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## MTN 001 Data Communiqué #6

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December 18, 2009

This is official study documentation for MTN 001. Please circulate it among relevant staff for their review, print it, and place it in your MTN 001 SSP Manual in the Data Communiqués section. This document is considered part of the MTN 001 SSP manual.

### UPDATES

#### 1. New SCHARP Clinical Affairs Safety Associate

Yevgeny Grigoriev will take over as the MTN-001 SCHARP Clinical Affairs Safety Associate while Molly Swenson is on maternity leave. Yevgeny will be responsible for identifying and placing clinical QCs, and works closely with the Protocol Safety Monitoring Team (PSRT) to monitor MTN-001 safety data. He can be reached by e-mail ([ygrigori@scharp.org](mailto:ygrigori@scharp.org)) or by phone (206-667-3440).

### CLARIFICATIONS

#### 1. Missing Page QCs

SCHARP asks each site to fax completed CRFs to SCHARP DataFax ideally within 1-2 days and up to 5 days after a given visit date. This is documented in each site's Data Management Standard Operating Procedures (SOP). (Exceptions are made for laboratory forms, log forms, and screening forms). If no CRFs are faxed to SCHARP DataFax for a given follow-up visit, SCHARP will not QC for missing forms for that visit until the visit window has closed. However, if one or more forms are faxed to SCHARP DataFax for a given visit, then DataFax will immediately QC for any required forms that are still missing for that visit (even if the visit window has not yet closed). For example, if a site laboratory faxes the Flow Cytometry form to SCHARP for the Week 6 Visit, and the site clinic has not yet faxed any Week 6 Visit CRFs for the participant, then DataFax will QC for the missing Week 6 Visit CRFs. The receipt of the Week 6 Flow Cytometry form will immediately trigger DataFax to QC for the rest of the required Week 6 Visit CRFs, even if the participant's Week 6 visit window has not yet closed. This is expected and is simply a function of DataFax technology. While it is important that sites follow up on these missing pages by completing the forms and faxing them to SCHARP, please note that these "missing page" QCs do not count against sites in the Data Management Quality Reports. These QCs will only raise concern and prompt SCHARP to follow-up with sites if they indicate that sites are not faxing CRFs to SCHARP within the specified time frame.

#### 2. Documenting Number of Completed Adverse Event Log Pages on the Follow-up Visit and Interim Visit Forms

Item 2a of the Follow-up Visit (FV) form and item 3e1 of the Interim Visit (IV) form ask how many new Adverse Event (AE) Log pages were completed for a participant at a given visit. This number includes all AE Log forms with the visit code of the given visit recorded in item 10; even AE Log forms that are subsequently marked for deletion. For example, at visit 3.0 two AEs are reported for a given participant.

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Each AE is recorded on an AE Log form with visit code "03.0" recorded in item 10. The second AE is later marked for deletion, since it was found to be a pre-existing condition. The response to FV-1 item 2a should remain "02" to indicate that two AE Log pages were completed for visit 3.0.

Deleted AE Log pages are still accounted for on the FV and IV forms since deleted AE Log pages remain in the database for regulatory purposes.

### **3. Documenting Highest Page Number Submitted for AE Logs and Product Hold/Discontinuation Logs**

Item 3a on the End of Study Inventory Form (ESI) asks for the highest AE Log page number submitted to SCHARP, and item 3d asks for the highest Product Hold/Discontinuation (PH) Log page number submitted to SCHARP for a participant during her MTN 001 study participation. Record the highest log page numbers submitted, even if the logs with the highest page number were marked for deletion.

Deleted AE Log pages and deleted PH Log pages are still accounted for on the ESI form, since these deleted pages remain in the database for regulatory purposes.

### **4. Recording Topical Medication Use on the Concomitant Medications (CM) Log**

When recording topical medication use on the CM Log, record the generic name of the medication in the "Medication" field, and include the percentage of active ingredient(s) if known. For example, "miconazole nitrate 2% cream". For "Dose/Units", record the dose in cubic-centimeters (cc) or milligrams (mg), if known. If the exact quantity is unknown, record the number of applications instead, for example, "1 application".

### **5. Recording Injections on the Concomitant Medications (CM) Log**

Record each injection (e.g., Depo-Provera injection) as its own separate entry, so that the "Date Started" and "Date Stopped" are the same date. Mark the "once" box for "Frequency" and the appropriate box for "Route" (e.g., "IM", or "Other" for subcutaneous injections).

### **6. Recording Specimen Weights on the Rectal PK Form**

When recording weights in items 2a-2c, include the weight of the sponge, insertion tube, AND cryovial.

## **REMINDERS**

### **1. Fax Times for Enrollment and AE Log Forms**

To ensure that SCHARP reports reflect accurate and current data, please fax Enrollment forms to SCHARP DataFax within 1-2 working days after the visit date, and fax AE Log forms to SCHARP within 1 working day after the visit date.

### **2. Assigning Severity Grade to Phosphate Values**

All study phosphate values must be graded according to the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (Version 1.0, December 2004; Clarification August 2009). Depending on a site's local laboratory reference ranges, it is possible for a participant's phosphate value to fall within a site's normal range, but still be gradable according to the DAIDS Table.

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Per the DAIDS Table, the grade 1 range for serum phosphate is 2.50 mg/dL to < LLN. If a site's lower limit of normal (LLN) is less than or equal to 2.50 mg/dL, then the grade 1 range for that site is simply the value 2.50 mg/dL.

### **3. Using the Creatinine Clearance Calculator Worksheets**

When calculating creatinine clearance, please use the version of the MTN 001 Creatinine Clearance Calculator that is appropriate for your site. Specifically, if your site's local lab reports serum creatinine results in units of  $\mu\text{mol/L}$ , please use the calculator with the link "Calculated Creatinine Clearance Worksheet CONVERT". Enter the serum creatinine result in  $\mu\text{mol/L}$  into the worksheet, and the worksheet will automatically convert the serum creatinine result to units of mg/dL (rounded to the nearest tenths digit). This converted value should be transcribed onto the Safety Laboratory Results CRF exactly as it appears in the worksheet

If your site's local lab reports serum creatinine results in units of mg/dL, no conversion is needed. Please use the calculator with the link "Calculated Creatinine Clearance Worksheet NO CONVERT" to calculate creatinine clearance at your site. Enter into the worksheet the serum creatinine result rounded to the nearest tenths digit, exactly as it appears on the Safety Laboratory Results CRF.

The MTN 001 Creatinine Clearance Calculators are posted on the MTN web site on the MTN 001 Study Implementation Materials page, which can be found at: <http://www.mtnstopshiv.org/node/371>.