

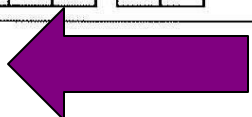
MTN-020

Data Communiqué #3

October 30, 2012

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” for 1a.

Screening STI Test Results		Alternate Collection Date			
		Not done/ Not collected	dd	MMM	yy
1. Vaginal Wet Prep	Go to item 2. ← <input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Not done	<input checked="" type="checkbox"/> 1a. Homogeneous vaginal discharge	negative <input type="checkbox"/>	positive <input type="checkbox"/>		
Not done	<input type="checkbox"/> 1b. pH <input type="text" value="3"/> <input type="text" value="5"/>	<i>If > 4.5, mark as positive.</i>	positive <input type="checkbox"/>		
Not done	<input checked="" type="checkbox"/> 1c. Whiff test	negative <input type="checkbox"/>	positive <input type="checkbox"/>		
Not done	<input checked="" type="checkbox"/> 1d. Clue cells \geq 20%	negative <input type="checkbox"/>	positive <input type="checkbox"/>		



Protocol Deviation Log CRF

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

Documentation of Pelvic Exam Findings re-assessed during Screening

- ❑ 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 and new Pelvic Exam Checklist are **not** required.
 - A Pelvic Exam Diagrams CRF should be completed to document the assessment
 - 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)

“As indicated” Physical Exam documentation – at 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.

Abbreviated Physical Exam							
VITAL SIGNS							
1. Weight	<table border="1"><tr><td></td><td></td><td></td></tr></table> kg						
2. Body Temp	<table border="1"><tr><td></td><td></td><td></td></tr></table> °C						
3. BP	<table border="1"><tr><td></td><td></td><td></td></tr></table> / <table border="1"><tr><td></td><td></td><td></td></tr></table> mmHg						
4. Pulse	<table border="1"><tr><td></td><td></td><td></td></tr></table> beats per minute						
5. Respirations	<table border="1"><tr><td></td><td></td><td></td></tr></table> breaths per minute						

} not done
29 OCT 12
JMB

HIV Rapid Test Kit Codes – Monthly Lab Results CRF

- Items 2 & 3: HIV Rapid Test Kit Codes have been updated to include new kit code '04' for the StatPak rapid HIV test kit currently used by MU-JHU, Kampala
- Kit code 01 has been updated from “Abbot Determine” to “Determine”
- Kit code 02 has also been updated from “OraSure OraQuick” to “OraQuick”

Item-specific Instructions:											
Items 2 and 3:	Record the assigned two-digit rapid test kit code. <i>Note: More test kit codes may be added to the list as the study proceeds.</i>										
	<table border="1"><thead><tr><th>Kit Code</th><th>Rapid Test</th></tr></thead><tbody><tr><td>01</td><td>Determine</td></tr><tr><td>02</td><td>OraQuick</td></tr><tr><td>03</td><td>Uni-Gold Recombigen</td></tr><tr><td>04</td><td>StatPak</td></tr></tbody></table>	Kit Code	Rapid Test	01	Determine	02	OraQuick	03	Uni-Gold Recombigen	04	StatPak
Kit Code	Rapid Test										
01	Determine										
02	OraQuick										
03	Uni-Gold Recombigen										
04	StatPak										

QC Report Distribution Schedule

SCHARP plans to distribute monthly QC Reports at approximately the 4th Tuesday of each month. Additional QC Reports will be issued during the study as needed for interim analysis/review purposes.





Questions???

- Please contact Jen Berthiaume and Missy Cianciola with any questions you have about this slide presentation or the Data Communiqué

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We are more than happy to hear from you!