
MTN-011 Data Communiqué #2

31 October 2012

This is official study documentation for MTN-011. Please circulate it among relevant staff for their review, print it, and place it in your MTN-011 SSP Manual in the Data Communiqués section.

This document is considered part of the MTN-011 SSP manual.

REMINDERS

1. Pharmacokinetics form (PK-1), for Group 2 Enrollment Visit

There are no pharmacokinetics (PK) specimens collected at the Enrollment Visit for Group 2 participants. This form was included in the Group 2 Visit 2 (Enrollment) Visit Code 02.0 Packets which were shipped to your sites, and therefore will need to be removed from the packets you received.

The visit packets which are available for future printing from the Atlas webpage have been updated accordingly.

Also, please be sure to update the Visit Checklist (list of forms at the end) accordingly.

2. Pharmacokinetics form (PK-1), comments

If a couple reports having prohibited sex (i.e. sex within 72 hours of coital visits) this must be documented on the Pharmacokinetics form on the Comments line. Please record the date and time that the prohibited sex occurred, as well as any additional pertinent details.

In addition, as stated in MTN-011 SSP Section 5.13, “if a participant reports a prohibited practice...the prohibited practice should be thoroughly documented in chart notes. In addition, the prohibited practice should be noted on the comments section of the Pharmacokinetics CRF.”

CLARIFICATIONS

1. Pelvic Exam (PE-1) and Pelvic Exam–Clinically-indicated (PCI-1) forms

In order to account for cases when more than one pelvic exam is done on the same day if clinically indicated (e.g. Group 1, Visit 3a/3b), we developed the Pelvic Exam–Clinically-indicated (PCI-1) form. Table 1 below aims to clarify which form is completed for a given visit for the Group 1 female participants. Visit 2a/2b is the only visit where two pelvic exams are required. As indicated in the table below, for Visit 2a/2b, you must complete the PE-1 form for the first (pre-coitus) exam, and the PCI-1 form for the second (post-coitus) exam. There are three visits (Visits 3a/3b, 4a/4b, and 7a/7b) where a pelvic exam is required post-coitus, but may also be done if clinically-indicated during the pre-coitus portion of the visit. As shown in the table below, the PCI-1 form will be used *if* a clinically-indicated pre-coitus exam is done. A PE-1 form must be completed at Visits 3b, 4b, and 7b, whether the required post-coitus exam is done or not. For Group 1, all other visits (i.e. Visit 5a, 5b, 6a, and 6b) occur on separate days. The required pelvic exams done at Visits 5b and 6b will be documented on the PE-1 form, regardless of whether the exam is done or not. The clinically-indicated pelvic exams done at Visit 5a and 6a will be documented on the PCI-1 form, only if the exam is done.

Table 1: Group 1 female participants													
Visit	1	2a	2b	3a	3b	4a	4b	5a	5b	6a	6b	7a	7b
Required (X) or Clinically-indicated (*)	X	X	X	*	X	*	X	*	X	*	X	*	X
CRF to complete <i>Note: CRF required anytime pelvic exam is required per protocol. If a clinically-indicated pelvic exam is not completed, do not complete a CRF.</i>	PE-1 <i>required</i>	PE-1 <i>required</i>	PCI-1 <i>required</i>	PCI-1	PE-1 <i>required</i>	PCI-1	PE-1 <i>required</i>	PCI-1	PE-1 <i>required</i>	PCI-1	PE-1 <i>required</i>	PCI-1	PE-1 <i>required</i>

Table 2 below aims to clarify which form is completed for a given visit for the Group 2 female participants. As indicated in the table below, there are two visits (Visits 3a/3b and 7a/7b) where the visits occur on the same day and a pelvic exam is required post-coitus, but may also be done if clinically-indicated during the pre-coitus portion of the visit. As shown in the table below, the PCI-1 form will be used *if* a clinically-indicated pre-coitus exam is done. A PE-1 form must be completed at Visits 3b and 7b, whether the required post-coitus exam is done or not. For Group 2, all other visits (i.e. Visit 1, 2, 4, 5, 6, 8, and 9) occur on separate days. The required pelvic exams done at Visits 1, 2, 5, and 9 will be documented on the PE-1 form, regardless of whether the exam is done or not. The clinically-indicated pelvic exams done at Visits 4, 6, and 8 will be documented on the PCI-1 form, only if the exam is done.

Table 2: Group 2 female participants											
Visit	1	2	3a	3b	4	5	6	7a	7b	8	9
Required (X) or Clinically-indicated (*)	X	X	*	X	*	X	*	*	X	*	X
CRF to complete <i>Note: CRF required anytime pelvic exam is required per protocol. If a clinically-indicated pelvic exam is not completed, do not complete a CRF.</i>	PE-1 <i>required</i>	PE-1 <i>required</i>	PCI-1	PE-1 <i>required</i>	PCI-1	PE-1 <i>required</i>	PCI-1	PCI-1	PE-1 <i>required</i>	PCI-1	PE-1 <i>required</i>

UPDATES

1. Group 2–Participant-reported Dosing form (PDC-1)

This form must be completed for Group 2 female participants at the Visit 3a/3b (visit code 23.0). The form was erroneously not included in the original visit packets which were posted on the Atlas webpage.

This has now been corrected. If you already printed the Group 2 Visit 3a/3b packets, please print the Group 2–Participant-reported Dosing form from (also available as an individual pdf) and add that form to the packets. The updated packets and individual form are now on the Atlas webpage.

2. Protocol Deviation Log form (PDL-1)

This form has been updated to allow deviations to be collected as codes rather than individual response box options.

If you have already printed copies of the Protocol Deviation Log form from the Atlas webpage, you will need to dispose of all previous versions of the form (dated 01-AUG-12). The updated version (dated 25-OCT-12) is now available on Atlas and should be used throughout the study, when required.

Instructions for printing CRFs are available on the Atlas webpage as well.