

Section 14 – Data Communiqués

For MTN-007, SCHARP will use “Data Communiqués” to document and communicate data decisions and procedures that are made or revised during the study. By using Data Communiqués, SCHARP avoids having to re-distribute a revised version of the Data Collection section of this SSP every time a form completion clarification or revision is made.

Data Communiqués are considered official study documentation. As such, each time a Data Communiqué is sent (via email), please circulate it among relevant staff for their review, print the Data Communiqué, and place it in this section of each MTN-007 SSP binder in your possession. Consider each Data Communiqué an official part of the SSP.

Each Data Communiqué sent will consist of three sections: a Reminders section, used to remind sites of specific data collection or forms completion procedures; a Clarification section, used to clarify data collection or form completion procedures; and an Updates section, used to communicate when an updated version of a form is being issued or to notify the sites that an updated version of the forms instructions is about to be distributed (for example).

Note that a “Data Communiqué” does not request specific actions or corrections to a particular participant’s data - it is just a listing of general items to keep in mind when performing data collection for the study.



MTN-007 Data Communiqué #1

September 3, 2010

This is official study documentation for MTN 007. Please circulate it among relevant staff for their review, print it, and place it in your MTN 007 Study Specific Procedures (SSP) Manual in the Data Communiqués section. This document is considered part of the MTN 007 SSP manual.

UPDATES

1. Revised Case Report forms – Adverse Experience Log, Pregnancy Outcome, and Medical Eligibility

Since the time MTN-007 CRFs were first distributed (January 2010), protocol changes present in protocol version 2.0 required that three CRFs be revised. A description of the form revisions is provided below.

- a. **Adverse Experience Log (AE-1):** Item 4 (“Relationship to Study Product”) had its response options changed from 5 categories to 2 (“Related”, “Not Related”), along with a revised note below the “Not Related” response category. These changes were made based on the most recent version of the DAIDS EAE Manual. Item 3 (“Severity”) had the word “Potentially” added to the description of the “Grade 4” response option. Updates were also made to the form instructions for item 4 based on the revised categories.
- b. **Pregnancy Outcome (PO-1, PO-2):** For item 4c-4f, the skip instruction present on the front of the form has been removed. The form instructions for these items has been revised to indicate that the site should refer to the protocol and the DAIDS EAE Manual to determine if the outcome and/or any complications resulting from the pregnancy outcome meet AE or EAE reporting requirements. On page 2, a skip instruction has been added above item 7, indicating that items 7-10 of the form are completed only for live births. A form instruction has also been added for these items with this same instruction.
- c. **Medical Eligibility (non-DataFax):** Item 1 of this form has been revised to match the wording of exclusion criterion #2 in the protocol (section 5.3). This item now reads “At screening, did the participant report symptoms and/or have a clinical or laboratory diagnosis of any of the following active rectal or reproductive tract infections”.

Once sites receive the revised CRFs, they should use the new CRF versions (dated 18-AUG-10) to replace the previous versions (dated 04-SEP-09). The 04-SEP-09 versions of the above CRFs should be destroyed. For the Medical Eligibility form, you will need to obtain the Screening Visit form packets previously provided and use the new version of this form to replace the old version.

CLARIFICATIONS

1. Anoscopy and Sigmoidoscopy Results CRF, “Bleeding” items (2a, 3a, 5a)

Note that expected spotting/bleeding associated with rectal specimen collection (i.e. biopsy collection) is not considered an abnormal finding. If such spotting/bleeding is observed, document the spotting/bleeding in a chart note, indicating its association with specimen

collection, but not on the Anoscopy and Sigmoidoscopy CRF (do not mark “Bleeding” for items 2a, 3a, or 5a).

2. Documenting reason for unreturned applicators on the Study Product Returns CRF

If a participant does not return all of the expected used and unused product applicators, record in the “Comments” field of the Study Product Returns CRF the reason the applicators were not returned.

