

SAMPLE: DO NOT FAX TO DATAFAX



MTN003 VOICE (160)

ELB-1 (360)

Participant ID

<input type="text"/>								
Site Number			Participant Number				Chk	

MTN 003B Eligibility

1. Has the participant been randomized to oral study product in MTN 003 within the past 14 days?

yes	no
<input type="checkbox"/>	<input type="checkbox"/>

 → **If no, participant is ineligible. End of form.**
2. Is the participant pregnant based on her most recent MTN 003 pregnancy test?

yes	no
<input type="checkbox"/>	<input type="checkbox"/>
3. Does the participant have a medical condition known to affect bone (e.g., hyperparathyroidism, bone cancer) or is she taking any medication known to affect bone (e.g., glucocorticoids, heparin, warfarin, cyclosporine, cancer drugs, and thyroid hormones)?.....

yes	no
<input type="checkbox"/>	<input type="checkbox"/>
4. Has the participant permanently discontinued oral study product in MTN 003?

yes	no
<input type="checkbox"/>	<input type="checkbox"/>
5. Does the participant have any other medical condition that, in the investigator's opinion, would preclude informed consent, make MTN 003B participation unsafe, complicate interpretation of MTN 003B outcome data, or otherwise interfere with achievement of MTN 003B objectives?

yes	no
<input type="checkbox"/>	<input type="checkbox"/>

 → **If yes to any, participant is ineligible. End of form.**
6. Was the participant offered enrollment into MTN 003B?

yes	no
<input type="checkbox"/>	<input type="checkbox"/>

 → **If yes, go to item 7.**

6a. Record the reason why the participant wasn't offered enrollment into MTN 003B:

_____ → **End of form.**

7. Was the participant able and willing to provide written informed consent for participation in MTN 003B?

yes	no
<input type="checkbox"/>	<input type="checkbox"/>

 → **If no, participant is ineligible. End of form.**

7a. When was the informed consent form for MTN 003B participation marked or signed?.....

dd		MMM			yy				

8. Did the participant enroll in MTN 003B?

yes	no
<input type="checkbox"/>	<input type="checkbox"/>

 → **If yes, go to item 8b.**

8a. Record the reason why the participant did not enroll in MTN 003B:

_____ → **End of form.**

8b. Date of MTN 003B enrollment:

dd		MMM			yy				

MTN 003B Eligibility (ELB-1)

Purpose: This form is used to collect information on MTN 003 participants randomized to oral study product during the MTN 003B accrual period. For those participants who are eligible, this form is also used to document enrollment into MTN 003B.

General Information/Instructions: Until MTN 003B accrual has finished, complete and fax this form to SCHARP DataFax for each MTN 003 participant randomized to oral study product (regardless of whether or not the participant is eligible for or enrolls in MTN 003B). SCHARP will inform each site in writing when this CRF is no longer required to be completed and faxed to SCHARP DataFax. If a participant is ineligible for or does not enroll in MTN 003B, do fax this form to SCHARP DataFax but do not complete or fax any other MTN 003B forms for that participant.

- **Visit code:** There is no visit code field on this form since it is only completed once at the Screening and Enrollment Visit.

Item-specific Instructions:

- **Item 1:** Enrollment into MTN 003B must occur no later than 13 days after enrollment into MTN 003 (with MTN 003 Enrollment = Day 0). For example, if a woman enrolls into MTN 003 on 10-NOV-09, the last day she can enroll into MTN 003B is 23-NOV-09.
- **Item 2:** Review the participant's most recent MTN 003 pregnancy test result and mark the appropriate box based on that result. In most cases, the most recent result will be from the pregnancy test performed at the participant's MTN 003 Enrollment Visit.
- **Item 6:** If the participant was eligible based on items 1–5 and was offered enrollment into MTN 003B, regardless of whether or not she actually enrolled into MTN 003B, mark the “yes” box. If the participant was eligible based on items 1–5 but, for some other reason, she was not offered enrollment into MTN 003B, mark the “no” box.
- **Item 8:** Mark the “yes” box if the participant was determined to be eligible for the study based on all protocol inclusion and exclusion criteria, if she signed the consent form, and if she was willing to participate in MTN 003B. If, after providing informed consent for MTN 003B, the participant is determined to be ineligible for enrollment into MTN 003B (for example, due to a positive MTN 003B pregnancy test performed at this visit), or if the participant decides not to participate in MTN 003B, mark the “no” box.

