Microbicide Trials Network

CLARIFICATION MEMO #02 TO:

MTN-005
Expanded Safety and Adherence Study of a Non-medicated Intravaginal Ring, Version 2.0, dated 19 October 2010

DAIDS Document ID 10635

Date of Clarification Memorandum: 5 October 2011

Site Instruction and Summary of Clarification

The procedures clarified in this Clarification Memorandum (CM) have been approved by the NIAID Medical Officer and are to be implemented immediately upon issuance. IRB approval of this CM is not required by the sponsor; however, investigators may submit the CM to the IRB overseeing the study at their site for information. This CM is official MTN-005 documentation and is effective immediately. A copy of this CM must be retained in the study site's Essential Documents file for MTN-005. No change in informed consent is necessitated by or included in this CM.

The primary goal of this CM is to allow for additional STI testing at the 16-Week/Study Termination Visit per local standards/guidelines, as a result of a country specific regulatory request.

Implementation

Except for modifications to the Protocol Team Roster and modifications to FHI 360, text to be deleted is noted by ~~strikethrough~~ and text to be added is noted below in **bold.**

---

1. The Protocol Team Roster is updated to reflect changes to the Protocol Team:

   The following addition is made to the Protocol Team Roster:

   Ken Ho, MD
   Safety Physician
   University of Pittsburgh
   Division of Infectious Diseases
   Keystone Building, Suite 533
   3520 Fifth Avenue
   Pittsburgh, PA 15213
   United States
   Phone: 412-383-7178
   Fax: 412-383-2900
   Email: hok2@upmc.edu

Throughout the document FHI has been updated to FHI 360.

2. Section 7.4, *16-Week/Study Termination Visit*, Table 7, the blood and pelvic samples laboratory rows and Appendix I: *Schedule of Study Visits and Evaluations* are updated to reflect that syphilis and GC/CT testing should be performed per local standards/ guidelines.

Table 7: 16-Week/Study Termination Visit:

Laboratory	**Blood**	• HIV-1 test • Syphilis serology*†
	Pelvic Samples	• Gram stained smear of vaginal fluid, obtained from lateral vaginal wall • Vaginal swabs for vaginal flora assessments • Cervical swab for innate factors (US sites only) • Vaginal fluid tested for *Trichomonas vaginalis* by rapid test (CLIA waived test)*† • Vaginal pH*† • Vaginal fluid for wet mount microscopy (KOH for vulvovaginal candidiasis)*† • Vaginal fluid for wet mount microscopy (saline for BV)*† • Herpes culture*† • Cervical NAAT for GC/CT*†

*If clinically indicated
†Per local standards/guidelines

Appendix I: Schedule of Study Visits and Evaluations:

	SCR	ENR	4W	8W	12W	16W/Study Term	Interim
	Up to and incl. 45 days prior to ENR	Day 0	Must occur within ±7 days of scheduled visit				
Syphilis Serology	x	▲	▲	▲	▲	▲†	▲
Cerv. NAAT for GC/CT	x	▲	▲	▲	▲	▲†	▲

▲ if clinically indicated ●For group A (randomized to Study IVR) ■ For group A (if permanently discontinued and removed by study clinician)∞For group A (randomized to Study IVR and removed by study clinician) †Per local standards + For Group A if indicated, + if applicable

The above information will be incorporated into the next version of the protocol at a later time if it is amended.