3. Interim Visit form instructions, Item 3 (pregnancy testing)

The form instructions on the back of the Interim Visit CRF state that pregnancy testing is done at interim visits only if clinically indicated. However, per protocol, pregnancy testing is *required* at all interim visits for females of childbearing potential. Please disregard the “only if clinically indicated” portion of the instructions for this item (first sentence).

REMINDERS

None.



MTN-007 Data Communiqué #2

September 13, 2010

This is official study documentation for MTN 007. Please circulate it among relevant staff for their review, print it, and place it in your MTN 007 Study Specific Procedures (SSP) Manual in the Data Communiqués section. This document is considered part of the MTN 007 SSP manual.

UPDATES

1. Revised Case Report forms – Medical Eligibility, Screening Visit Eligibility

To better match the eligibility criteria listed in protocol version 2.0, some modifications have been made to these two non-DataFax forms as described below.

- a. **Medical Eligibility (non-DataFax):** Item 2e of this form, which asks about excessive daily alcohol use by the participant, has been removed and placed on the (new) Enrollment Visit Eligibility form (non-DataFax). The revised form version has a date of 08-SEP-10.
- b. **Screening Visit Eligibility (non-DataFax), pages 1 and 2:** The wording of item 7 (page 1) has been revised to match the corresponding eligibility criterion in the protocol. For this same reason, item 11e (page 2) has been added. Both of these form pages are dated 08-SEP-10 (note that page 3 of this form has mainlined its original date of 04-SEP-09).

2. New Case Report form – Enrollment Visit Eligibility form (non-DataFax)

A new form, Enrollment Visit Eligibility (non-DataFax), has been created and added to the Enrollment Visit packet. This form is completed at the Enrollment Visit, and documents the participant's eligibility for the study based on two eligibility criteria required (per protocol) to be assessed at enrollment. This is a one-page form, dated 08-SEP-10.

SCHARP will send hard-copies of these revised and new CRFs to each site. Once sites receive the revised CRFs, they should use the CRF versions dated 08-SEP-10 to replace the Medical Eligibility and Screening Visit Eligibility forms currently present in their Screening Visit form packets. The old versions of these CRFs should be destroyed.

The new Enrollment Visit Eligibility form needs to be added to all existing Enrollment form packets along with the revised Enrollment Visit Packet cover sheet page (both dated 08-SEP-10). The old version of the Enrollment Visit Packet cover page should be destroyed.

3. Updated Data Collection section of SSP Manual

In order to include the revised and new CRFs described above, the Data Collection section of the MTN-007 SSP Manual will be updated. This revised section (Section 13) will be posted to the MTN-007 webpage shortly, version number of 2.1.

CLARIFICATIONS

None

REMINDERS

None.



MTN-007 Data Communiqué #3

September 23, 2010

This is official study documentation for MTN 007. Please circulate it among relevant staff for their review, print it, and place it in your MTN 007 Study Specific Procedures (SSP) Manual in the Data Communiqués section. This document is considered part of the MTN 007 SSP manual.

UPDATES

1. Revised Enrollment Visit Eligibility case report form (non-DataFax)

The Enrollment Visit Eligibility non-DataFax form has been revised to correct two minor wording errors present on the front of the form. The date of the new form is 22-SEP-10 (bottom left-hand corner). The revised form will be provided to sites as a pdf file, which should be printed (2-sided printing). Please use the revised form dated 22-SEP-10 to replace the current version of this form present in all of the Enrollment Visit form packets present at your site (and remove and destroy the previous version).

CLARIFICATIONS

None

REMINDERS

None.

Not a DataFax form. Do not fax to DataFax.

MTN007 (172)

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Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	
Site Number				Participant Number						Chk	

Enrollment Visit Eligibility

Form Completion Date

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
dd		MMM			yy		

I now need to ask you one more question regarding your study participation. There is no right or wrong answer, so please be as honest and as accurate as you can.

1. Do you agree to not participate in any other trials involving drugs, medical devices, or genital products while you are on this study?

yes

no

➔ **If no, participant is ineligible.**

End of interview.

