
MTN-003B Data Communiqué #2

March 3, 2010

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. SCHARP Staffing Changes

Karen Patterson has taken over as sole SCHARP Project Manager on MTN-003B. Please contact Karen (karen@scharp.org or karenp@scharp.org) regarding any questions related to data collection or data management in MTN-003B.

2. Date of Birth Estimator Tool

When performing bone density scans, site staff must enter the participant's date of birth into the Hologic Explorer. If a participant is unable to provide her exact date of birth, please use the MTN-003B Date of Birth Estimator tool to estimate the day, month, and year of the participant's birth. Enter the participant's estimated date of birth into the Hologic Explorer exactly as it appears in the tool, and print out the tool for filing as source documentation in the participant's MTN-003B study notebook. The tool is programmed based on the same algorithm used to estimate participant date of birth in the SCHARP database. The tool is posted on the MTN web site under "MTN-003B Study Implementation Materials", and can be found online at <http://www.mtnstopshiv.org/node/1326>.

CLARIFICATIONS

1. Assigning Visit Codes to Adverse Events (AEs) Reported at MTN-003B Visits

If a new, reportable AE is first identified at an MTN-003B Visit, site staff should assign the AE Log CRF the MTN-003B visit code. For example, a participant has a bone density scan at her MTN-003B Screening/Enrollment Visit, which occurs a week after her VOICE Enrollment Visit. The scan reveals a new reportable AE of grade 2 bone mineral density. The participant also reports a new AE of dysuria at the MTN-003B Screening/Enrollment Visit. Since both AEs are reportable and were first identified at the MTN-003B Screening/Enrollment Visit, complete an AE Log CRF for each AE. Assign the AE Log CRFs the MTN-003B Screening/Enrollment visit code (3.0) by recording "03.0" for item 10.

2. Assigning Visit Codes When Additional Procedures Are Conducted at MTN-003B Visits

There may be situations in which site staff need to conduct interim VOICE procedures, such as an examination or blood draw, at an MTN-003B visit in order to follow up on an AE. If the VOICE interim procedures require completion of one or more new DataFax CRFs (other than the AE Log), then assign the DataFax CRFs a VOICE interim visit code. For example, site staff conduct a urinalysis at the MTN-003B Screening/Enrollment Visit to follow up on a participant-reported AE of dysuria. Since the urinalysis is not part of MTN-003B visit procedures, it represents a VOICE interim visit procedure. Complete the VOICE Safety Laboratory Results CRF to

document the urinalysis results, and assign the form interim visit code 3.1. Remember to complete and submit an Interim Visit form, along with any other CRFs that require completion to document the interim VOICE procedures that were conducted.

3. Faxing DXA Scan CRFs to SCHARP After Pittsburgh Scan Review

One data management quality goal of 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. This 10-day window is provided to accommodate the Quality Assurance (QA) process specific to the bone density scans. The process is outlined below.

- Sites are asked to upload scan files twice a week for those weeks in which a scan is done. The files are uploaded via ftp to the DXA technologists in Pittsburgh.
- The DXA technologists review files for each scan within 5 working days of when the files were uploaded. The DXA technologists adjust the scans that require adjustment, then send feedback along with any adjusted scan files back to the site.
- Site staff upload the new modified scan files into the Hologic Explorer. This will overwrite the original scan files and replace them with the new modified scan files.
- Site staff print out the new scan images/results for filing as source documentation in the participant study notebook. These printouts of the new modified scan data are used to complete the DXA Scan CRFs.

***NOTE:** Site staff should not complete the DXA Scan CRF for a given scan until feedback is received from the DXA technologists in Pittsburgh. The DXA Scan CRFs should only be completed based on adjusted scan data, for those scans that are adjusted.*

In order to monitor adherence to these DXA Scan CRF completion instructions, as well as the QA process in general, SCHARP has added a “Mean Days to Fax DXA Scan CRF” measure to the monthly MTN-003B Data Management Quality Reports. In addition, the DXA technologists, Network Lab, SCHARP, and FHI are working to develop an internal QC process in which the DXA Scan CRF data in the SCHARP database is compared to the bone scan data provided by the DXA technologists.

REMINDERS

None