MTN-020 Data Communiqué #7- March 12, 2013

This is official study documentation for MTN- 020. Please circulate it among relevant staff for their review, print it, and place it in your MTN-020 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-020 SSP manual.

UPDATES

1. Revised Ring Collection/Insertion (RCI-1) case report form

   In an effort to obtain more data on ring use, a new item, item 7, has been added to the RCI-1 CRF. The intent is to have this item ("Appearance of most recently-used ring) completed by site staff each time the RCI-1 is completed. If no used ring was returned at the visit (item 2 is "none", then item 7 is still completed. In this case, item 7 is marked "no ring".

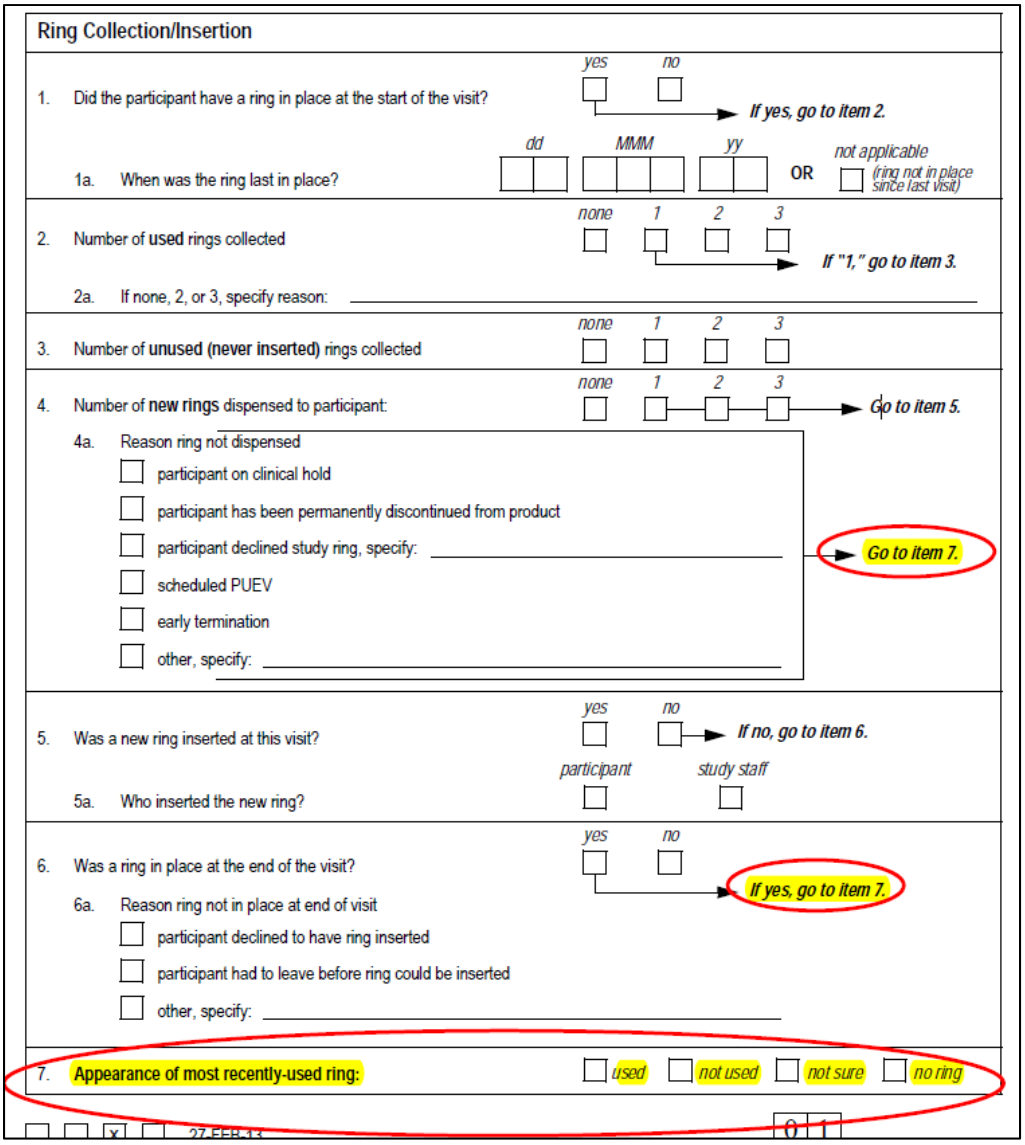
   Note that the skip instructions off of items 4a and 6 (for the "yes" response) have been updated to direct you to item 7, as item 7 should be answered even if item 4a is completed or item 6 is "yes".