2. Within the past 12 months, did the participant report a history of excessive daily alcohol use (as defined by the CDC as heavy drinking consisting of an average consumption of more than 2 drinks per day for men, and more than 1 drink per day for women), frequent binge drinking, or illicit drug use that includes any injection drugs, methamphetamines (crystal meth), heroin, or cocaine, including crack cocaine?

yes

no

➔ **If yes, participant is ineligible.**

Enrollment Visit Eligibility (non-DataFax) - Page 1

Purpose: This form is used at the Enrollment Visit to document the participant's eligibility with regard to two eligibility criteria. This form is completed once, at the participant's Enrollment Visit.

General Information/Instructions: This is a mixed form—one item (item 1) is interviewer administered while item 2 is not. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

- *Note: If a participant is being re-screened, a new Enrollment Visit Eligibility form must be completed as part of the subsequent screening attempt. See the Data Collection Section of the Study-Specific Procedures (SSP) Manual for more instructions regarding re-screening form completion procedures.*



MTN-007 Data Communiqué #4

November 10, 2010

This is official study documentation for MTN 007. Please circulate it among relevant staff for their review, print it, and place it in your MTN 007 Study Specific Procedures (SSP) Manual in the Data Communiqués section. This document is considered part of the MTN 007 SSP manual.

UPDATES

1. Revised LDMS Specimen Tracking Sheet – Version 2.0, dated 01-NOV-10

The LDMS Specimen Tracking Sheet (non-DataFax) has been revised to reflect changes to the processing instructions for the ARB and FSR biopsy specimens for cytokines. The revised version (v2.0) was distributed to sites via email on November 1, 2010. Sites are required to print the 2-page form and use it to replace current versions of the form present on-site. This includes bulk supplies of this form as well as LDMS forms present in the Enrollment, Treatment 1, and Final Clinic Visit CRF packets.

2. Timing of Pre-existing Conditions form completion

Per protocol version 2.0, the Pre-existing Conditions assessment and form completion first occurs at the Screening Visit. Note that the Pre-existing Conditions form is included in the Enrollment Visit CRF packet. As such, please remove the Pre-existing Conditions form present in all unused Enrollment Visit packets and move it to the Screening Visit packet. The visit checklists will correctly prompt you to complete this form at the Screening Visit, and update it at the Enrollment Visit.

CLARIFICATIONS

1. Biopsy collection sites – normal or abnormal finding?

Note that biopsy collection sites that are healing normally and as expected are considered normal findings. Normally-healing biopsy sites should be documented as “normal findings” on the Anoscopy and Sigmoidoscopy Results form (items 2, 3, and 5),

2. Completion of Severity Grade, AE Log Page #, and Not Reportable as an AE fields of the Laboratory Results form (LR-1, LR-2)

For non-gradable (Grade 0) lab values, leave the “Severity Grade”, “AE Log Page #”, and “Not reported as an AE” boxes of the LR form blank. If a lab value is grade 1 or higher, record the severity grade and complete either the “AE Log Page #” field or the “Not reported as an AE” field as applicable.

REMINDERS

None.



MTN-007 Data Communiqué #5

February 18, 2011

This is official study documentation for MTN-007. Please circulate it among relevant staff for their review, print it, and place it in your MTN-007 Study Specific Procedures (SSP) Manual in the Data Communiqués section. This document is considered part of the MTN-007 SSP manual.

UPDATES

None.

CLARIFICATIONS

1. Classification of normally-healing biopsy collection sites as normal findings

Note that biopsy collection sites that are healing normally and as expected are classified as “normal findings” on the Anoscopy and Sigmoidoscopy Results form (ASR-1 items 2, 3, and 5),

2. STI Laboratory Results - Item 1a

This item (1a) is where the site records the result of the HIV EIA test performed by study staff. The instructions for this item specify a non-rapid HIV EIA in error – this item is used to document both rapid and non-rapid HIV EIA test results as performed by study staff.

REMINDERS

None.