SAMPLE: DO NOT FAX TO DATAFAX



MTN003 VOICE (160)

LCH-1 (365)

Participant ID

			-					-		
Site Number				Participant Number					Chk	

MTN 003B Lactation and Contraceptive History

Form Completion Date

dd		MMM		yy	

1. Has the participant **ever** breastfed? *yes* *no* → **If no, go to statement above item 2.**
- 1a. What is the total duration the participant has spent breastfeeding in her lifetime? *< 2 years* *2-5 years* *> 5 years*
- 1b. How long has it been since the participant last breastfed? *< 6 months* *6-12 months* *> 12 months*

Review the participant's MTN 003 baseline contraceptive history with her to answer the following questions. Update the MTN 003 contraceptive history, Baseline Family Planning form, and/or Contraceptives Log, if applicable.

2. Has the participant **ever** used hormonal contraceptives? *yes* *no* → **If no, end of form.**
- 2a. Has the participant ever used... **If yes, record total duration used:**
- | | | | | | | |
|---|-------------------------------------|------------------------------------|--|--|--|---------------------------------------|
| 2a1. Medroxyprogesterone acetate injectable (Depo-Provera)? | <input type="checkbox"/> <i>yes</i> | <input type="checkbox"/> <i>no</i> | <input style="width: 30px; height: 20px; border: 1px solid black;" type="text"/> | <input type="checkbox"/> <i>months</i> | <input style="width: 30px; height: 20px; border: 1px solid black;" type="text"/> | <input type="checkbox"/> <i>years</i> |
| 2a2. Other injectables (besides Depo-Provera)? | <input type="checkbox"/> <i>yes</i> | <input type="checkbox"/> <i>no</i> | <input style="width: 30px; height: 20px; border: 1px solid black;" type="text"/> | <input type="checkbox"/> <i>months</i> | <input style="width: 30px; height: 20px; border: 1px solid black;" type="text"/> | <input type="checkbox"/> <i>years</i> |
| 2a3. Oral contraceptives? | <input type="checkbox"/> <i>yes</i> | <input type="checkbox"/> <i>no</i> | <input style="width: 30px; height: 20px; border: 1px solid black;" type="text"/> | <input type="checkbox"/> <i>months</i> | <input style="width: 30px; height: 20px; border: 1px solid black;" type="text"/> | <input type="checkbox"/> <i>years</i> |
| 2a4. Implants? | <input type="checkbox"/> <i>yes</i> | <input type="checkbox"/> <i>no</i> | <input style="width: 30px; height: 20px; border: 1px solid black;" type="text"/> | <input type="checkbox"/> <i>months</i> | <input style="width: 30px; height: 20px; border: 1px solid black;" type="text"/> | <input type="checkbox"/> <i>years</i> |
| 2a5. The Patch (Ortho Evra)? | <input type="checkbox"/> <i>yes</i> | <input type="checkbox"/> <i>no</i> | <input style="width: 30px; height: 20px; border: 1px solid black;" type="text"/> | <input type="checkbox"/> <i>months</i> | <input style="width: 30px; height: 20px; border: 1px solid black;" type="text"/> | <input type="checkbox"/> <i>years</i> |
| 2a6. Vaginal Ring? | <input type="checkbox"/> <i>yes</i> | <input type="checkbox"/> <i>no</i> | <input style="width: 30px; height: 20px; border: 1px solid black;" type="text"/> | <input type="checkbox"/> <i>months</i> | <input style="width: 30px; height: 20px; border: 1px solid black;" type="text"/> | <input type="checkbox"/> <i>years</i> |
| 2a7. Other hormonal contraceptives? | <input type="checkbox"/> <i>yes</i> | <input type="checkbox"/> <i>no</i> | <input style="width: 30px; height: 20px; border: 1px solid black;" type="text"/> | <input type="checkbox"/> <i>months</i> | <input style="width: 30px; height: 20px; border: 1px solid black;" type="text"/> | <input type="checkbox"/> <i>years</i> |
- Specify: _____

Comments: _____

MTN 003B Lactation and Contraceptive History (LCH-1)

Purpose: This form is used to document the lactation and contraceptive history of each participant enrolled in MTN 003B.

General Information/Instructions: This form is completed once for each enrolled participant, at the MTN 003B Screening and Enrollment Visit.

- **Visit code:** There is no visit code field on this form since it is only completed once at the Screening and Enrollment Visit.

