

**Microbicide Trials Network
CLARIFICATION MEMO #01 TO:**

**MTN-003D
DAIDS Document ID #11893**

An Exploratory Study of Potential Sources of Efficacy Dilution in the VOICE Trial

Version 1.0 / 15 May 2012

Date of Clarification Memorandum: 13 November 2012

Section 1: Summary of Clarifications and Rationale

The items clarified in this Clarification Memorandum (CM) have been approved by the NIAID Medical Officer and are to be implemented immediately upon issuance. IRB/EC approval of this CM is not required by the sponsor; however, investigators may submit the CM to the IRB/EC overseeing the study at their site for information. This CM is official MTN-003D documentation and is effective immediately. A copy of this CM must be retained in each study site's Essential Documents file for MTN-003D. No change in informed consent is necessitated by or included in this CM.

The purpose of this CM is to update the protocol team roster and to correct table calculations for the estimated overall stratified recruitment sample.

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

Section 2: Implementation

1. The Protocol Team Roster is updated.

The following additions have been made to the Protocol Team Roster:

**Funeka Mthembu
Interviewer**

HIV Prevention Research Unit
South African Medical Research Council
Westville, Durban, South Africa
Phone: 27-31-242-3600
Fax: 27-31-242-3800
E-mail: Funeka.Mthembu@mrc.ac.za

**Josephine Nabukeera
Consultant**

Makerere Institute of Social Research
PO Box 16022
Kampala, Uganda
Phone: 0772-566235/ 0757-636908
Fax: 256-414-543002
Email: josephinenabukeera@yahoo.co.uk

**Sarita Naidoo, BSc (HONS)
Site Investigator**

HIV Prevention Research Unit
South African Medical Research Council
Westville, Durban, South Africa
Phone: 27-31-242-3600
Fax: 27-31-242-3800
E-mail: sarita.naidoo@mrc.ac.za

**Nozipho Lucia Vilakazi
Interviewer**

HIV Prevention Research Unit
South African Medical Research Council
Westville, Durban, South Africa
Phone: 27-31-242-3600
Fax: 27-31-242-3800
E-mail: Nozipho.Vilakazi@mrc.ac.za

Zvavahera Mike Chirenje, MD, FCROG
Site Investigator
UZ-UCSF Collaborative Research Programme
15 Phillips Avenue
Belgravia Harare, Zimbabwe
Phone: 263-4-704920
Fax: 263-4-704897
Email: chirenje@uz-ucsf.co.zw

The following individuals have been removed from the Protocol Team Roster: Nyaradzo Mgodzi, MBChB and Gita Ramjee, PhD.

2. Section 5.1, *Selection of the Study Population and Recruitment*, Table 1 has been modified to correct the planned Overall Stratified Recruitment Sample.

Table 1. Estimated Overall Stratified Recruitment Sample

Study Group:	Tablet Users	Gel Users	Total
Reported Anal Sex	5	5	10
Acquired HIV while enrolled in VOICE	5	5	10
All other women	4938	4938	7876
Total	5948	5948	9896

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