MTN 015 Data Communiqué #12

June 13, 2017

This is official study documentation for MTN 015. Please circulate it among relevant staff for their review, print it, and place it in your MTN 015 SSP Manual in the Data Communiqués section. This document is considered part of the MTN 015 SSP manual.

UPDATES

1. **Update to "ART Enrollment" CRF – Version 2, 05MAY2017**

   SCHARP has updated the ART Enrollment CRF, dated 05-May-17, to remove the form instruction in Item 2. Per protocol v2.0 (03May2013), the Follow-up Behavior Assessment is required at Months 3, 12, and 24 for all participants who enroll in the study after initiation of ART or who initiate ART during the study. No other changes have been made to this form.

   This form is posted on the MTN-015 Atlas web page (https://atlas.scharp.org/cpas/project/MTN/015/begin.view?) within the ART Visit Packet and Complete Set CRFs section, as well as an Individual PDF.

2. **SDMC Clinical Data Manager update**

   Please contact Jen Berthiaume (jberthia@scharp.org) for any data related issues for MTN-015.

CLARIFICATIONS

1. **Recording Parent Protocol Visit Code on Microbicide Trial Participation CRF**

   Item 3a on the Microbicide Trial Participation CRF asks that the visit code of a parent protocol visit be recorded if the participant completed an MTN-015 visit on the same day as a parent protocol visit. Visit codes (also known as visit numbers) in MTN-025/HOPE contain 2 digits to the right of the decimal point. For example, the visit number associated with the Month 1 Visit is 3.00.

   When recording an MTN-025/HOPE visit code within item 3a of the Microbicide Trial Participation CRF, remove the first 0 after the decimal point in the MTN-025/HOPE visit code before recording it onto the MTN-015 CRF. For example, when recording MTN-025/HOPE visit code 3.02, remove the 0 after the decimal point and write "03.2" onto the MTN-015 CRF. If the parent protocol visit code is higher than 3.09 (e.g., 3.10), contact the SDMC Clinical Data Manager for additional guidance.

REMINDERS

None