Item-specific Instructions:

- **Item 1a:** Ask the participant for the total length of time she has ever spent breastfeeding over her entire lifetime, and mark the appropriate box. For example, if the participant reports that she breastfed two children in total (not overlapping), and that she breastfed each for a period of 12 months respectively, then the total length of time she spent breastfeeding in her lifetime is 24 months, and the “2–5 years” box should be marked.
- **Item 2:** When asking this question, have the participant's MTN 003 baseline contraceptive history documentation available for review. Update the participant's MTN 003 baseline contraceptive history, Baseline Family Planning and/or Contraceptives Log forms, if applicable.
- **Items 2a1–2a7:** Mark “yes” or “no” for each method of contraception listed. If the “yes” box is marked for any item listed in 2a1–2a7, record the **total** amount of time the participant reports having used that method of contraception (throughout her lifetime) in either months or years. If a participant cannot remember the total amount of time she used a specific contraceptive method, ask for her best guess.
 - **Recording duration:** Right-justify the response and use leading zeros. If time is recorded as years (complete years, that is, “1 year,” “2 years,” etc.), mark the “years” box. If time is recorded as months, mark the “months” box. For example, if a participant says she used oral contraceptives for 4 years, record her answer as “004” and mark the “years” box. If she reports using a method for 3-and-a-half years, record “042” and mark the “months” box.

Round, if necessary. If a participant reports using a method for 2-and-a-half months, report 3 months. If a participant reports using a method for 2 years and 1 week, report 2 years. If a participant reports only using a certain method of contraception for less than 1 month (less than 30 days), record her answer as “000” and mark the “months” box.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code

□□□.□□

1

MTN003 VOICE (160)

VP-1 (363)

Participant ID

□□□-□□□□□□-□
Site Number Participant Number Chk

MTN 003B Visit Procedures

Visit Date

□□ □□□□ □□
dd MMM yy

If this is the participant's Screening and Enrollment Visit, go to item 2.

1. Since her last MTN 003B visit, has the participant breastfed, or is she currently breastfeeding? yes no → If no, go to item 2.

1a. What is the total duration the participant has spent breastfeeding since her last MTN 003B visit? < 1 month 1-5 months 6-12 months > 12 months

2. Does the participant have physical signs of malnutrition? yes no

3. Was an hCG pregnancy test done today as part of an MTN 003 visit? yes no → If no, perform a pregnancy test.

If yes and positive, do not perform DXA scan or store serum or urine. If yes, go to item 5.

4. hCG for pregnancy: negative positive not done → If positive or not done, do not perform DXA scan or store serum or urine.

If applicable, complete Product Hold/Discontinuation Log. If newly positive, complete Pregnancy Report and History form.

5. Was serum stored? not required stored not stored → Reason: _____

6. Was urine stored? not required stored not stored → Reason: _____

7. Weight: □□□ kg

8. Height: □□□ cm

If any new AEs are reported or a new product hold/discontinuation is initiated at this MTN 003B visit, update the MTN 003 Follow-up Visit or Interim Visit forms, if applicable. Complete AE Log and/or Product Hold/Discontinuation Log, if applicable.

Comments: _____

MTN 003B Visit Procedures (VP-1)

Purpose: This form is used to document the required (regularly scheduled) visit procedures for MTN 003B including the MTN 003B Screening and Enrollment Visit.

General Information/Instructions: This form is completed at the MTN 003B Screening and Enrollment Visit and at each required follow-up visit, regardless of whether the visit is conducted within the protocol-specified window or made up outside the visit window.

- **Visit code:** Record the visit code assigned to the visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

Item-specific Instructions:

