

<p><b>WOMEN'S INTERAGENCY HIV STUDY</b></p> <p><b>QUESTION BY QUESTION SPECIFICATIONS</b></p> <p><b>FORM 22MED: MEDICATION HISTORY</b></p>
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**General Instructions:**

1. Before beginning this section, interviewers should make sure that they have one blank copy of the *Antiretroviral Dosage Form (DSGs1)* and at least two blank copies each of *Drug Form 2* and *Drug Form 3* available in case they are needed.
2. All dates should be recorded in the MM/DD/YY format unless otherwise noted. For dates that must be completed on the form, if the participant cannot remember the exact month (and day), probe for the season. Use "15" for the day if the specific day cannot be recorded. Probe for the season and assign the month as follows:

Summer	=	July	=	07
Fall	=	October	=	10
Winter	=	January	=	01
Spring	=	April	=	04

Interviewers should have available an appropriate calendar to aid the participant in determining dates. Years in response to questions inquiring about occurrences "since last visit" should be 1995 and thereafter.

3. Times should be recorded in the HH:MM format. Remember to use leading zeros, e.g., 08:00.
4. For questions containing an open-ended specify box, interviewers should print responses exactly in the words of the respondent.
5. Obtain the date the form was last administered from the *Visit Control Sheet (VCS)* In most cases, this will be the date of the last core visit; however, if the previous visit was abbreviated, the date of the abbreviated visit should be used. The month in this date should be used in the questions wherever (MONTH) appears.
6. Interviewers should ignore any markings related to data entry such as "START F22MEDS3." These indicators mark the beginning and end of all subforms; they have been added for data entry purposes only and will not affect how the form is completed.

**General Instructions for Collection of Prescription Medication Data:**

There are various methods by which WIHS participants can report prescription medication use at the WIHS core visit: (1) self report from memory, (2) self report with documentation (such as medication bottles, a pharmacy record, or a list of medications), or (3) medication records obtained directly from the pharmacy. Please follow the general instructions below regarding collection of prescription medication data based on these three methods for all sections of the F22MED that ask about medication usage.

- (1) If the participant does not bring any documentation to her visit (i.e., is recalling medication use by memory only), the interviewer should utilize the appropriate medication response card set to determine which medications the participant has used since her last study visit. For example, to determine ARV use, the interviewer would hand the participant the **Antiretroviral Photo Medication Cards**, and ask the participant, "*Since your (MONTH) study visit, have you taken (DRUG NAME)?*" for each medication.
- (2) If the participant brings documentation of medication use to her visit (e.g., brings a list of medications or brings pill bottles), it is not necessary for the interviewer to read aloud each medication listed on the F22MED. In this case, medication use data may be transferred directly from the list (or bottles) onto the F22MED. Please continue to ask **Question E12i**, "*Since your (MONTH) study visit, have you taken any other prescribed medications not previously mentioned?*" in order to verify that her prescription medication data are complete.

- (3) If the site has obtained medication records directly from the participant's pharmacy, it is also not necessary for the interviewer to read aloud each medication listed on the F22MED. The interviewer can again transfer data directly from the pharmacy record to the F22MED. Please continue to ask **Question E12i**, "*Since your (MONTH) study visit, have you taken any other prescribed medications not previously mentioned?*" in order to verify that her prescription medication data are complete.

Interviewers can ignore the three-digit numbers next to each medication in **Questions B2b, C1a** through **C1c**, and **D1a**. These numbers are necessary for data entry, but can be ignored during the actual interview.

Detailed instructions on collection of the different types of prescription medications (e.g., ARV, OI prophylaxis, etc.) are included below by question number.

## SECTION B: ANTIRETROVIRAL HISTORY

- B1. A vaccine against HIV-1 can include vaccines that prevent infection with HIV or therapeutic vaccines (those that prevent progression of the infection).
- B2. a. Ask the participant if she has taken any antiretroviral medications since her last study visit. If the response is "no," skip to **Question B17**. Please keep in mind that HIV-negative women may have taken antiretrovirals as part of PEP or PrEP and such use should result in a "yes" response to **Question B2a**.
- b. Ask the participant what antiretroviral medications she has taken and record the antiretroviral medications used by the participant since her most recent study visit.

