

MTN-020 Data Communiqué #1 - September 18, 2012

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-020SSP manual.

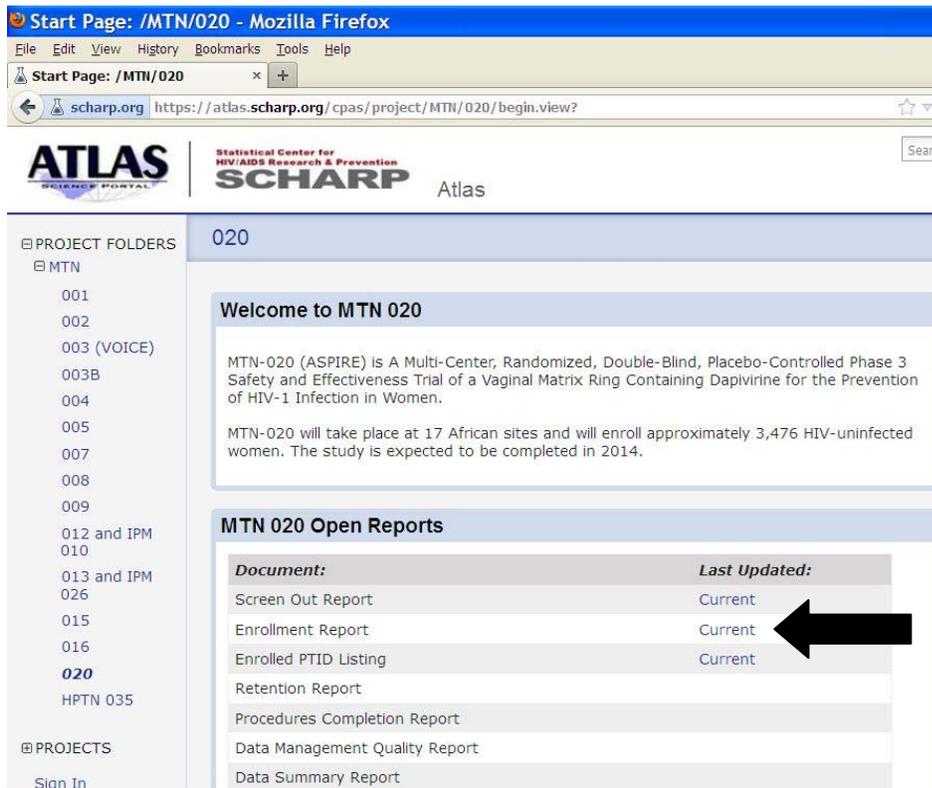
UPDATES

1. Screen Out Report and Enrollment (Accrual) Report now on Atlas

The MTN-020 Screen Out Report, which reports on data from participants screened for the study, and the Enrollment (Accrual) Report are now available in the MTN-020 Open Reports section of the MTN-020 Atlas web page (link below). No sign-in or password is required – you will just need to agree to the terms of use when prompted.

Click on “Current” under the “Last Updated” column to view each report. These reports are updated each day based on data received and entered at SCHARP.

Web page address: <https://atlas.scharp.org/cpas/project/MTN/020/begin.view?>



Document:	Last Updated:
Screen Out Report	Current
Enrollment Report	Current
Enrolled PTID Listing	Current
Retention Report	
Procedures Completion Report	
Data Management Quality Report	
Data Summary Report	

Click on “Current” under the “Last Updated” column to open the report

CLARIFICATIONS

CRF Completion Clarifications (in order by CRF title)

1. Behavior Assessment, Item 15

If a participant reports a new social harm at a non-quarterly visit, mark Item 15 as ‘yes’ when next completed. For example, if a social harm is reported via a Social Impact Log CRF at Month 4, at Month 6 mark item 15 of the Behavior Assessment CRF as “yes”. This way, the Month 6

Behavior Assessment CRF will accurately reflect that a new Social Impact Log has been completed since Month 3 (the most recent quarterly visit).

2. Concomitant Medications Log, Start Date form instruction for injectable medications

This instruction currently reads that when recording injectable medications, record each injection as a separate entry. This applies to contraceptive injectable medications only. Non-contraceptive injectables (like medications given in the hospital) may be recorded as a single entry.

3. Injection Contraceptive Medications injected prior to the Screening Visit

Injections of contraceptive medications used before the Screening Visit are not recorded on the Concomitant Medications Log CRF. This CRF only captures medications used on or after the Screening Visit date. If an injection used prior to the Screening Visit is recorded, this will result in a QC since the “Date Stopped” will be prior the Screening Visit date, and you will be asked to mark the entry for delete.

4. Enrollment, Items 9-12 form instruction

The last sentence of this instruction (on the back of the CRF) currently reads “If any procedures are not completed, bring the participant back to the clinic for procedure completion as soon as possible.” We have since determined this sentence only applies to collection of plasma for archive. If plasma for archive was not collected on the day of randomization (Enrollment), the site should make every attempt to bring the participant back as soon as possible to collect and archive this specimen as part of an interim visit (prior to Month 1). Contact SCHARP with any CRF completion questions if this situation occurs.

5. Physical Exam CRFs (Screening, Enrollment, Abbreviated)

The CRF and database can only capture one blood pressure reading per visit. If more than one blood pressure reading is performed at a visit, record the blood pressure reading used for clinical assessment/management on the CRF. All other readings, along with a note explaining why multiple readings were taken, should be documented in the participant’s study file.

Within the symptom-directed findings section of these CRFs, the “Notes” field is required for any item with “abnormal” marked. Sites may also record ‘Notes” for items marked ‘normal’ (for example, if a normally –healed scar is noted as a normal finding).

