MTN-020 (ASPIRE) Operational Guidance 8:
Updated Guidance for Intra-Vaginal Ring Storage

This operational guidance addresses a change in procedures described in Section 13.8.8, Intra-Vaginal Ring Storage.

When two or more rings are returned at a study visit, sites are currently asked to label the specimens to indicate which ring was more recently used within the LDMS Comments field. In addition, when two or more rings are returned, designated staff should now indicate in LDMS the visit month at which each ring was expected to be returned, if known.

New guidance for the procedures in Section 13.8.8, sub-item 1d will be as follows:

d. If a participant returns two rings at one study visit
    i.   Store both rings. Affix the SCHARP label to each ring pouch, and record on the label the PTID, date and visit code from the visit when the rings were collected.
    ii. Also, if possible, label each ring with the visit month/code of the visit when the ring was expected to be returned, based on when it was inserted.
    iii. Enter both rings in LDMS. Note that two rings were returned at the visit in the specimen comments field in LDMS. For example, "Two rings were stored at this visit." The comments will appear on the shipping manifest.
    iv. The Visit Month/Code should be entered in the other specimen ID field in LDMS. If the visit month of the additional ring(s) is unknown, enter "unknown" in the other specimen ID field.

Example: A participant is dispensed two rings at visit 7.0 because she is unable to attend visit 8.0. She returns for visit 9.0 and brings with her the 2 rings (used) that she was dispensed at visit 7.0. Site staff should follow guidance in item d above as follows:
    i.   Store both rings. Record on the SCHARP label the PTID, visit code 9.0 and the date of visit 9.0.
    ii. If the participant is able to distinguish which ring she used first, label each ring with the visit month/code when the ring was expected to be returned. Specifically, on the original pouch label, record "should have been returned at visit 8.0" for the ring that was inserted at Month 7, and record "returned at visit 9.0" for the other ring.
    iii. In LDMS, enter in the comments field the note, "Two rings were stored at this visit."
    iv. In the other specimen ID field in LDMS, enter "8.0" for the ring that was used first, and "9.0" for the other ring.

Retroactive updates in LDMS are not necessary. Please apply these new procedures as of May 12, 2014. Contact mtn020mgmt@mtnstopshiv.org with any questions.

All Operational Guidance documents must be printed and filed with regulatory documentation.