If the participant has brought medication bottles or a list of prescription medications you may transfer this information directly to the F22MED without asking the participant about use of each individual medication listed.

If the participant is recalling her antiretroviral medication use from memory, please hand the participant the current version of the **Antiretroviral Photo Medication Cards** and go through each card with the participant, asking for each medication, "*Since your (MONTH) study visit, have you taken (DRUG NAME)?*" ("*Desde su visita al estudio en (MES), ¿ha tomado usted...*")

For all participants using antiretroviral medications, mark each drug the participant has taken since her last study visit by placing an "X" in the corresponding box. Ensure that, in addition to her prescribed antiretrovirals, the participant includes all antiretroviral medications that may have been taken as part of a research study, including those in which she may have been blinded (**PROBE: unaware of whether you were taking the actual medication or a placebo**) to the treatment.

If the participant reports using one of the four antiretroviral medications marked with "\*" (i.e., Efavir, Viread, Emtriva, Truvada), the interviewer should ask, "*Do you take [EFVIR, VIREAD, EMTRIVA, TRUVADA] (read name of appropriate medication only) to treat HIV only, hepatitis (B or C) only, or to treat both HIV and hepatitis?*"

- If use is for HIV treatment only, interviewer should mark the medication in **Question B2b** only and proceed with administration of the *Antiretroviral Dosage Form* and *Drug Form 1* (if participant has taken the medication in the past three days).
- If use is for hepatitis treatment only, interviewer should mark the medication in **Question D1a** only and complete *Drug Form 3* at the appropriate point in the interview.
- If use is for HIV and hepatitis treatment (or participant is unsure of reason for use), interviewer should mark medication in both **Questions B2b** and **D1a** and complete an *Antiretroviral Dosage Form*, a *Drug Form 1* (if participant has taken the medication in the past three days) and a *Drug Form 3*.

The antiretroviral drug listing in **Question B2b** is not complete. However, it does contain currently used medications to the best of our knowledge. This list is updated every six months. For any other antiretroviral medication used by the participant against HIV-1 that is not on the list in **Question**

**B2b**, check “*Other antiretroviral(s)*” and print the name of the drug in the specify box. Check **Drug List 1** to see if it is on this list. If so, record the three-digit code in the space allotted next to the “Specify” box. If the drug is not on Drug List 1, check the drugs listed in **Questions C1a through C1c** to see if it is on one of these lists. If the drug is listed in **Questions C1a through C1c**, record its use there. Otherwise, bring this to the attention of the clinic coordinator/director. If the drug is not on the coding list, the center’s director should contact the coordinator at WDMAC to inquire about the applicability of getting a new drug code assigned. Use the drug code obtained from WDMAC.

If a participant indicates that she is taking an antiretroviral medication, but does not know or cannot remember the name of the medication, check “*Other antiretroviral(s)*” and print “*unknown*” in the specify box. Enter “*999*” in the space provided for the three-digit drug code. If the participant reports more than one unknown antiretroviral medication, please list them as *unknown1, unknown2*, etc., for tracking purposes.

If the participant indicates that she is taking a combination antiretroviral, for example, “Combivir,” you would mark only the “Combivir” box (code 227). The individual boxes for AZT and 3TC should not be checked. If, for example, the participant indicates that she is taking “Trizivir,” mark only the “Trizivir” box (code 240). The individual boxes for abacavir, AZT and 3TC should not be checked.

After marking all the antiretrovirals reported by the participant in **Question B2b**, review the participant’s *Visit Control Sheet (VCS)*. All antiretrovirals reported by the participant at her previous WIHS visit will be listed. If any antiretrovirals are included on the *VCS* as being used at her last visit, but are not reported as being used since the last visit in **Question B2b**, you will need to ask the participant to resolve this inconsistency. In this case, please ask the participant, “*Last visit you said you were taking [DRUG], have you stopped taking that since your (MONTH) study visit or are you still taking it?*” (“*En la última visita Ud. dijo que estaba tomando [DRUG], ¿ha dejado de tomarlo después de la última visita o todavía lo está tomando?*”) You should then amend the response to **Question B2b** as necessary based on the participant’s response and proceed with the rest of the interview.

