

---

## MEMORANDUM

---

**Date:** June 1, 2009  
**To:** MTN 002 Protocol Team  
**From:** MTN 002 SDMC  
**RE:** **MTN 002 Visit Adherence Report**

### Purpose

To summarize site performance regarding study primary endpoint data collection, by site and overall, with particular attention given to: 1) Distribution of visits, as the number of days between enrollment and gel administration date, 2) the number of days between target and actual visit date; 3) Number and percentage of required procedures - pelvic exams; pharmacokinetic measures for maternal blood collections and stored specimen collections.

### Expectations and Data Used in this Report

The measures above can only be accurately assessed if the relevant forms are expected to have been collected in the database, and have actually been received. For purposes of this report, forms are expected for visits for which the allowable window has passed. Participant visits are required and expected only if the participant comes in for a visit. Missed visits are not considered expected for purposes of this report.

### Table Descriptions

#### Distribution of Visits: Number of Days Between Enrollment and Gel Administration

All participants who are enrolled and evaluable are scheduled to receive the study product within the allowable visit window. Table 1a displays the distribution of the time (days) from enrollment date to the gel administration date. The table provides the following statistics which describe the distribution of the time from enrollment to gel administration: 1) "N", which is the number of participant-visits being summarized; 2) "Mean", which is the average; 3) "STD", which is the standard deviation; 4) "Max", which is the maximum or the highest value; 5) "75<sup>th</sup>%tile", which is the third quartile; 6) "Median", which is the median, or middle value of the distribution; 7) "25<sup>th</sup>%tile", which is the first quartile; and 8) "Min.", which is the minimum or the lowest value.

#### Distribution of Visits: Number of Days Between Target and Actual Visit Date

For each of the visits in follow-up, we subtract the actual visit date from the target visit date among visits that were expected and completed (missed visits are not considered). The table provides the following statistics which describe the distribution of the time between target and actual visit date: 1) "N", which is the number of participant-visits being summarized; 2) "Mean", which is the average, a mean *greater* than 0 indicates the actual visit occurred *after* the target date, on average, and a mean *less* than 0 indicates the actual visit occurred *before* the target date, on average; 3) "STD", which is the standard deviation; 4) "Max", which is the maximum or the highest value; 5) "75<sup>th</sup> %tile", which is the third quartile; 6) "Median", which is the median, or middle value of the distribution; 7) "25<sup>th</sup>%tile", which is the first quartile; and 8) "Min", which is the minimum or the lowest value (see Table 1b).

---

## **Completion of Procedures: (Pelvic exams; Pharmacokinetic Measures for Maternal Blood Collection and Stored Specimen Collections)**

Each of the measures in this table has separate requirements regarding the visits at which the procedures are required, and the data elements on the Case Report Form (CRF) that must be received in order for the procedure to be considered “Completed.”

Pharmacokinetic (PK) measures for all participants are required at the gel administration visit (day 0) and 24 hour evaluation visit. PK measures consists of pre-, post-gel blood draws and stored specimen collections. Post-gel blood draws are at 1, 2, 4, 5, 8, 12 and 24 hrs after gel administration. These procedures are considered “Completed” if the sampling dates/times are recorded for all the draws. If the sampling date/time is missing for at least one required draw at a given study period visit, the procedures are considered “Partially Completed”. If the sampling time is missing for all required draws at a given study period visit, the procedures are considered “Not Completed”.

Pelvic exam is required at gel administration (day 0) visit. A pelvic exam is considered “Completed” if abnormal findings or no abnormal findings box is marked for the visit.