- **Item 1a:** If a participant reports the amount of time spent breastfeeding since her last MTN 003B visit in days or weeks, convert the amount of time to months. For example, if a participant reports breastfeeding for the last 10 days, mark the “< 1 month” box. If a participant reports breastfeeding for the last 10 weeks, mark the “1–5 months” box.
- **Item 2:** Refer to the SSP for clarification on physical signs of malnutrition.
- **Item 3:** If the participant had a pregnancy test performed today (the day of her MTN 003B visit) as part of her MTN 003 visit procedures, mark the “yes” box and go to item 5. If the MTN 003 pregnancy test result is positive, **do not** perform the DXA scan or store urine or serum for the MTN 003B visit. If the participant **did not** have a pregnancy test performed today as part of an MTN 003 visit, mark the “no” box and perform a pregnancy test.
- **Item 4:** Record the result of the pregnancy test that was done as part of the MTN 003B visit. If the pregnancy test is positive, **do not** perform the DXA scan or store urine or serum. If the participant is *newly* positive (that is, if this is the first positive test for this pregnancy), complete a Pregnancy Report and History form and a Product Hold/Discontinuation Log.
- **Item 5:** If serum was not stored at this visit, mark the “not stored” box and record the reason why in the space provided. If serum was not stored because the participant is pregnant, mark the “not required” box.
- **Item 6:** If urine was not stored at this visit, mark the “not stored” box and record the reason why in the space provided. If urine was not stored because the participant is pregnant, mark the “not required” box.
- **Item 7:** If the participant’s weight was measured within the last 14 days as part of her MTN 003 visit, transcribe the weight from the MTN 003 source documentation for weight onto this form. If it was not recorded as part of her MTN 003 visit within the last 14 days, measure the participant’s weight at this visit and record the weight. Right justify the response and use leading zeros.
- **Item 8:** If the participant’s height was measured within the last 14 days as part of her MTN 003 visit, transcribe the height from the MTN 003 source documentation for height onto this form. If it was not recorded as part of her MTN 003 visit within the last 14 days, measure the participant’s height at this visit and record the height. Right justify the response and use leading zeros.

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code

MTN003 VOICE (160)

PAQ-1 (361)

Participant ID

- -
Site Number Participant Number Chk

MTN 003B Physical Activity Questionnaire

Visit Date

dd MMM yy

I am going to ask you about the time you spent being physically active in the last 7 days. Please answer each question even if you do not consider yourself to be an active person. Think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise, or sport.

Now, think about all the **vigorous** activities which take hard physical effort that you did in the last 7 days. Vigorous activities make you breathe much harder than normal and may include activities such as heavy lifting, digging, carrying heavy loads on your head or back while walking **long** distances, cutting and fetching firewood, collecting water for household use, farming activities, or fast bicycling. Think only about those physical activities that you did for at least 10 minutes at a time.

1. During the **last 7 days**, on how many days did you do **vigorous** physical activities?

0 days 1 day 2 days 3 days 4 days 5 days 6 days 7 days don't know/not sure
If 0 or don't know/not sure, go to statement above item 3.

2. How much time did you **usually** spend doing **vigorous** physical activities on one of those days?

minutes/day OR don't know/not sure
 hours/day

Now think about activities which take **moderate** physical effort that you did in the last 7 days. Moderate physical activities make you breathe somewhat harder than normal and may include carrying light loads, bicycling at a regular pace, and household chores such as sweeping, mopping, and polishing floors. Do not include walking. Again, think about only those physical activities that you did for at least 10 minutes at a time.

3. During the **last 7 days**, on how many days did you do **moderate** physical activities?

0 days 1 day 2 days 3 days 4 days 5 days 6 days 7 days don't know/not sure
If 0 or don't know/not sure, go to statement above item 5 on page 2.

4. How much time did you **usually** spend doing **moderate** physical activities on one of those days?

minutes/day OR don't know/not sure
 hours/day

MTN 003B Physical Activity Questionnaire (PAQ-1)

Purpose: This form is used to collect information about a participant's physical activity.

General Information/Instructions: This is an interviewer-administered form. This form is completed at each regularly scheduled MTN 003B visit.

- **Probing:** In general, if a participant cannot answer a question on this form, ask for her best guess. Please refer to the Data Collection section of the Study-Specific Procedures (SSP) Manual for more general information on probing techniques.
- **Review:** Before the participant leaves, review both pages of this form for any errors or skipped items and correct any errors or skipped items as appropriate.
- **Visit code:** Record the visit code assigned to the visit. Refer to the SSP for more specific information on assigning visit codes.

Item-specific Instructions:

- **Item 2:** If the participant needs clarification, tell her that this question is asking about how much time she spent doing vigorous physical activities on a typical day (that is, a day that represents her usual level of vigorous physical activity) in the past 7 days. If the participant reports that her amount of vigorous physical activity varied widely over the last 7 days, ask her how much time **in total** she spent doing vigorous physical activities over the last 7 days and record her response in the white space next to item 2. At the end of the interview, divide the participant's response by 7 and record her average amount of daily vigorous physical activity.