After completion of **Question B2b**, if the participant is taking any antiretroviral medications, complete the *Medication History, ARV Subform (F22MEDs3)*.

### **Instructions for Completion of F22MEDs3:**

1. Review *Response Card DSGI*. Find the “Drug Name” on *RC DSGI* as reported by the participant. Enter the first medication “Code” into Question 1.

The list of antiviral medications on *RC DSGI* is not complete, but contains FDA-approved medications to the best of our knowledge. For any other antiviral medication used by the participant against HIV-1 that is not listed on *RC DSGI*, print the name of the drug in the Specify field. Refer to the current **Drug List 1** to obtain codes for drugs not listed on *RC DSGI* and enter the code from **Drug List 1**. If the drug is not on **Drug List 1**, record code “*998*” for “other antiviral.” Bring this to the attention of the clinic coordinator/director. Notify WDMAC of any frequently-used medications that do not have unique codes.

If a participant indicates that she is taking an antiviral medication, but does not know or cannot remember the name of the medication, print “*unknown*” in the Specify field. Enter “*999*” in the space provided for the three-digit drug code. If the participant reports more than one unknown antiretroviral medication, please list them as “*unknown1*,” “*unknown2*,” etc., for tracking purposes.

2. Indicate how use of the ARV medication was reported, e.g., did participant bring a list of medications to her visit, did she bring the medication bottles, etc.
3. Ask the participant if she has taken the antiretroviral in the **past three days**.

**NOTE:** Use in the past three days refers to any antiretroviral the participant has taken at least once today, yesterday, or the day before yesterday. If a participant takes a particular medication only once per week, or on a one-week-on one-week-off schedule, and is currently taking the medication even though she has not taken it in the past three days, please code on this form as if she has taken it in the past three days.

If, however, a participant has stopped taking a particular medication more than three days prior to her core visit (e.g., because she thought she was pregnant), but intends to restart taking the medication, please code on this form as if she has not taken it in the past three days and record the date she last took the medication in subquestion e.

If **YES**, i.e., the participant has taken the medication in the **past three days**, circle “1.” Proceed to **Question #4**.

If **NO**, i.e., the participant has taken the medication since her (MONTH) study visit but **has not taken it in the past three days**, circle “2.” Skip to **Question #9**.

4. This question refers to whether or not the participant started the medication since her last study visit. We want to know if this is a new medication **or** a previous medication that the participant has started re-using since their last visit. If the participant has been on a medication break and then started using the same drug again, she should respond “YES” to this question. If the medication is not a new medication that the participant has begun taking since her last visit, skip to **Question #6**.
5. Ask the participant when she began taking the medication. If the medication is a previous one that the participant is re-using since their last visit, be sure to record the most recent date that she began re-taking that medication.

If the participant cannot remember the exact month she began taking the medication, probe for the season and assign month as follows:

Summer	=	July	=	07
Fall	=	October	=	10
Winter	=	January	=	01
Spring	=	April	=	04

Interviewers should have available an appropriate calendar to aid the participant in determining dates.

6. Record the total number of doses taken per day by the participant.
7. Record the total number of tablets or capsules or mL taken with each dose.
8. Review **RC DSGI** to determine the correct response to Question #8. Enter the correct “**Formulation**” as reported by the participant. Some pills have different formulations (tablets or capsules or liquid forms). Indicate the actual medication dose, size and form taken (e.g., 300 mg tablet or 10 mg/ml liquid).

For “other” or “unknown” antiretrovirals, enter code “99” to indicate “other,” and specify the dose (e.g., 300, 200, etc.), size (e.g., mg, mg/5ml, etc.), and form (e.g., tablet, liquid, etc.) in the space provided.

**NOTE:** If the participant does not take a medication every day (e.g., takes it only every other day, or once per week), enter code “99” (for “other”) in Question #8. Then enter the actual dosing schedule (e.g., “300 mg per week”) in the Specify field. Questions #6 and #7 should be coded as “-9.”

Example 1: A participant takes one 300 mg tablet of Viread per week. In Question #6 (doses/day), enter “-9.” In Question #7 (pills/dose), enter “-9.” In Question #8 (formulation of drug), enter “99,” with “300mg per week” in the Specify field.

