

Clarification Memo #01 to:

MTN-020

A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Phase 3 Safety and Effectiveness Trial of a Vaginal Matrix Ring Containing Dapivirine for the Prevention of HIV-1 Infection in Women

DAIDS Document ID#: 11840

IND#: 108,743

Version 1.0 / 28 September 2011

Clarification Memo Date: 7 August 2013

Site Instruction and Implementation

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-020 documentation and is effective immediately. A copy of this CM must be retained in the study site's Essential Documents file for MTN-020. No change in informed consent is necessitated by or included in this CM.

Summary of Revisions

The purpose of this CM is to update the Protocol Team Roster, to clarify language in Section 7.7, *Behavioral Evaluations*, Section 9.5, *Genital Sexually Transmitted Infection, Reproductive Tract Infection and Other Clinical Findings*, and Section 13.6, *Participant Confidentiality*.

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

Implementation

1. Contact information for the following individual has been updated in the Protocol Team Roster:

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The following individuals have been removed from the Protocol Team Roster: Missy Cianciola, Nicola Coumi, Shayhana Ganesh, Vijayanand Guddera, Karen Isaacs, Marwah Jenneker, Newton Kumwenda, Tsitsi Magure, Modulakgotla Anthony Sebe, Yuktेशwar Sookrajh

2. Within Section 7.7, *Behavioral Evaluations, Sexual Activity, Condom Use and Intravaginal Practices* subsection, a clarifying statement has been added:

Note: Behavioral evaluations – which may include questions on sexual activity, condom use, and intravaginal practices – will be conducted quarterly, though the frequency of asking about each topic may vary. Behavioral evaluations will be tailored to each visit according to appropriate timing of the specific topic.

3. To maintain consistency with Section 6.7, *Use of Intravaginal Medications and Practices*, Section 9.5, *Genital Sexually Transmitted Infection, Reproductive Tract Infection and Other Clinical Findings*, the last sentence of the first paragraph has been updated:

Vaginally applied medications ~~should not be used~~ **will be discouraged**, except that vaginal azoles should be used to treat symptomatic candidiasis among pregnant women.

4. Section 13.6, *Participant Confidentiality*, the sixth sentence of the second paragraph has been edited to more closely align with the principles of ICH GCP 2.10 and 2.11:

[...] Forms, lists, logbooks, appointment books, and any other listings that link participants' identification numbers to identifying information will be stored in a ~~separate~~, locked file in an area with limited access. [...]

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