MTN-023/IPM 030 Data Communiqué #2

2 March 2015

This is official study documentation for MTN-023/IPM 030. Please circulate it among relevant staff for their review, print it, and place it in your MTN-023/IPM 030 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-023/IPM 030 SSP manual.

UPDATES

1. New SCHARP Project Manager

   Melissa Peda has joined the SCHARP team as a Project Manager working on the MTN-023 study. Please include Melissa (mapeda@scharp.org) on any and all correspondences that you send to Karen Patterson.

2. New Visit Codes for Protocol Version 2.0

   Under protocol version 1.0, the length of follow-up was 3 months (13 weeks). This has been extended to 6 months (25 weeks) under protocol version 2.0, resulting in three additional study visits at weeks 16, 20 and 24.

   To accommodate these additional study visits, the visit schedule has been updated to the following:

Visit	Visit Code
Screening	**1.0**
Enrollment	**2.0**
1-Week Follow-up Phone Call	**3.0**
2-Week Visit	**4.0**
4-Week Visit	**5.0**
8-Week Visit	**6.0**
12-Week Visit	**7.0**
16-Week Visit	**9.0***
20-Week Visit	**10.0**
24-Week Visit	**11.0**
25-Week Follow-up Phone Call	**12.0**

*It should be noted that under protocol version 2.0, there will be no visit code 8.0; visit code 8.0 is reserved for data that was collected at the 13-week follow-up phone call under protocol version 1.0.

This information has been updated in Section 11-Data Collection of the SSP, which can be found on the MTN website (http://www.mtnstopshiv.org/node/5648).

3. Updated CRFs (dated 27-FEB-15) for Data Collected Under Protocol Version 2.0

In response to the release of protocol version 2.0, some of the MTN-023 Case Report Forms (CRFs) have been updated (dated 27-FEB-15), as specified in the sub-sections below. Please note that those CRFs that did not undergo any changes still maintain the original date of 19-FEB-14.

For those CRFs that have been updated, each site should continue to use the previous version (dated 19-FEB-14) to collect data under protocol version 1.0. Once a site obtains the necessary approvals to begin implementation of protocol version 2.0, the site should begin using the new versions of these CRFs (dated 27-FEB-15) *exclusively*, and dispose of blank copies of the older version to avoid any mix-up. For QC purposes, the site should **notify the SCHARP Project Managers of the date when the site first begins to use the updated version of these CRFs**.

Please note that version 2.0 CRFs (dated 27-FEB-15) should *not* be faxed to SCHARP until SCHARP sends notification to the protocol team confirming database readiness.

The updated CRFs, dated 27-FEB-15, and updated visit packets will be posted at the bottom of the MTN-023 Atlas web page: https://atlas.scharp.org/cpas/project/MTN/023%20and%20IPM%20030/begin.view?
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a. Updated Visit Code Structure

In order to accommodate the additional study visits, the visit code structure has been updated from X.X to XX.X. The additional box allows sites to record study visit codes that have more than two digits (e.g., a participant comes in for her 20-week study visit, which has three digits and is classified as visit code 10.0). Below is an example, as shown on the updated Follow-up Visit Summary CRF.

The following CRFs have been updated with the new visit code structure:

1) Physical Exam (PX-1)
2) Follow-up Visit Summary (FVS-1)
3) Vaginal Ring Storage (VRS-1)
4) Ring Adherence (RA-1)
5) Ring Collection and Insertion (RCI-1)
6) Pelvic Exam (PE-1)
7) Laboratory Results (LR-1)
8) Specimen Storage (SS-1)
9) Follow-up ACASI Tracking (FCT-1)
10) Pharmacokinetics (PK-1)
11) Vaginal Practices (VP-1)
12) STI Test Results (STI-1)
13) HIV Confirmatory Results (HCR-1)
14) Pregnancy Report and History (PR-1)
15) Pregnancy Outcome (PO-1)
16) Pregnancy Outcome (PO-2)
17) Missed Visit (MV-1).

In addition, the visit code structure within the body of some CRFs has also been updated to the same format as mentioned above. For example, item 3 on the Vaginal Ring Storage CRF has an additional box in the visit code field structure as shown below.

The visit code field structures have been updated for the following CRFs:

1) Vaginal Ring Storage (VRS-1)—Items 2 and 3
2) HIV Confirmatory Results (HCR-1)—Item 2
3) Clinical Product Hold/Discontinuation Log (PH-1)—Item 1
4) Adverse Experience Log (AE-1)—Item 10
5) Participant Transfer (PT-1)—Item 3.

b. Updated Form Instructions

On the back of some CRF forms, instructions were updated to accommodate the additional study visits in protocol version 2.0. For example, on item 8 of the Enrollment CRF, the instructions have been updated to the following: “Record whether the participant has been randomized to complete the in-depth interview that takes place at the *24-week* Final Clinic Visit.” This was formerly the *12-week* final clinic visit.