If the amount of time is recorded in minutes, mark the "minutes/day" box and leave the "hours/day" box blank. If the amount of time is recorded in hours, mark the "hours/day" box and leave the "minutes/day" box blank. Right-justify the response and use leading zeros.

- **Item 4:** If the participant needs clarification, tell her that this question is asking about how much time she spent doing moderate physical activities on a typical day (that is, a day that represents her usual level of moderate physical activity) in the past 7 days. If the participant reports that her amount of moderate physical activity varied widely over the last 7 days, ask her how much time **in total** she spent doing moderate physical activities over the last 7 days and record her response in the white space next to item 4. At the end of the interview, divide the participant's response by 7 and record her average amount of daily moderate physical activity.

If the amount of time is recorded in minutes, mark the "minutes/day" box and leave the "hours/day" box blank. If the amount of time is recorded in hours, mark the "hours/day" box and leave the "minutes/day" box blank. Right-justify the response and use leading zeros.

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code

MTN003 VOICE (160)

PAQ-2 (362)

Participant ID

- -
Site Number Participant Number Chk

MTN 003B Physical Activity Questionnaire

Now think about the time you spent **walking** in the last 7 days. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation or leisure.

5. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

0 days 1 day 2 days 3 days 4 days 5 days 6 days 7 days don't know/not sure
If 0 or don't know/not sure, go to statement above item 7.

6. How much time did you **usually** spend **walking** on one of those days?

minutes/day OR don't know/not sure
 hours/day

Now think about the time you spent **sitting** on week days during the last 7 days. Include time spent at work, at home, while doing course work, and during leisure time. This may include time spent sitting at a desk, visiting friends, weaving baskets and mats, sorting grain, sewing or knitting, reading, listening to the radio or watching television.

7. During the last 7 days, how much time did you **usually** spend **sitting** on a **work day**? This includes time spent lying down awake as well as sitting.

minutes/day OR don't know/not sure
 hours/day

MTN 003B Physical Activity Questionnaire (PAQ-2)

General Information/Instructions:

- **Visit code:** Make sure the visit code recorded on this page matches the visit code recorded on page 1 of this form for a given participant and visit.

Item-specific Instructions:

- **Item 6:** If the participant needs clarification, tell her that this question is asking about how much time she spent walking on a typical day (that is, a day that represents her usual amount of walking) in the past 7 days. If the participant reports that her amount of walking varied widely over the last 7 days, ask her how much time **in total** she spent walking over the last 7 days and record her response in the white space next to item 6. At the end of the interview, divide the participant's response by 7 and record her average amount of daily walking.

If the amount of time is recorded in minutes, mark the "minutes/day" box and leave the "hours/day" box blank. If the amount of time is recorded in hours, mark the "hours/day" box and leave the "minutes/day" box blank. Right-justify the response and use leading zeros.

- **Item 7:** If the participant needs clarification, tell her that this question is asking about how much time she spent sitting on a typical work day (that is, a work day that represents her usual amount of sitting activity) in the last 7 days. If the participant reports that she does not work, ask her how much time she usually spent sitting on one week day (Monday–Friday) in the last 7 days. If the participant reports that her amount of sitting varied widely over the last 7 days, ask her how much time she spent sitting on the most recent work day (if she works) or most recent week day (if she doesn't work).

If the amount of time is recorded in minutes, mark the "minutes/day" box and leave the "hours/day" box blank. If the amount of time is recorded in hours, mark the "hours/day" box and leave the "minutes/day" box blank. Right-justify the response and use leading zeros.

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code

1

MTN003 VOICE (160)

DXA-1 (364)

Participant ID

- -
 Site Number Participant Number Chk

MTN 003B DXA Scan

Scan Date

dd MMM yy

1. Was a DXA scan performed? yes no not required **→ If not required, end of form.**
→ If no, record reason not performed. End of form.
2. Participant's age at enrollment into MTN 003B: years _____