6. Pre-Existing Conditions, severity grade

If a pre-existing condition is resolved as of the Enrollment Visit, do not make any changes to the severity grade (similar to what is done when resolving adverse events). Mark that the condition as not ongoing at Enrollment.

If a pre-existing condition first identified at the Screening Visit, is ongoing at Enrollment, assess the severity at the Enrollment Visit and update the severity grade (up or down) as applicable to reflect the severity at the time of enrollment/randomization.

7. Protocol Deviations Log

Note that the actions documented in Items 7 and 8 (steps taken to address and prevent future deviations) are not required to be completed in order to transmit the CRF. The Protocol Deviation Log page should be transmitted to SCHARP once the CRF is completed, even if all of the actions/plans described in items 7 and 8 are still in-progress.

8. Screening Behavioral Eligibility item 17

This item asks the potential participant if she has participated in any other HIV prevention study using gel or tablet medications. Note that this question also includes HIV prevention studies that use a vaginal ring (IPM 027, for example) as well as HPTN 052. If a potential participant has been enrolled in IPM 027 or HPTN 052, she must wait until 12 months have passed since this study termination in order to be eligible for MTN-020.

Note that MTN-001 participants are eligible based on this criterion, as the last termination visit for MTN-001 was July 30, 2010 (approximately 24 months prior to 020 initiation).

9. Screening Menstrual History, item 2 “specify” line for amenorrheic for past 6 months

If “amenorrheic for past 6 months” is marked, record on the “specify” line a brief description of why the participant is currently amenorrheic. For example, record on the specify line “Depo”, “contraception”, or “unknown”. More details can be provided in item 8 of the CRF as needed.

10. Screening Menstrual History, Items 3-7

Complete these items based on the participant’s usual menstrual periods as experienced prior to the Screening Visit. If the participant has been amenorrheic (consistently or partially), complete the items based on the description of her most recently-experience menstrual periods and provide additional details (as needed) in item 8. If the participant reports more than 99 days between her usual menses, record “99” for item 3 (maximum boxes) and provide more details in item 8.

11. Screening STI Test Results, item 1b form instruction

This form instruction, which states that vaginal fluid pH is required at all semi-annual visits and the PUEV, while correct, it does not apply to the Screening Visit and should be ignored. Vaginal fluid pH is required at the Screening Visit per Letter of Amendment #1.

12. Social Impact Log CRF, Item 7 (current status)

Item 7, which documents the current status of the social harm, is based on participant self-report. For example, mark ‘unresolved’ if the participant reports that she feels the social harm is ongoing (not resolved). Note that SCHARP will provide sites with a monthly listing of all unresolved social harms (harms that are ongoing for more than 30 days) to help sites follow-up with participants on social harms that are ongoing

13. Vaginal Practices, item 5d

Item 5d of the Vaginal Practices CRF asks participants whether they have inserted fingers inside the vagina in order to clean or insert something. Note that this question does not include instances where the participant has used her fingers to insert a study vaginal ring.

GENERAL CLARIFICATIONS

1. CRF completion when required visit procedures are repeated at the 2nd part of a split visit

In cases where a participant has required visit procedures repeated at the 2nd part of a split visit, document the repeated procedures as an interim visit using a new Visit Summary CRF. For example, a participant has a split Month 6 visit, and at the first part of the visit on 13-NOV-12, all required procedures are completed except for the pelvic exam. At the 2nd part of her split Month 6 visit on 18-NOV-12, the pelvic is done and her safety labs are repeated in order to follow-up on an AE.

The pelvic exam CRFs are assigned Visit Month 06.0. The Visit Summary for the Month 6 visit is dated 13-NOV-12, Visit Month 06.0. For the safety labs done on 18-NOV-12, assign Visit Month 06.1 to the Quarterly Lab Results CRF (date of 18-NOV-12), and complete a new Visit Summary dated 18-NOV-12, Visit Month 06.1, to document the interim visit (interim procedure is the safety lab testing).

2. Ring Adherence CRF completion at Interim Visits

Note that the Ring Adherence CRF is not completed at interim visits – only at the required Monthly, Quarterly, Semi-Annual, and PUEV.

3. Ring Collection/Insertion CRF completion for participants permanently discontinued from product use

The Ring Collection/Insertion CRF is not required to be completed once a participant has been permanently discontinued from ring use (due to confirmed HIV infection, for example).

REMINDERS

1. Creatinine result (item2c) on Screening and Quarterly Laboratory Results CRFs

Note that per the forms instructions, only one creatinine result is recorded on the CRF (item 2c). SCHARP can only accept one creatinine result in order to properly perform our safety monitoring checks. If two creatinine results are recorded on a CRF, a QC will be created requiring you to mark for delete (line-through) one of the results.

2. Case Report Form (CRF) pdf files for printing and participant notebook covers on Atlas

As a reminder, sites are encouraged to print their own CRF supplies using the pdf files available on the 020 Atlas page (link below).

<https://atlas.scharp.org/cpas/project/MTN/020/begin.view?>

Visit Packets and All CRFs

Document:	Language:	Page size:
Screening Packet	English	A4
Enrollment Packet	English	A4
Monthly Visit	English	A4
Quarterly Visit	English	A4
Semi-annual Visit	English	A4
Product Use End Visit (PUEV)	English	A4
Early Termination Visit	English	A4
Study Exit/Termination Visit	English	A4
As Needed	English	A4

+ Interviewer-administered Visit-based Packets

Document:	Language:	Page size:
CRF Printing Instructions	English	A4
Participant Notebook - Cover/spine	English	A4

CRF printing instructions and notebook cover/spine labels are under "Other"

To open the pdf, click on "A4".under the "Page size" column.

Click on the "+" to the left of each heading to expand the section.