The following CRFs have updated form instructions:

1) Enrollment (ENR-1) – Item 8
2) Follow-up Visit Summary (FVS-1) – Item 4
3) Pelvic Exam (PE-1) – Item 1
4) Pharmacokinetics (PK-1) – Items 1 and 2
5) Pelvic Exam Diagrams (non-DataFax) – General Information/Instructions.

c. Ring Collection and Insertion CRF (RCI-1), item 3a

The reference to the Final Clinic Visit was updated from Week 12 to Week 24, as shown below.

3a. Reason ring not dispensed:

- ☐ participant on clinical hold
- ☐ participant has been permanently discontinued from product
- ☐ participant declined study ring, specify: _____
- ☐ early termination
- ☐ 24-Week Final Clinic Visit
- ☐ other, specify: _____

d. Eligibility Criteria CRF (ECI-1), item 4d

Item 4d language was updated from "penile-vaginal" intercourse to "sexual" intercourse. This reflects the updated language in the Inclusion Criteria section in protocol version 2.0.

4. Reason(s) for ineligibility: *Mark all that apply.*

- ☐ 4a. <15 or >17 years old
- ☐ 4b. not Tanner stage 4 or 5 at Screening
- ☐ 4c. HIV infected at Screening or Enrollment
- ☐ 4d. no reported history of sexual intercourse at Screening

e. Enrollment CRF (ENR-1), item 8 and instructions

For Item 8, a third response option of "N/A" has been added. The form instructions have been updated to the following: "Mark 'N/A' if the participant was randomized to the in-depth interview, but was not selected to participate in the interview as the site had already completed all required interviews." This was done because, under protocol version 2.0, 6 participants per site will be randomized to complete in-depth interviews at the 24-Week Final Clinic Visit/Early Termination Visit. This was formerly 10 participants per site under protocol version 1.0. If a participant is randomized to the in-depth interview, but the site has already met their quota of 6 participants, mark "N/A".

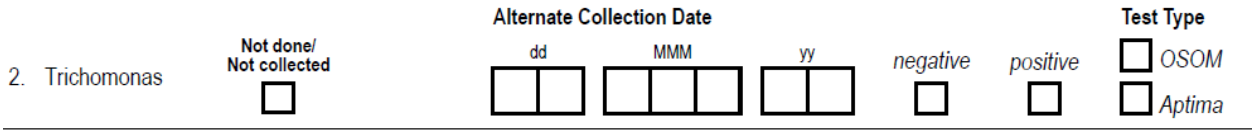
f. STI Test Results CRF (STI-1), items 1c and 2

i. Item 1c – Clue Cells

Per Data Communique #1, clue cells should be reported and marked as "positive" if 20% *or more* of the cells observed are clue cells. The 19-FEB-14 version of the form and its instructions incorrectly referenced ">" 20% clue cells.. The form has been corrected to show "≥" 20%.

ii. Item 2 – "Trichomonas" was updated to remove the "rapid test" line.

Also, the specific test types approved for study use - Aptima and OSOM - have been added. When recording a Trichomonas result, sites should mark which test type was used.



For previously documented Trichomonas results, sites will need to update the STI Results CRF (dated 19-FEB-14) by writing a note in the Comments section at the bottom of the form to indicate which test type was used.

g. New "Version 2.0 Reconsent" CRF

SCHARP has issued a new form, Version 2.0 Reconsent CRF, dated 27-FEB-15, to document whether a participant re-consents to protocol version 2.0. Completion of the form is required for each participant who provided informed assent/consent under protocol version 1.0 and is still participating in the study at the time her site begins implementation of protocol version 2.0 (regardless of whether or not the participant re-consents to protocol version 2.0).. (Participants who have already terminated from the study under protocol version 1.0 will not be asked to rejoin the study and will not be asked to re-consent under protocol version 2.0). The Version 2.0 Re-consent CRF should be completed at the visit when a participant either signs the version 2.0 assent/consent, or is asked but refuses to re-consent under protocol version 2.0. Completion of this form is expected at visits that fall between visit codes 2.0 and 8.0, inclusive.

The UAB, Fenway, Denver, and Bronx sites are expected to begin implementing the Version 2.0 Re-consent form when they begin implementing protocol version 2.0. This form is not applicable and should not be used at the Memphis and Pittsburgh sites, as they will receive site activation and begin study implementation under protocol version 2.0.

REMINDERS

None

CLARIFICATIONS

None