	Scan #1	Scan #2	Severity Grade
3. Total Spine			
3a. BMD	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> g/cm ²	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> g/cm ²	T- or Z-score severity grade, if applicable <input type="checkbox"/>
3b. T-score	<input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> + <input type="text"/> <input type="text"/>	<input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> + <input type="text"/> <input type="text"/>	
3c. Z-score	<input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> + <input type="text"/> <input type="text"/>	<input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> + <input type="text"/> <input type="text"/>	
4. Total Hip			
4a. BMD	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> g/cm ²	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> g/cm ²	T- or Z-score severity grade, if applicable <input type="checkbox"/>
4b. T-score	<input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> + <input type="text"/> <input type="text"/>	<input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> + <input type="text"/> <input type="text"/>	
4c. Z-score	<input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> + <input type="text"/> <input type="text"/>	<input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> + <input type="text"/> <input type="text"/>	
5. Femoral Neck of Hip			
5a. BMD	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> g/cm ²	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> g/cm ²	T- or Z-score severity grade, if applicable <input type="checkbox"/>
5b. T-score	<input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> + <input type="text"/> <input type="text"/>	<input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> + <input type="text"/> <input type="text"/>	
5c. Z-score	<input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> + <input type="text"/> <input type="text"/>	<input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> + <input type="text"/> <input type="text"/>	

6. Do any of these T- or Z-scores warrant reporting of a new AE? yes no **→ If no, go to item 7.**
- 6a. Record AE Log page #: AE Log page #
7. Technician's code: Scan #1 Scan #2

13-MAY-09

0 1
Language

Staff Initials / Date

MTN 003B DXA Scan (DXA-1)

Purpose: This form is used to document DXA scan results.

General Information/Instructions: This form is completed each time a DXA scan is performed, as well as each time an MTN 003B visit is conducted but the DXA scan is not performed. Note that this form documents the results of two separate DXA scans performed on the same day (as part of the same visit).

- **Visit code:** Record the visit code assigned to the visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

Item-specific Instructions:

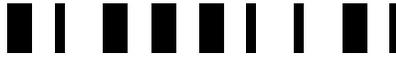
- **Item 1:** If a DXA scan was not performed as part of this visit, mark the “no” box and record the reason why in the space provided. If the DXA scan was not performed because the participant is pregnant, mark the “not required” box.
- **Item 2:** Record the participant’s age (in completed years) at the time of her MTN 003B enrollment.
- **Items 3a, 4a, and 5a (BMD):** Record the **Total BMD** (bone mineral density) that appears on the DXA scan summary report for the spine (item 3a) or for the hip (item 4a). For the femoral neck of the hip, record the BMD score just for the femoral neck (item 5a).
- **Items 3b, 3c, 4b, 4c, 5b, and 5c (T-scores and Z-scores):** Record both the T- and Z-scores from each of the DXA scans. If the T- or Z-score is positive, mark the “+” box. If the T- or Z-score is negative, mark the “-” box.
- **Severity Grade:** Use the Protocol-specific *Grading Table for Bone Mineral Loss* when grading the severity of a bone mineral density-related AE. Throughout the study, when determining which scores to evaluate for severity grading, use the age of the participant at enrollment into MTN 003B. If a participant is less than 30 years old at enrollment into MTN 003B, use the Z-scores when determining the severity grade. If a participant is 30 or more years old at enrollment into MTN 003B, use the T-scores when determining the severity grade.

Per body region, when assigning severity grade, compare the age-appropriate scores across Scan #1 and Scan #2. Record the worse severity grade for each body region. If, for a given body region, the scores do not meet criteria for grading, leave the severity grade box blank.

- **Item 6:** Compare the severity grades recorded for each body region in items 3, 4, and 5. If any of the scores warrant reporting as a **new** AE, complete an AE Log form. Update the MTN 003 Follow-up Visit or Interim Visit form, if applicable. Consult the MTN 003 SSP for more information on AE grading and reporting for MTN 003B.
- **Item 6a:** If item 6 is marked “yes,” record the page number of the AE Log associated with the DXA scan results.
- **Item 7:** Record the code associated with the technician(s) who performed Scan #1 and Scan #2.

SAMPLE. Do NOT FAX
TO DATAFAX

MTN003 VOICE (160)



FFQ-1 (370)

Visit Code

Participant ID

- -
Site Number Participant Number Chk

MTN 003B Food Frequency Questionnaire

Visit Date

dd MMM yy

Your participation in this part of the study will help us to understand how the study tablets might affect your bones. In addition to the bone test that you will have, it is important to know how much calcium you eat. Calcium is a nutrient found in some foods and drinks and it helps your bones and teeth stay strong. I'm only going to ask you about a few things you may eat or drink because these are foods that contain high amounts of calcium.

