

WIHS ID#

START F22MEDS3

B2. Now I'm going to ask about any antiretroviral medications you may have taken since your (MONTH) study visit. In addition to all your prescribed medications, please include any antiretroviral medications you have taken as part of a research study, including those in which you may have been blinded to the study medication.

PROMPT: REVIEW QXQS FOR INSTRUCTIONS ON HOW TO COLLECT ARV DATA.

PROMPT: HAND PARTICIPANT ANTIRETROVIRAL PHOTO MEDICATION CARDS.

CHECK THE DRUG(S) THE PARTICIPANT HAS TAKEN FOR HIV SINCE HER LAST STUDY VISIT. FOR DRUGS NOT ON THE LIST, RECORD THE NAME UNDER "OTHER" AS STATED BY THE PARTICIPANT AND FILL IN THE CORRESPONDING THREE-DIGIT DRUG CODE FROM DRUG LIST 1.

a. Since your (MONTH) study visit, have you taken...

Combination Medications

- 262 ___ Atripla (Sustiva + Viread + Emtriva)
- 227 ___ Combivir (AZT + 3TC)
- 254 ___ Epzicom (Ziagen + Efavirenz)
- 240 ___ Trizivir (abacavir + AZT + 3TC)
- 253 ___ ***Truvada** (Viread + Emtriva)
- 280 ___ Complera (FTC + RPV + TDF)
- 287 ___ Stribild (FTC + Viread + EVG + cobicistat)

Entry Inhibitors

- 233 ___ Fuzeon (T-20, enfuvirtide)
- 265 ___ Selzentry (maraviroc)

Nucleoside/Nucleotide RTIs

- 239 ___ ***Emtriva** (emtricitabine, FTC)
- 204 ___ ***Epivir** (lamivudine, 3-TC)
- 092 ___ Retrovir (AZT, zidovudine, ZDV)
- 147 ___ Videx / Videx EC (didanosine, ddI)
- 234 ___ ***Viread** (tenofovir)
- 159 ___ Zerit (stavudine, d4T)
- 218 ___ Ziagen (abacavir)

Integrase Inhibitors

- 264 ___ Isentress (raltegravir, MK 0518)
- 286 ___ Tivicay (dolutegravir)

Non-Nucleoside RTIs

- 255 ___ Intelence (etravirine, TMC 125)
- 194 ___ Rescriptor (delavirdine)
- 220 ___ Sustiva (efavirenz)
- 191 ___ Viamune (nevirapine)
- 276 ___ Edurant (rilpivirine, TMC 278)

Protease Inhibitors

- 238 ___ Aptivus (tipranavir)
- 212 ___ Crixivan (indinavir)
- 210 ___ Invirase (saquinavir)
- 217 ___ Kaletra (lopinavir + ritonavir)
- 249 ___ Lexiva (fosamprenavir)
- 211 ___ Norvir (ritonavir)
- 256 ___ Prezista (TMC-114, darunavir)
- 243 ___ Reyataz (atazanavir)
- 216 ___ Viracept (nelfinavir)

Other

- 207 ___ Droxia or Hydrea (hydroxyurea)
- ___ Other anti-viral(s) (from Drug List 1)

Specify name of "other" antiviral:
Specify name of "other" antiviral:

→ Drug Code: |_|_|_|_|

→ Drug Code: |_|_|_|_|

END F22MEDS3

PROMPT: IF PARTICIPANT BROUGHT MEDICATION BOTTLES OR LIST TO REPORT ARV USE, PLEASE ASK THE FOLLOWING QUESTION (B2b) AND MAKE SURE ALL MEDICATIONS ARE CHECKED IN QUESTION B2a. IF PARTICIPANT IS HIV-NEGATIVE, OR INTERVIEWER HAS ALREADY REVIEWED PHOTO MED CARDS WITH PARTICIPANT, CIRCLE "3" FOR N/A AND PROCEED TO QUESTION B2c.

b. Besides the [bottles/list] that you brought in today, have you tried any other antiretroviral medications, even for a short period of time, since your (MONTH) study visit?

- YES 1
- NO 2
- Not applicable (N/A) 3

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[Empty box for WIHS ID#]

PROMPT: IF B2b=YES, REVIEW PHOTO MEDICATION CARDS WITH PARTICIPANT TO DETERMINE WHICH ADDITIONAL MEDICATIONS SHE HAS USED. REPORT ANY ADDITIONAL MEDICATIONS ABOVE IN QUESTION B2a.

PLEASE COMPLETE THE DOSAGE FORM IF PARTICIPANT REPORTS HAVING TAKEN ANY ANTIRETROVIRAL MEDICATIONS SINCE HER LAST STUDY VISIT IN QUESTION B2a.

- c. PARTICIPANT HAS **NOT TAKEN ANY** ART SLV1 (B10)
- PARTICIPANT HAS TAKEN **AT LEAST ONE** ART SLV2

d. ENTER THE TOTAL NUMBER OF ANTIRETROVIRAL MEDICATIONS
 THE PARTICIPANT REPORTED TAKING IN QUESTION B2a: [][]

B3. FROM VCS AND DSG, HAS PARTICIPANT STARTED ANY ANTIRETROVIRAL
 MEDICATIONS SINCE HER LAST STUDY VISIT?