Example 2: A participant takes ½ 600 mg tablet of Sustiva every other day. In Question #6, enter “-9.” In Question #7, enter “-9.” In Question #8, enter “99,” with “300 mg every other day” in the Specify field.

9. If the participant has taken the antiretroviral since her (MONTH) study visit but has not taken it in the past three days, record the month and year when she stopped taking the medication. If the participant cannot remember the exact month she stopped taking the medication, probe for the season and assign month as follows:

Summer	=	July	=	07
Fall	=	October	=	10
Winter	=	January	=	01
Spring	=	April	=	04

Interviewers should have available an appropriate calendar to aid the participant in determining dates.

Repeat Questions #1 through #9, as appropriate, for each antiretroviral reported. When done with recording ARV data, return to F22MED, Question B2c.

PROMPT: IF PARTICIPANT BROUGHT MEDICATION BOTTLES OR LIST TO REPORT ARV USE, PLEASE ASK THE FOLLOWING QUESTION (B2c) AND MAKE SURE ALL MEDICATIONS ARE CHECKED IN QUESTION B2b. IF INTERVIEWER HAS ALREADY REVIEWED PHOTO MED CARDS WITH PARTICIPANT, CIRCLE “3” FOR N/A AND PROCEED TO QUESTION B2d.

- B2. c. If a participant brought her medication bottles or a list of medications to her visit to report antiretroviral use, ask the participant if she, even for a short period of time, took any additional antiretroviral medications not already mentioned in **Question B2b**. If the participant indicates that she has taken antiretroviral medications not previously mentioned, then review the **Photo Medication Cards** with the participant to determine which additional medications she has used. Report any additional medications in **Question B2b**. This question need not be asked if the interviewer has already reviewed the **Photo Medication Cards** with the participant. In this case, circle “3” for not applicable and proceed to **Question B2d**.
- d. Enter the total number of antiretroviral medications the participant has taken from **Question B2b**.
- B3. The interviewer should review the participant’s *Visit Control Sheet (VCS)* and the *F22MEDs3* to determine whether or not the participant has started taking any new antiretroviral medications since her last study visit. For new recruit baseline visits, please ask, “*In the past six months, have you started any antiretroviral medications?*” If she has not started any new medications, skip to **Question B6**.
  - a. Ask the participant if this is the first time she has ever taken any antiretroviral medications. The participant should only answer “YES” if she has never before taken any antiretroviral medication.
- B6. Indicate if the participant had a period of time of one week or more when she was off treatment since her (MONTH) study visit (**PROBE: “not taking any of your antiretroviral medications”**).
- B7. a-c. For Question B7b, hand the participant **Response Card DØa**, and for Question B7c, hand the participant **Response Card DØb**. This three item (B7a, B7b, B7c) adherence measure (by I. Wilson 2013) asks about ARV use **in the last 30 days**. Ensure that the participant is aware of this time frame when asking these three questions.
  - d. Hand the participant **Response Card DØ**. This question is designed to assess the participant’s general level of adherence to all of her prescribed antiretroviral medications.
- B8. Indicate if the participant is HIV-positive or HIV-negative. If she is HIV-positive, skip to **Section C**.
- B11. This question should be asked only of women who are HIV-negative. Indicate whether the participant has used PEP (post-exposure prophylaxis) or PrEP (pre-exposure prophylaxis) since her (MONTH) study visit. If she responds “no,” skip to **Section C**.
- B12. Record from where the participant received the medication for PEP or PrEP.
- B13. Record if the participant is currently taking PEP or PrEP.
  - a. Record the year the participant first began taking PEP or PrEP.

- B14. Indicate whether or not the participant began taking PEP or PrEP after a possible unprotected sexual or injection drug exposure. If she responds “yes,” skip to **Question B16**.
- B15. Indicate whether or not the participant began taking PEP or PrEP for her general protection, i.e., when it was not prompted by a risky sexual or drug exposure.
- B16. Indicate for how long the participant has been taking or had taken PEP or PrEP.
- B17. Hand the participant **Response Card D3** before asking her **Question B17**.

