



## MTN-020 Data Communiqué #3 - October 29, 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-020 SSP manual.

### **UPDATES**

### 1. Spelling Correction to Data communiqué #2

Note that in Data Communiqué #2, the term "oligomenorrhea" was mistakenly listed as "oligoamenorrhea". Please use the correct spelling (oligomenorrhea) whenever possible.

### **CLARIFICATIONS**

## 1. Screening STI Test Results, item 1a (homogenous vaginal discharge)

The intent of item 1a is to document the presence of homogenous vaginal discharge in cases where the clinician is assessing for bacterial vaginosis (BV). If an assessment for BV is not done, mark "not done".

## 2. Protocol Deviation Log CRF and Participants Who Do Not Enroll

Protocol deviations are reported (using the Protocol Deviations Log CRF) for all screened participants, even if the participant does not enroll in the study.

# 3. Documentation When Pelvic Exam Findings are Re-assessed During Screening (prior to randomization)

If a visual exam is done after the required Screening Pelvic Exam to confirm eligibility or check on a normal (non-exclusionary) finding, completion of a new Screening Pelvic Exam CRF is not required, nor is completion of a new Pelvic Exam Checklist. A Pelvic Exam Diagrams CRF should be completed to document the assessment, and the status of the finding should be updated on either the Pre-existing Conditions CRF (for abnormal findings) or the Enrollment Abbreviated Physical Exam CRF (for normal findings).

If a clinically-indicated pelvic exam is performed at the Enrollment Visit after randomization, document using a Pelvic Exam Diagrams CRF and Pelvic Exam CRF (coded 98.0).

### 4. Documentation of "as indicated" Physical Exams During Follow-up

Physical exams done during follow-up on an "as indicated" basis should be documented using the Abbreviated Physical Exam CRF. If vital signs (items 1-5) are not completed at an "as indicated" exam, you can line through each set of response boxes, bracket, and add a note "not done", and initial/date the note to indicate these assessments were not done.

### 5. HIV Rapid Test Kit Codes on the Monthly Lab Results CRF

These codes (on the back of the MLR-1 CRF) have been updated to include a new kit code (04) for the StatPak rapid HIV test kit currently in use by the Kampala site. Kit code 01 has been updated from "Abbot Determine" to "Determine". Kit code 02 has also been updated from "OraSure OraQuick" to "OraQuick".

### 6. Effective Dates for Data Communiqués

Unless otherwise specified, the guidance provided in each Data Communiqué is meant to be effective as of the date listed on the communiqué (CRFs already completed do not need to be changed/corrected).

### **REMINDERS**

#### 1. QC Report Distribution Schedule

SCHARP plans to distribute QC Reports monthly, approximately on the 4<sup>th</sup> Tuesday of each month. Additional QC Reports will be issued as needed during the study for interim analyses/review purposes.