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## MTN-003B Data Communiqué #1

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November 23, 2009

This communiqué is official study documentation for MTN-003B. It is considered part of the MTN-003 Study-Specific Procedures (SSP) Manual. Please circulate this communiqué among relevant staff for their review, and print and file a copy in Section Appendix 18-8 of each MTN-003 SSP Manual maintained at your site.

### UPDATES

#### 1. Separate MTN-003B Site Data Management Quality Report

A separate monthly Site Data Management Quality Report will be generated for MTN-003B. Therefore the MTN-003 Site Data Management Quality Report will not include information on CRFs submitted for MTN-003B.

### CLARIFICATIONS

#### 1. MTN-003B Visits Split Across Visit Windows

If a participant is not able to complete all required procedures for a given MTN-003B visit within the MTN-003B visit window (e.g., Month 6), schedule her, if possible, to complete the remaining procedures when the next VOICE monthly visit window opens (e.g., Month 7). In this case, all of the CRFs listed as required for the MTN-003B visit (per SSP Manual Section 18) should be completed within the MTN-003B visit window and assigned the MTN-003B visit code (e.g., Month 6 = visit code 9.0). Procedures not done within the MTN-003B visit window should be recorded as such on the form (e.g., by marking the “Not done/Not collected” box, if available, or writing a note to this effect at the top of the form, initialing and dating the note, and leaving the form items blank). When the next monthly visit window opens (e.g., Month 7), complete the remaining MTN-003B visit procedures. In addition, complete a new MTN-003B Visit Procedures form and any other forms needed to capture data from the procedures completed in this next monthly visit window. Assign the forms the visit code associated with the current study month in which the remaining visit procedures were completed (e.g., Month 7 = visit code 10.0).

For example, a participant completes all Month 12 MTN-003B visit procedures within the Month 12 visit window, except for the DXA Scan. At Month 12, complete all required Month 12 MTN-003B CRFs (including the DXA Scan form), assign them the Month 12 visit code (15.0), and fax them to SCHARP DataFax. Since the DXA scan was not done, indicate in the response to item 1 on the DXA Scan form that a DXA scan was not done and record the reason on the line provided. Schedule the participant to return to the site as soon as possible to complete the DXA scan. If the participant is able to return to the site clinic to complete the DXA scan in the Month 13 visit window, complete a new MTN-003B Visit Procedures form and a new MTN-003B DXA scan form, assign them both the Month 13 visit code (16.0), and fax both to SCHARP DataFax.

*Note: If the DXA scan is performed on a different day than the participant’s VOICE visit, conduct a pregnancy test prior to the scan, as pregnancy testing is required on the same day prior to when each DXA scan is done, and the test result must be documented as negative before a scan is performed.*

## **2. “Total Spine” on DXA Scan CRF**

Item 3 of the MTN-003B DXA Scan CRF provides a place to record the participant’s bone mineral density (BMD), T-score and Z-score of the “Total Spine”. On the DXA Scan CRF, “Total Spine” only refers to the lumbar spine, specifically L1-L4. If a DXA scan of only the lumbar spine is performed, the DXA scan output will list the BMD for “L1”, “L2”, “L3”, “L4”, and “Total”. On the DXA scan output, “Total” refers to the total lumbar spine. Therefore, record the BMD number from the “Total” row of the DXA scan output in item 3a of the MTN-003B DXA Scan CRF.

## **3. Sexual Activity as it Relates to Physical Activity Questionnaire (PAQ) CRF**

The purpose of the MTN-003B PAQ CRF is to document the participant’s history of weight-bearing exercise. Sexual activity should not be captured on the MTN-003B PAQ, as it is not typically considered a weight-bearing exercise.

## **4. Average BMD Measurements**

Per protocol section 7.4 (page 25), the DXA scans will be performed in duplicate, “and an average of both measurements will be recorded.” Please note that site staff do not need to record the average of both BMD measurements on any MTN-003B CRF or other document. This calculation will be done by SCHARP based on the data for both scans as recorded on the DXA Scan CRF.

## **5. Faxing DXA Scan CRFs After Uploading Scans for Review**

According to site SOPs, sites will upload the MTN-003B DXA scans to the MTN-003B DXA scan/bone mineral density consultant in Pittsburgh via the MTN FTP server at least twice a week (if scans are performed that week). The DXA scan consultant will review the scans and send feedback on each scan within 5 working days of uploading. Once sites receive this feedback and any necessary corrections have been addressed, they should only then complete the DXA Scan CRF and fax it to SCHARP DataFax. The goal for MTN-003B is for sites to fax the DXA Scan CRF and any resulting AE Log CRFs to SCHARP within 10 working days of when the scan is performed. The delay in faxing the DXA Scan CRF will not count against sites regarding the “mean days to fax in” on the Site Data Management Quality Report. If this process is revised during the study, sites will be informed in writing of the changes.

## **REMINDERS**

### **1. Technician Code on DXA Scan CRF**

Each site is responsible for developing and maintaining a site-specific list of codes that correspond to each DXA scan technician. The codes should be a 3-digit number, with the legal range being 001-999, and should be assigned only to those persons primarily responsible for performing the DXA scans in the MTN-003B study. When a MTN-003B visit is conducted, the code(s) corresponding to the person(s) who completed scan #1 (the first scan of the spine and hip) and scan #2 (the second scan of the spine and hip) will be recorded in item 7 of the MTN-003B DXA Scan CRF. It is assumed that the same DXA scan technician will perform both scans for each participant at a given visit. However, if this is not the case (i.e., a second DXA scan technician performs the second scan of the spine and hip), record the DXA scan codes for the scan #1 technician and the scan #2 technician in the corresponding boxes for item 7 of the MTN-003B DXA Scan CRF.

### **2. Recording Height and Weight on Visit Procedures CRF**

On 16-SEP-09, MTN-003B Clarification Memo #2 was issued. This CM stated that “Height and weight measurements performed and documented for VOICE within 14 days (inclusive) of an MTN-003B visit may be used for MTN-003B”. As a reminder, if weight and height are measured as part of a VOICE visit, and the VOICE visit occurred within 14 days of the MTN-003B Visit, weight and height do not have to be measured as part of the MTN-003B Visit. Rather, the weight and height recorded for the VOICE visit can be transcribed onto the MTN-003B Visit Procedures CRF for items 7 and 8 respectively. Write a short note in the Comments section at the bottom of the form stating that weight and height were measured on a different date, and specify the date [dd-MMM-yy].