This question asks for the main reason a participant is not taking any antiretroviral medications. Read the responses to the participant and then circle the one answer that matches her response. If the participant’s main reason for not taking any antiretroviral medications is not listed as one of the responses, circle “*any other reason*” and print her response in the specify field.

### SECTION C. OI AND OTHER CO-INFECTION MEDICATION HISTORY

- C1. Record the non-antiretroviral (i.e., OI prophylaxis) medications used by the participant since her most recent study visit.

If the participant has brought medication bottles or a list of prescription medications you may transfer this information directly to the *F22MED* without asking the participant about use of each individual medication listed.

If the participant is recalling her prescription medication use from memory, please hand the participant the current version of the **Response Card D4** and go through the card with the participant, asking for each medication, “*Since your (MONTH) study visit, have you taken (DRUG NAME)?*”

For all participants using OI prophylaxis medications, mark each drug the participant has taken since her last study visit by placing an “X” in the corresponding box.

If the participant reports using one of the two OI medications marked with “\*” (i.e., pegylated interferon, Rebetrone), the interviewer should ask, “*Do you take [PEGYLATED INTERFERON, REBETRON] (read name of appropriate medication only) to treat hepatitis (B or C) only, to treat or prevent another condition, or to both treat hepatitis and treat/prevent another condition?*”

- If use is for treatment or prevention of another condition only, interviewer should mark the medication in **Question C1b** or **C1c** only (as appropriate) and proceed with administration of *Drug Form 2*.
  - If use is for hepatitis treatment only, interviewer should mark the medication in **Question D1a** only and complete *Drug Form 3* at the appropriate point in the interview.
  - If use is for hepatitis treatment and to treat/prevent another condition (or participant is unsure of reason for use), interviewer should mark the medication in both **Questions C1b/C1c** and **D1a** and complete both a *Drug Form 2* and a *Drug Form 3*.
- a. Indicate if the participant has taken the inhaled medication listed in **Question C1a** since her last study visit.
- b. Indicate if the participant has taken any of the injected or infused medications listed in **Question C1b** since her last study visit. See instructions above if participant is taking a medication marked with “\*.”
- c. Indicate if the participant has used any of the pills, liquids or creams listed in **Question C1c** since her last study visit. See instructions above if participant is taking a medication marked with “\*.”
- i. Circle the appropriate response to indicate if the participant has not taken any medications in **Questions C1a, C1b** or **C1c** or has taken at least one medication in **Questions C1a, C1b** or **C1c** since her (MONTH) study visit. If she has taken none, skip to **Section D**.

If the participant is taking any of the medications in **Questions C1a, C1b** or **C1c**, complete a *Drug Form 2* for each medication the participant reports that she has taken since her last study visit. If the participant is taking

multiple OI medications, mark each drug on the *F22MED* and complete a separate *Drug Form 2* for each medication.

- d. Enter the total number of OI medications the participant reported taking in **Questions C1a, C1b and C1c**.

#### SECTION D. HEPATITIS MEDICATION HISTORY

- D1. Ask the participant if she has taken any medications to treat Hepatitis B or C since her last study visit. If the response is “no,” skip to **Question SECTION E**.
- a. Record the Hepatitis B and C medications used by the participant since her most recent study visit.  
**NOTE:** If the participant indicates that she has taken Epivir, Viread, Emtriva or Truvada, but is uncertain if it was taken for her HIV or her Hepatitis infection, please complete *Drug Form 3*. If participant indicates that she has taken pegylated interferon or Rebetron, but is uncertain if it was taken for her hepatitis infection or for another condition, please complete a *Drug Form 3*, in addition to *Drug Form 2*.
  - b. For each Hepatitis medication named by the participant in **Question D1a**, in **Question D1b**, indicate if its use was for Hepatitis B, Hepatitis C, both Hepatitis B and C, or if the participant is unsure whether she was taking the medication for Hepatitis B or C.
  - c. Enter the total number of Hepatitis B and C medications the participant reported taking in **Question D1a**.

If the participant is taking any of the medications in **Question D1a**, complete a *Drug Form 3* for each medication the participant reports that she has taken since her last study visit. If the participant is taking multiple Hepatitis medications, mark each drug on *F22MED* and complete a separate *Drug Form 3* for each medication.