1. During the **past 6 months**, on average, how often have you consumed a serving of the following dairy foods?

Showcard #4			Less than once a month	1-3 times a month	once a week	2-4 times a week	5-6 times a week	once a day	2-3 times a day	4-5 times a day	6 or more times a day
Dairy Foods	Average Serving										
1a. Whole milk	1 cup		<input type="checkbox"/>								
1b. Skimmed milk	1 cup		<input type="checkbox"/>								
1c. Lacto	1 cup		<input type="checkbox"/>								
1d. Cottage Cheese	30 grams		<input type="checkbox"/>								
1e. Other (Hard) Cheeses	30 grams		<input type="checkbox"/>								
1f. Ice Cream	1 cup		<input type="checkbox"/>								
1g. Yogurt	1 cup		<input type="checkbox"/>								
1h. Powdered milk for tea	1 table-spoon		<input type="checkbox"/>								

MTN 003B Food Frequency Questionnaire (FFQ-1)

Purpose: This form is used to document how much and how often a participant eats calcium-containing foods.

General Information/Instructions: This is an interviewer-administered form. This form is completed at each regularly scheduled MTN 003B visit.

- **Visit code:** Record the visit code assigned to the visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
- **Showcard:** Present the participant with the showcard when item 1 is read aloud. Read the answer choices aloud to the participant while indicating with your finger which response you are reading. Keep the showcard out while administering the entire FFQ, since the same response categories will be used to answer all of the questions.
- **Plastic food:** Plastic serving sizes of various foods listed in this form will be provided to the sites. These plastic food items can be used to show a participant what a ½ cup of cooked vegetables or 90–120 grams of fish look like, for example. Some food items are more recognizable if they are placed in a bowl or onto a plate. Prior to the interview, make sure all sample food items and plates or bowls are available for reference.
- **Probing:** In general, if a participant cannot answer a question on this form, ask for her best guess. Present a calendar to the participant and indicate the 6 calendar months to which the questions refer. If a participant has difficulty answering a question, site staff may ask her to start by answering how much she ate of a particular food in the past week, then in the past month, then in the prior month, and slowly work backwards, etc. If the participant has never eaten a given food in the past 6 months, mark the “Less than once a month” box. Please refer to the Data Collection section of the SSP for more general information on probing techniques.
- **Review:** Before the participant leaves, review both pages of this form for any errors or skipped items and correct any errors or skipped items as appropriate.

SAMPLE. Do NOT FAX
TO DATAFAX



Visit Code

1

MTN003 VOICE (160)

FFQ-2 (371)

Participant ID

- -

Site Number Participant Number Chk

MTN 003B Food Frequency Questionnaire

2. During the **past 6 months**, on average, how often have you consumed a serving of the following cooked vegetables?

Showcard #4		Less than once a month	1-3 times a month	once a week	2-4 times a week	5-6 times a week	once a day	2-3 times a day	4-5 times a day	6 or more times a day
Cooked Vegetables	Average Serving									
2a. Dark greens (such as spinach, mowa, bok choy, kale, mustard greens, broccoli, collard greens, pumpkin leaves, black jack leaves, nyevhe, and dark green lettuce)	1/2 cup	<input type="checkbox"/>								
2b. Okra	1/2 cup	<input type="checkbox"/>								
2c. Peas (such as pigeon peas, field peas)	1/2 cup	<input type="checkbox"/>								
2d. Beans (such as soybeans, lentils, cowpeas, and butter beans)	1/2 cup	<input type="checkbox"/>								

3. During the **past 6 months**, on average, how often have you consumed a serving of the following fish?

Showcard #4		Less than once a month	1-3 times a month	once a week	2-4 times a week	5-6 times a week	once a day	2-3 times a day	4-5 times a day	6 or more times a day
Fish	Average Serving									
3a. Small whole fish (such as kapenta, enkejje, and mukene)	100 grams	<input type="checkbox"/>								
3b. Fish without bones	90-120 grams	<input type="checkbox"/>								

End of interview. Site staff to complete items 4 and 5 based on review of participant's Concomitant Medications Log.

4. In the past 6 months, has the participant taken a Vitamin D supplement or multivitamin containing Vitamin D? *yes* *no*
5. In the past 6 months, has the participant taken a calcium supplement or multivitamin containing calcium? *yes* *no*

13-MAY-09

0 1

Language

Staff Initials / Date

MTN 003B Food Frequency Questionnaire (FFQ-2)

General Information/Instructions:

- **Visit code:** Make sure the visit code recorded on this page matches the visit code recorded on page 1 of this form for a given participant and visit.