   If more than one used ring is returned at a visit, item 7 should be answered based on the appearance of the most recently-used ring. This item should be answered based only on the appearance of the ring – do not include factors such as self-reported ring use or other information when answering this item. Please see the form instructions for this item for these and other clarifications related to this new item.

   The site-ready version of the revised RCI-1 CRF (form date of 27-Feb-13) is provided with this communique, and is also available via the CRF packets and "As Needed" pdf files on the MTN-020 Atlas web page.

   We ask that by March 19, 2013, all sites print out the revised CRF and use it to replace all unused current versions of the RCI-1 CRF present in participant study binders and unassigned follow-up visit packets (Monthly, Quarterly, Semi-annual, PUEV, Early Termination). Starting on March 20, 2013, we will expect to only receive the revised RCI-1 form for visits completed on this date forward.

(over)



Item 7 instructions (on back of CRF): Document the clinic staff's assessment of the appearance of the participant's most recently-used ring. Base this assessment only on the appearance of the ring, do not factor in the participant's reported use of the ring or other information when marking a response. If no ring was returned (item 2 of this form is "none"), mark "no ring" to indicate no ring was available for this assessment at this visit. If 2 or more rings are collected, record the appearance of the ring most recently-used by the participant.

CLARIFICATIONS

1. Follow-up ACASI Tracking (FAT-1) completion when a participant is informed of her permanent discontinuation from study product

At the visit (regular or interim) when a participant is informed she is permanently discontinued from study product, complete a FAT-1 CRF to document whether or not the PUEV/Discontinuers ACASI was administered at that visit.

If the PUEV/Discontinuers ACASI is not administered (at sites not operating under Letter of Amendment #2, for example), complete the FAT-1 by marking item 1 "no" and in the Comments section, note that the PUEV ACASI was not done since not under LoA #2.

Example: A participant's Western Blot result is received at the clinic on March 15, and it confirms her HIV-infection. On March 18 (an interim visit), the participant reports to the clinic to receive her Western Blot results and she is informed she is permanently discontinued from ring use.

- If the site has LoA #2 approved, the PUEV/Discontinuers ACASI will be administered at this visit.
- If the site does not have LoA #2 approved, this ACASI will not be administered at this visit, but will be at the participant's next quarterly visit.

At all sites, a FAT-1 is completed for the March 18 visit to document whether or not the PUEV/Discontinuers ACASI was administered, as well as a Visit Summary (VS-1) CRF.

2. FAT-1 completion for participants permanently discontinued from study product at Month 3

If a participant permanently discontinues from product use at her Month 3 Visit, the PUEV/Discontinuers ACASI should be administered at this time in lieu of the Month 3 ACASI questionnaire. Only one FAT-1 CRF should be completed at Month 3, with the PUEV/Discontinuers survey marked as completed; we do not need documentation on the FAT-1 that the Month 3 survey was not completed.

REMINDERS - None

iDATAFAX CORNER

1. New pop-up message in iDataFax

The following message is a new EDC pop-up message that you will begin seeing that addresses the times when there is a clinical QC that is not viewable through the "View Queries" tab:

"This record has an internal query that was placed by Clinical Affairs that is not visible in iDatafax. There may also be external queries that are visible which should be addressed. This record cannot be saved as "final" until all queries have been addressed. "

Click the OK button to get through this message and review the CRF.

As a reminder, clinical queries are provided in a separate Clinical Query email from the MTN-020 SCHARP Clinical Affairs Safety Associate, Maija Anderson. Questions about clinical queries should be directed to Maija at maanders@scharp.org.