results are available):
- Update HIV Western Blot Test Results CRF previously started (visit code = 89.0) with Sample 2 collection date and Sample 2 result/final HIV status once available)
- Complete Termination CRF (or update previously-compiled form) – make sure the Termination Date is the date of interim visit 89.1.

If a participant does not come back for her scheduled Sample 2 collection visit, continue to try and collect this sample (and do not terminate) up through the study end date of August 13, 2012. If the participant has not come back for Sample 2 collection by August 13, 2012, terminate her on that day by completing the Termination CRF (item 1 = 13-AUG-12), item 2 = 2g (unable to contact participant).

#### **5. End of Study Inventory CRF, item 1**

Do not record “89.0” for item 1 on the End of Study Inventory CRF, even if the participant completed the Study Exit/Termination Visit. All participants will have the SEV-1 CRF submitted to SCHARP, which has a visit code of 89.0 pre-printed on the form. For ESI-1 item 1, SCHARP needs to know the highest visit code of the last visit (including a missed visit) ending in “.0” that was recorded on a CRF for the participant, prior to the Study Exit/Termination Visit.

For example, if a participant had her PUEV at Month 28, and completed her Study Exit/Termination visit as planned, record “31.0” (corresponding to the Month 28 visit) for ESI-1 item 1.

## **REMINDERS**

### **1. Participants who decline the Study Exit/Termination Visit**

If a participant does not wish to continue with the study after completing her PUEV, meaning she is withdrawing consent and does not want to return for her Study Exit Visit (SEV), complete the following CRFs for the Study Exit Visit: Study Exit Visit (mark item 1 “no” and specify ppt withdrew consent/refused further participation), Termination (mark item 2c as reason for termination), and an End of Study Inventory (see item 5 above for completion instructions related to item 1). Do not complete a Missed Visit form or any other CRFs for the Study Exit/Termination visit.

This guidance is also in the SSP, Section 6.12.1.

### **2. Re-faxing of forms when no change/update has been made to the CRF**

Please remember that CRF corrections/new CRFs sent to SCHARP within approximately 7 days of distribution of a QC Report will likely not be reflected in the QC Report. It may take several days for SCHARP to enter the data, and another few days to resolve the QC.

If, while going through the QC Report, you realize you have already made the correction and faxed the form to SCHARP within 7 days of the QC Report, please do not re-fax the form or ask SCHARP if we have received the corrected form. While we did not have a chance to resolve the QC in time for the current QC Report, the QC should not appear on the next report.