Microbicide Trials Network

CLARIFICATION MEMO #0 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:

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The following individuals have been removed from the Protocol Team Roster: Nyaradzo Mgodi, 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

<table>
<thead>
<tr>
<th>Study Group</th>
<th>Tablet Users</th>
<th>Gel Users</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reported Anal Sex</td>
<td>5</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td>Acquired HIV while enrolled in VOICE</td>
<td>5</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td>All other women</td>
<td>4938</td>
<td>4938</td>
<td>9876</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>5948</strong></td>
<td><strong>5948</strong></td>
<td><strong>9896</strong></td>
</tr>
</tbody>
</table>

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