

MTN-017 Data Communiqué #7 - February 17, 2015

This is official study documentation for MTN-017. Please circulate it among relevant staff for their review, print it, and place it in your MTN-017 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-017 SSP manual and is posted on the MTN web site at <http://www.mtnstopshiv.org/node/4643>.

UPDATES

1. New SCHARP Project Manager

Melissa Peda has joined the SCHARP team as a second Project Manager working on the MTN-017 study. Please include Melissa (mapeda@scharp.org) on any and all correspondences that you send to Karen Patterson.

2. Entering Year on Web-based CASI Follow-up Behavioral Questionnaires

For the Web-based CASI follow-up daily gel, RAI gel, and tablet questionnaires, 2015 is not a menu option when entering the Interview Date. Therefore, for the remaining follow-up questionnaires, please enter the correct month and day and enter the year as “2014”. Each questionnaire is time-stamped automatically, so we will be able to distinguish those taken in 2014 from those in 2015.

3. Documenting Data Convergence Interview Transcription Errors

If a site discovers a transcription error on the Data Convergence Interview (DCI) form (e.g., the number of applicators used is incorrectly transcribed from the Product Dispensation and Return CRF), and the interview has already been conducted, do not correct the error(s) on the DCI form. (If the errors were corrected, update the form again to reflect the original responses). Instead, add an initialed and dated note to the item 7 comments section to document the transcription error(s) and explain what the correct value(s) are. Enter the data into the web-based form as follows:

- a. If the DCI form data has not yet been entered into the web-based form, enter the data into the web-based form exactly as it appears on the DCI form. Enter each transcription error as it appears on the form. In the comments section (item 7), enter the initialed and dated note, explaining the transcription error, as it appears on the form.
- b. If the DCI form data has already been entered into the web-based form, and the transcription errors were not entered or documented, contact the SCHARP Project Managers to request removal of the electronic record from the analysis dataset. Then, enter the DCI form data into the web-based form exactly as it appears on the DCI form. Enter each transcription error as it appears on the form. In the comments section (item 7), enter the initialed and date note, explaining the transcription error, as it appears on the form.

As needed, remind relevant site staff to check for and correct transcription errors going forward, prior to conducting the Data Convergence Interviews.

The SCHARP Project Managers can be contacted by e-mail: Melissa Peda (mapeda@scharp.org) and Karen Patterson (karen@scharp.org).

CLARIFICATIONS

None

REMINDERS

None