

Microbicide Trials Network

CLARIFICATION MEMO #01 TO:

MTN-034

**A Phase 2a Crossover Trial Evaluating the Safety of and Adherence to a Vaginal Matrix Ring Containing Dapivirine and Oral Emtricitabine/Tenofovir Disoproxil Fumarate in an Adolescent and Young Adult Female Population**

DAIDS Protocol #: 12066

IND#: 139,598

Version 2.0 / 7 December 2017

**Clarification Memo Date: 25 July 2019**

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*Section 1: Summary of Clarifications and Rationale*

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/IEC approval of this CM is not required by the sponsor; however, investigators may submit the CM to the IRB/IEC overseeing the study at their site for information. This CM is official MTN-034 documentation and is effective immediately. A copy of this CM must be retained in each study site's Essential Documents file for MTN-034. No change in informed consent is necessitated by or included in this CM.

This document includes a clarification related to occurrence of product adherence disclosure counseling as part of the study's protocol adherence counseling. Protocol adherence counseling occurs at all study visits except the Screening and Study Exit visits. Product adherence disclosure counseling, which involves presentation of laboratory drug level testing results to participants, is described in the protocol as being required twice per study product use period (after the second and fifth months of product use). This document clarifies that incorporation of product adherence disclosure counseling into the study's protocol adherence counseling activities is also permissible during study visits other than those explicitly required by the protocol. In retrospect, the protocol language is unnecessarily rigid and seemingly restricts the use of this important and beneficial counseling tool to only two times per study product use period, after the second and fifth months of product use. This document also updates the Protocol Team Roster.

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*Section 2: Implementation*

With the exception of updates to the protocol team roster, text to be deleted is noted below with a ~~strike through~~, text to be added is in **bold**, and text in **bold italics** is not to be added, but to serve as a clarification of the implementation item in question. This information will be included in the protocol the next time the protocol is updated.

- 1.) The following clarification applies to Section 7.4.2, Visits 4-9, Visits 11-16, Visits 18-22: Week 4 through Week 68, third paragraph; Section 7.4.2, Visits 4-9, Visits 11-16, Visits 18-22: Week 4 through Week 68, Table 10: Visits 4-9, Visits 11-16, Visits 18-22: Week 4 through Week 68, procedure descriptor labeled "" at the end of the table; Section 7.8, Protocol and Product Adherence Counseling, fifth sentence; and Appendix I, Table of Visits and Study Procedures, procedure descriptor labeled "" at the end of the table:

***Site staff involved in protocol adherence counseling for the MTN-034 study may, at their discretion and pending the availability of laboratory drug level results, incorporate product adherence disclosure counseling into their participant-centered counseling activities at monthly follow-up clinic visits other than those visits where explicitly required in the protocol, i.e., Visits 5, 8, 12, 15, 19, and 22.***

- 2.) Protocol Team Roster – Deletions: Kevin Cain, Mitesh Desai, Jennifer Thomas, Jennifer Berthiaume, and Wayne Hall.

3.) Protocol Team Roster – Updates: Added Nelly Mugo’s credentials and Carolyn Akello’s study title.

4.) Protocol Team Roster – Additions:

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