If the participant has brought medication bottles or a list of prescription medications you may transfer this information directly to the *F22MED* without asking the participant about use of each individual medication listed in **Question D1a**.

If the participant is recalling her prescription medication use from memory, please hand the participant the current version of the appropriate **Response Card D4a** and go through the card with the participant, asking for each medication, “*Since your (MONTH) study visit, have you taken (DRUG NAME)?*”

For all participants using Hepatitis medications, mark each drug the participant has taken since her last study visit by placing an “X” in the corresponding box. If participant reports that she has taken medication(s) for Hepatitis B or C that are not listed on the form, write the medication in one of the specify boxes provided and enter the appropriate drug code.

#### SECTION E. OTHER PRESCRIPTION MEDICATION USE

- E1f. Indicate “yes” or “no” for whether the participant has received vaccination for HPV (human papillomavirus) since her (MONTH) study visit.
- E11. Record the hormone replacement therapies used by the participant since her most recent study visit.

If the participant has brought medication bottles or a list of prescription medications you may transfer this information directly to the *F22MED* without asking the participant about use of each individual medication listed.

If the participant is recalling her prescription medication use from memory, please hand the participant the current version of the **Response Card D4h** and go through the card with the participant, asking for each medication, “*Since your (MONTH) study visit, have you taken (DRUG NAME)?*”

This question should be recorded as “YES” only if the participant took any of the listed therapies for more than one month since her (MONTH) study visit.

**NOTE:** Do not include medications the participant reports taking solely for birth control, as their use will be captured on WIHS Form *F23 Obstetric, Gynecologic and Contraceptive History*.

If the participant reports no use of hormone replacement therapy, skip to **Question E12a**.

- a. This question should not be read aloud to the participant. Based on the medications the participant reports taking in **Question E11**, the interviewer should record the type of hormone replacement therapy taken by the participant since her last study visit. Be sure to specify the therapy taken if **“other HRT”** was indicated in **Question E11**. If the participant reports use of both estrogen and progesterone hormone replacement therapies, record this as **“combination”** in **Question E11a**.

E12. Record any other prescription medications used by the participant since her most recent study visit.

- a. This question asks if the participant has taken any medication for blood pressure or her heart. Hand the participant **Response Card D4b**. If she has taken any blood pressure or heart medications since her last study visit (whether they are included on the list or not), then also ask about use in the last five days. Record use of blood pressure or heart medications in the specify boxes provided in **Question E13a**.
- b. This question asks if the participant has taken any medication to lower her cholesterol, triglyceride or blood lipid level. Hand the participant **Response Card D4c**. If she has taken any cholesterol, triglyceride or blood lipid medications since her last study visit (whether they are included on the list or not), then also ask about use in the last five days. Record use of cholesterol, triglyceride or blood lipid medications in the specify boxes provided in **Question E13a**.
- c. This question asks if the participant has taken any medication to lower her blood sugar. Hand the participant **Response Card D4d**. If she has taken any medications to lower her blood sugar since her last study visit (whether they are included on the list or not), then also ask about use in the last five days. Record use of blood sugar medications in the specify boxes provided in **Question E13a**.
- d. This question asks if the participant has taken any medication to treat or prevent osteoporosis or fracture. Hand the participant **Response Card D4e**. If she has taken any osteoporosis medications since her last study visit (whether they are included on the list or not), then also ask about use in the last five days. Record use of osteoporosis medications in the specify boxes provided in **Question E13a**. **NOTE:** Do not record calcium and/or vitamin D supplements in Question E13a; they should be recorded instead in Section F, Alternative/Complementary Medication Use.
- e. This question asks if the participant has taken any medication for seizures. Hand the participant **Response Card D4f**. If she has taken any seizure medications since her last study visit (whether they are included on the list or not), then also ask about use in the last five days. Record use of seizure medications in the specify boxes provided in **Question E13a**.
- f. This question asks if the participant has taken any medication for psychological conditions or depression. Hand the participant **Response Card D4g**. If she has taken any psych medications since her last study visit (whether they are included on the list or not), then also ask about use in the last five days. Record use of psychological or depression medications in the specify boxes provided in **Question E13a**.
- g. This question asks if the participant has taken any medication for HIV lipodystrophy or body fat changes related to HIV. Hand the participant **Response Card D4h**. If she has taken any medications for lipodystrophy or body fat changes since her last study visit (whether they are included on the list or not), then also ask about use in the last five days. Record use of HIV lipodystrophy or body fat change medications in the specify boxes provided in **Question E13a**.
- h. This question asks if the participant has taken any medication for breathing or lung problems. Hand the participant **Response Card D4k**. If she has taken any medications for breathing or lung problems since her last study visit (whether they are included on the list or not), then also ask about use in the last five days. Record use of breathing or lung problem medications in the specify boxes provided in **Question E13a**.

