

Microbicide Trials Network

CLARIFICATION MEMO #01 TO:

MTN-042

Phase 3b, Randomized, Open Label Safety Trial of Dapivirine Vaginal Ring and Oral TRUVADA® Use in Pregnancy

DAIDS Protocol #: 38544

IND#: 139,598

Version 1.0 / 16 April 2019

Clarification Memo Date: 17 August 2020

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-042 documentation and is effective immediately. A copy of this CM must be retained in each study site's Essential Documents file for MTN-042. No change in informed consent is necessitated by or included in this CM.

This document corrects the infant blood draw volume amounts expected for research purposes from the Truvada and Dapivirine vaginal ring group infants, added via Letter of Amendment #01 dated 17 December 2019. This document also updates the Truvada tablet package insert version.

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 correction applies to the second and third sentences of the first paragraph of Section 7.12, *Laboratory Evaluations*:

The maximum amount required to be drawn for research purposes from infants in the Truvada arm is ~~5-6~~ mL over 12 months of study participation (with ~~≤ 3-4~~ mL in a single day and ~~≤ 5-6~~ mL in any given eight-week period). The maximum amount required to be drawn for research purposes from infants in the DPV VR arm is ~~4-6~~ mL over 12 months of study participation (with ~~≤ 2-4~~ mL in a single day and ~~≤ 4-6~~ mL in any given eight-week period).

- 2.) The following correction applies to Table 15, Protocol-required Infant Blood Draw Volumes by Study Arm and by Clinic Visit, in Section 7.12, *Laboratory Evaluations*:

Table 15. Protocol-required Infant Blood Draw Volumes by Study Arm and by Clinic Visit

Clinic Visit	Truvada Group	DPV VR Group
PPO Visit	3-4 mL	2-4 mL
6-week PPO Visit	2 mL	2 mL
6-month PPO Visit	0 mL	0 mL
12-month PPO Visit	0 mL	0 mL
TOTAL	5-6 mL	4-6 mL

- 3.) Protocol references to the Truvada Package Insert were updated to the most current version dated June 2020.

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