Item-specific Instructions:

- **Item 3b:** This question asks if the participant ate fish without bones; that is, fish filets or whole fish without the bones.

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code

. 0

1

MTN003 VOICE (160)

MVB-1 (464)

Participant ID

- -
Site Number Participant Number Chk

MTN 003B Missed Visit

Form Completion Date

dd MMM yy

dd MMM yy

1. Target MTN 003B visit date:

2. Reason the MTN 003B visit was missed. *Mark only one.*

- unable to contact participant
- unable to schedule appointment within visit window
- participant refused visit
- participant incarcerated
- participant admitted to a health care facility → **Complete AE Log, if applicable.**
- participant deceased → **Complete MTN 003 Termination form, AE Log, and EAE Reporting form, if not already done as part of MTN 003.**
- participant relocated
- DXA machine not functioning or not available
- other, specify: _____

Comments: _____

MTN 003B Missed Visit (MVB-1)

Purpose: This form is used to document whenever an enrolled participant misses a required MTN 003B visit according to the visit window outlined in the protocol and Study-Specific Procedures Manual (SSP).

General Information/Instructions: Complete and fax this form when it is determined that a MTN 003B visit cannot be completed within the visit window, and is thus considered “missed.” Once the MTN 003B Missed Visit form is completed, no other MTN 003B case report forms are expected to be faxed for the participant for that visit.

- **Visit code:** Record the visit code of the MTN 003B visit that was missed.
- **Form completion date:** Record the date the form was completed. This will not necessarily be the date of the missed visit. A complete date is required.

Item-specific Instructions:

- **Item 1:** Record the target date of the MTN 003B visit that was missed. A complete date is required.
- **Item 2:** Mark only the primary reason the participant missed the MTN 003B Visit.
 - **participant admitted to a health care facility:** If an AE Log was already completed (that is, if the participant missed her MTN 003 visit for the same reason and an AE Log was already filled out), do not complete a new AE Log for the same AE.
 - **participant deceased:** If the MTN 003 Termination Form, AE Log, and EAE Reporting form were already completed due to the participant’s death, do not complete these forms again.

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code

. 0

1

MTN003 VOICE (160)

ETB-1 (390)

Participant ID

- -
Site Number Participant Number Chk

MTN 003B Early Termination

1. MTN 003B early termination date: ^{dd} ^{MMM} ^{yy} *Date the site determined that the participant was no longer in MTN 003B.*

2. Was a final MTN 003B visit conducted as part of the early termination? *yes* *no*

3. Reason for MTN 003B early termination. *Mark only one.*

- participant refused further participation, specify: _____
- inappropriate enrollment
- other, specify: _____

Comments: _____

MTN 003B Early Termination (ETB-1)

Purpose: This form is used to document when a participant terminates early from MTN 003B, that is, when a participant terminates from MTN 003B prior to her expected MTN 003B final visit. The MTN 003B Early Termination form is **not** completed for a **scheduled/expected** MTN 003B final visit. Instead, the MTN 003 (VOICE) Termination Form will be used to document a MTN 003B participant's regularly scheduled study exit/termination from MTN 003B.

General Information/Instructions: This form must be faxed to SCHARP DataFax **ONLY** within an MTN 003B visit window (Month 6, Month 12, Month 18, etc.), regardless of when in her follow-up visit schedule a participant decides to terminate early from MTN 003B. If a participant terminates early from MTN 003B and is within an MTN 003B visit window, complete this form at the time of early termination. If a participant terminates early from MTN 003B and is outside an MTN 003B visit window, complete this form once the next MTN 003B visit window opens. For example, if a participant decides to terminate early from MTN 003B during Month 4, fax this form to SCHARP DataFax once the Month 6 visit window opens. If a participant decides to terminate early from MTN 003B at Month 12 (regardless of whether she is willing and able to complete the MTN 003B Month 12 Visit), fax this form to SCHARP DataFax within the Month 12 visit window.

- **Visit code:** Record the visit code associated with the follow-up month when this form is faxed to SCHARP DataFax. Use only visit codes associated with regularly scheduled MTN 003B visits (for example, 09.0, 15.0, 21.0, etc.).

Item-specific Instructions:

- **Item 1:** Record the date the site determined that the participant was no longer in MTN 003B.
- **Item 2:** If the participant completed one last MTN 003B visit as part of her early termination from MTN 003B, mark the “yes” box.
- **Item 3:** Mark only the primary reason the participant terminated early from MTN 003B.