MTN 004 Data Communiqué #1

July 31, 2008

This is official study documentation for MTN 004. Please circulate it among relevant staff for their review, print it, and place it in your MTN 004 SSP Manual in the Data Communiqués section. This document is considered part of the MTN 004 SSP manual.

UPDATES

1. New SCHARP Project Manager

Corey Kelly has joined MTN 004 as the study's SCHARP Project Manager. Please copy both Karen Patterson (karenp@scharp.org) and Corey Kelly (ckelly@scharp.org) on all correspondences to SCHARP (until otherwise notified) in order to ensure a smooth transition.

2. Revised CRFs – Version 2.0, Dated 23-JUL-08

To account for changes present in protocol version 3.0, the following CRFs were updated as follows:

a. Follow-up Visit form

Item 4 (# of used applicators returned) was grayed out, since used applicators are no longer collected. The item 4 form instructions were deleted.

b. Interim Visit form

Item 5 (# of used applicators returned) was grayed out, since used applicators are no longer collected. The item 5 form instructions were deleted.

c. Follow-up Pelvic Exam form

i. The colposcopy questions were renumbered as items 9 and 9a so that they now appear *after* the series of questions that ask about non-colposcopic findings which may lead to product holds/discontinuations.

ii. The previous item 4 ("Do any of these exam findings involve vaginitis?") was removed, since "vaginitis" was changed to "abnormal vaginal discharge" in protocol Appendix II. The form instructions for this item were also deleted. (Abnormal vaginal discharge is already captured in item 1a).

iii. The word "(ulceration)" was added to the questions numbered as items 3 and 3a in the new version of the form.

iv. The word "suggest" was replaced with "involve presumed" and appears before the word "cervicitis" for item 4 in the new version of the form.

v. The note off the new item 9 "If finding is new, complete Adverse Experience Log as applicable" was removed.

vi. Form instructions were added for items 1a2, 1a8, 1a16, and 2-8.

vii. Item 7 text “intermenstrual bleeding” was replaced with “unexpected genital bleeding”, and the text “(that is not associated with an abnormal exam finding)” was added for further clarity.

viii. The instructions off the “yes” box for item 7 now refer to the Genital Bleeding Assessment form instead of the AE Log form.

ix. The follow-up question “Was the bleeding/spotting observed with no identifiable source?” was deleted.

d. Adverse Experience Log

The form instructions only changed to match the current standard MTN AE Log form instructions at SCHARP. These include reference to the DAIDS Female Genital Toxicity Table.

e. Screening 1 Visit Eligibility (non-DataFax) form

Items 22 and 23 were reworded to match the rewording of these eligibility criteria in protocol version 3.0.

f. Screening 2 Visit/Enrollment Eligibility (non-DataFax) form

Item 8 was reworded to match the rewording of this eligibility criterion in protocol version 3.0.

g. Screening Summary (non-DataFax) form

Items 2k and 2af were reworded to match the rewording of these eligibility criteria in protocol version 3.0.

These updated revised forms are version 2.0 and dated 23-JUL-08. All unused, previous versions of these forms (version 1.0, dated 26-MAR-07) must be destroyed.

3. CASI Tracking form

A new form, the CASI Tracking form, was added to the MTN 004 CRFs. The CASI Tracking form (version 1.0, dated 31-JUL-08) is a DataFax form and is used to capture completion of the web-based CASI questionnaires. One CASI Tracking form must be completed for each enrolled participant at her study exit visit.

The SCHARP Project Manager will contact each site to request that a CASI Tracking form be completed for each of the seven participants who enrolled in the study prior to the study pause.

CLARIFICATIONS

1. Pre-Existing Conditions form

Record on the Pre-Existing Conditions form *only* those conditions that are ongoing at the time of the participant’s Enrollment Visit. This includes chronic conditions, such as asthma and pre-menstrual symptoms.

REMINDERS

None

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