

Microbicide Trials Network

CLARIFICATION MEMO #03 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: 17 March 2015

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 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 each study site's Essential Documents file for MTN-020. No change in informed consent is necessitated by or included in this CM.

This CM clarifies the procedures to be performed at the Product Use End Visit (PUEV) when the PUEV coincides with a Semi-Annual Visit.

Section 2: Implementation

Text to be deleted is noted with a ~~strike through~~ and text to be added is in **bold**.

- 1.) The description attached to the semi-annual visit symbol under Table 6: *Follow-up Visits: Monthly, Quarterly, Semi-Annually* has been updated:
 - ▶ = to be completed at all semi-annual visits ~~only~~ (Months 6, 12, 18, etc.) **and at PUEV when the PUEV coincides with a semi-annual visit. Procedures related to the provision of study product will be omitted at PUEV.**
- 2.) To align with the clarification to Table 6: *Follow-up Visits: Monthly, Quarterly, Semi-Annually*; Appendix I: *Schedule of Study Visits and Procedures* a note has been added to the PUEV column:

	SCR	ENR	Monthly Visits	Quarterly Visits	Semi-Annual Visits**	PUEV**	Study Exit/Term. Visit
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****= When the PUEV coincides with the timing of a Semi-Annual Visit (Months 6, 12, 18, etc.), all procedures except for the provision of study product and related procedures will be conducted.**

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