- i. This question should be asked of all participants. Ask the participant if she has taken any other prescribed medications not previously mentioned since her last study visit. If she has taken any other prescription medications, list those medications named in the specify fields provided in **Question E13a**. If possible, enter the exact name of the medication the participant is taking. However, if the participant knows that she is taking, for example, an anti-depressant or blood pressure medication, but can't remember the medications' specific name(s), record "*anti-depressant*" or "*blood pressure medication*."

E13. Enter the total number of prescription medications that are listed in the **F22MEDs6** section.

**PROMPT: ALL COMPLEMENTARY/ALTERNATIVE THERAPIES (INCLUDING CALCIUM AND VITAMIN D) SHOULD BE REPORTED IN SECTION F, REGARDLESS OF WHETHER THEY ARE PRESCRIBED.**

If **Question E13 = 0**, skip to **Section F**. If **Question E13  $\geq$  1**, list in Column "a" all the medications taken by the participant and complete Columns "b" and "c" for each medication.

- b. For each medication listed in **Question E13a**, ask the participant whether she has taken it within the past five days.
- c. For each medication listed in **Question E13a**, the interviewer should record how use of the medication was reported by the participant, i.e., self report, participant brought written list to visit, participant brought medication bottle to visit, participant brought pharmacy record to visit, record obtained directly from pharmacy, or other.

#### **SECTION F. ALTERNATIVE/COMPLEMENTARY MEDICATION USE**

- F1. a. Hand the participant **Response Card D5**. Ensure that the participant is aware that all enzyme therapies, flower remedies, herbs, homeopathic remedies and nutritional supplements such as vitamins or minerals should be reported in this question. If the participant has not taken any complementary or alternative medications since her last study visit, skip to **Question G3**.
- b. **THIS LIST IN F1b IS NOT MEANT TO BE READ TO THE PARTICIPANT.** Rather, the participant should read the list of possible responses on **Response Card D5**. If the participant cannot read or has problems with her vision, read the list of therapies and treatments to her. For each therapy the participant indicates that she has taken since her (MONTH) study visit, circle the corresponding drug code, and then ask the participant about her frequency of use, and if she is currently taking the therapy.

**NOTE:** If the participant reports a combination supplement, such as combined calcium/vitamin D, each supplement should be reported individually. For example, if she reports a combined calcium/vitamin D supplement, then both calcium and vitamin D should be recorded individually.

If the participant names a therapy that is not listed in **Question F1b**, or if she knows that she is taking a particular class of alternative therapies but does not know the exact therapies, record her response in one of the specify fields at the end of the table. If the therapy is listed on **Drug List 3**, record the appropriate three-digit drug code in the corresponding boxes. If the therapy is not listed on **Drug List 3**, record the drug code as 699 (other alternative/complementary medication).

**NOTE:** Beginning with visit 20, codes 503 (other nutritional supplements, unspecified) and 539 (other herbs, unspecified) have been deleted from **Question F1b** and **Drug List 3**. Henceforth, all alternative/complementary therapies that cannot be classified using one of the specific codes on **Drug List 3** should be listed in one of the specify boxes with drug code 699 (other alternative/complementary medication). WDMAC will periodically review all therapies listed with code 699 to determine whether a new drug code is warranted.

- c. Enter the total number of alternative/complementary medications the participant reported taking in **Question F1b**.

G3. Record the time module ended. Circle the code for AM (code 1) or PM (code 2).