

Clarification Memo #01 to:

MTN-011

Phase 1 Evaluation of the Impact of Coitus on the Pharmacokinetics and Pharmacodynamics of Tenofovir 1% Gel Following Pericoital or Daily Gel Dosing

DAIDS Document ID#: 11825

IND#: 73,382

Version 1.0 / 24 April 2012

Clarification Memo Date: 21 May 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-011 documentation and is effective immediately. A copy of this CM must be retained in the study site's Essential Documents file for MTN-011. 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 and to clarify the timing of product dispensation and instructions at Visit 5 (Group 2) to ensure protocol consistency.

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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2. In order to maintain consistency with Section 6.0, Section 7.5, *Group 2 (Multiple Dose Cohort) – Enrollment and Study Follow-up*, Table 14, *Group 2- Visit 3b: Post-Coital Sampling, Visit 5: Sampling, Visit 7b: Post-Coital Sampling* and Appendix II, *Schedule of Study Visits and Evaluations: Group 2*, have been revised to allow for the provision of study product and study product use instructions at Visit 5.

Table 1: *Group 2- Visit 3b: Post-Coital Sampling, Visit 5: Sampling, Visit 7b: Post-Coital Sampling*

Group 2 Group 2- Visit 3b: Post-Coital Sampling, Visit 5: Sampling, Visit 7b: Post-Coital Sampling	
Component	Female Participants
Study Product Supply	<ul style="list-style-type: none">• Provision of study product ◇• Study product use instructions ◇

◇= Visit 5 only

APPENDIX II: SCHEDULE OF STUDY VISITS AND EVALUATIONS: GROUP 2

	Visit 1	Visit 2	Visit 3a	Visit 3b	Visit 4	Visit 5	Visit 6	Visit 7a	Visit 7b	Visit 8	Visit 9
	SCR	ENR	Gel -1/Sex	Post Coital Sampling (♀)	Provision of Product (♀)	Sampling (♀)	Provision of Product (♀)	Gel -72/ Sex	Post Coital Sampling (♀)	Provision of Product (♀)	Sampling / Final Clinic
Study Product											
Provision of study product		X	X		X	X	X			X	
Study product use instructions		X	X		X	X	X			X	

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