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## MEMORANDUM

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**Date:** March 11, 2010  
**To:** MTN 003B Protocol Team  
**From:** MTN 003B SDMC  
**RE:** **MTN 003B Visit Adherence and Procedure Completion 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 target and actual visit dates, 2) the number of days between sequential semi-annual visits; 3) Number and percentage for completing the required procedures - DXA scans; nutritional assessments including physical signs of malnutrition, height and weight; dietary and physical activity history; storage of urine and serum for evaluating the markers of BMD.

### 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 presents herself at the site for a 003B visit. Missed visits are not considered expected for purposes of this report.

### Table Descriptions

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

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 time between target and actual visit dates: 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) “SD”, 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 Sequential Semi-annual Visits

For all participants, we summarize the table by subtracting the two visit dates of the visits that are consecutive to each other (the date of the current month and the date of the previous month), among visits that were expected and completed (missed visits are not considered). The table provides the following statistics which describe the distribution of time between sequential semi-annual visits: 1) “N”, which is the number of participant-visits being summarized; 2) “Mean”, which is the average; 3) “SD”, 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.

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## **Completion of Procedures: (DXA scans; Nutritional assessments including physical signs of malnutrition, height and weight; Dietary and Physical Activity history; Storage of urine and serum for evaluating the markers of BMD)**

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.” This study has procedures that need to be completed at enrollment, semi-annual and product use end (PUEV) or Early termination visit (ETV).

DXA Scan is required at semi-annual and PUEV/ETV visits for all participants; except for participants who are determined to be pregnant during follow-up. If the response to Q 1 on DXA-1 CRF is "yes" then it is considered to be completed.

Physical Signs of Malnutrition is required at semi-annual and PUEV/ETV visits for all participants. If Q 2 on the Visit Procedures CRF has a response then it is considered to be completed.

Height and Weight is required at semi-annual and PUEV/ETV visits for all participants. If both Q 7 and Q 8 on the Visit Procedures CRF have a response then it is considered to be completed.

Food Frequency questionnaire is required at semi-annual and PUEV/ETV visits for all participants. If there is at least a response for Q 1 on the Food Frequency Questionnaire CRF then it is considered to be completed.

Physical activity questionnaire is required at semi-annual and PUEV/ETV visits for all participants. If there is at least a response for Q 1 on the Physical Activity Questionnaire CRF then it is considered to be completed.

Storage of Serum is required at semi-annual and PUEV/ETV visits for all participants; except for participants who are determined to be pregnant during follow-up. If the response for Q 5 on the Visit Procedures CRF is "stored" then it is considered to be completed.

Storage of Urine is required at semi-annual and PUEV/ETV visits for all participants; except for participants who are determined to be pregnant during follow-up. If the response for Q 6 on the Visit Procedures CRF is "stored" then it is considered to be completed.