- YES1
- NO2 (B6)

a. Is this the first time you have taken any antiretroviral medications(s)?

- YES1
- NO2

B6. Since your (MONTH) study visit, has there been a period of time of one week or more when you
 were off treatment (PROBE: not taking any of your antiretroviral medications)?

- YES1
- NO2

B7. a. **HAND PARTICIPANT RESPONSE CARD DØ.**

In general, **over the past six months**, how often did you take your antiretrovirals as
 prescribed?

- 100% of the time1 (SECTION C)
- 95-99% of the time.....2
- 75-94% of the time.....3
- <75% of the time.....4
- I haven't taken any of my prescribed medications5

b. **In the last 30 days**, on how many days did you miss at least one
 dose of any of your HIV medicines? [][]
 DAYS

c. **HAND PARTICIPANT RESPONSE CARD D0a.**

In the last 30 days, how good a job did you do at taking your HIV medicines in the way you were supposed to?

- Very poor1
- Poor2
- Fair3
- Good.....4
- Very good.....5
- Excellent6

d. **HAND PARTICIPANT RESPONSE CARD D0b.**

In the last 30 days, how often did you take your HIV medicines in the way you were supposed to?

- Never.....1
- Rarely2
- Sometimes.....3
- Usually4
- Almost always.....5
- Always6

PROMPT: GO TO SECTION C.

B10. **PROMPT: HAND PARTICIPANT RESPONSE CARD D3.**

What is your **main** reason for not taking any antiretroviral medications or treatments? **CIRCLE ONE ANSWER ONLY.**

- I am HIV negative.....1
- My CD4+ was too high / viral load too low2 (SECTION C)
- I feel too healthy3 (SECTION C)
- I am taking alternative treatments.....4 (SECTION C)
- I don't want side effects.....5 (SECTION C)
- They are too hard to swallow.....6 (SECTION C)
- My doctor did not prescribe them.....7 (SECTION C)
- I can't afford them / have no insurance coverage.....8 (SECTION C)
- I am concerned about resistance9 (SECTION C)
- I'm having a baby10 (SECTION C)
- Personal decision to wait11 (SECTION C)
- They didn't work for my friends.....12 (SECTION C)
- Liver problems14 (SECTION C)
- Any other reason.....13

SPECIFY: _____ (SECTION C)

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B11. Since your (MONTH) study visit, have you taken medications to prevent getting HIV infection – this is sometimes called pre- or post-exposure prophylaxis, PEP or PrEP?

- YES1
- NO2 **(SECTION C)**
- POSSIBLY, FROM A STUDY3

B12. From where did you get the medication?

- Your primary care provider or clinic1
- A clinic such as an STD or public health clinic2
- A non-clinical person, such as a friend or person on the street3
- As part of a study4
- Other5

SPECIFY: _____

B13. Are you still taking it?

- YES1
- NO2

a. In what year did you first take this medication?

B14. Are you taking or did you begin to take this medicine **after** having a possible unprotected sexual or drug injection exposure?

- YES1 **(B16)**
- NO2

B15. Are you taking or did you begin to take this medicine for your general protection (and not prompted by a risky exposure)?

- YES1
- NO2

B16. For how long did you or will you take this medication?

- < 1 week1
- 1 – 3 weeks2
- 3 – 6 weeks3
- > 6 weeks4

SECTION C. OI AND OTHER CO-INFECTION MEDICATION HISTORY

START F22MEDS4

C1. PROMPT: HAND PARTICIPANT RESPONSE CARD D4.

a. Since your (MONTH) study visit, have you taken the following inhaled medication?

114 ___ Pentamidine (aerosolized)

b. Since your (MONTH) study visit, have you taken any of the following injected or infused drugs?

091 ___ Foscarnet (Foscavir)

125 ___ Ganciclovir (DHPG, Cytovene IV)

232 ___ Nandrolone (Deca-durabolin)

157 ___ Medication to increase white blood cell count (G-CSF, GM-CSF, Neupogen)

117 ___ Medication to increase red blood cell count (Erythropoietin, Epogen, Procrit, EPO)

124 ___ Amphotericin B (Ampho B)

242 ___ ***Pegylated interferon** (PEGASYS, PEG-Intron, Peginterferon alfa-2a, Peginterferon alfa-2b)

c. Since your (MONTH) study visit, have you used any of the following pills, liquids or creams?

112 ___ Bactrim (Septra, cotrimoxazole, trimethoprim-sulfamethoxazole, TMP/SMZ)

184 ___ Biaxin (clarithromycin)

113 ___ Dapsone

116 ___ Diflucan (fluconazole)

213 ___ Famvir (famciclovir)

125 ___ Ganciclovir (Cytovene, valganciclovir, Valcyte)

138 ___ INH (isoniazid)

190 ___ Mepron (atovaquone)

540 ___ Methadone

705 ___ Methyl-prednisolone (Medrol)

229 ___ Monistat (miconazole)

137 ___ Myambutol (ethambutol)

145 ___ Mycelex or Lotrimin (clotrimazole)

127 ___ Nizoral (ketoconazole)

144 ___ Nystatin (Mycostatin)

228 ___ Oxandrin (oxandrolone)

707 ___ Prednisolone (Prelone)

704 ___ Prednisone (Deltasone)

182 ___ PZA (pyrazinamide)

235 ___ ***Rebetron** (Ribavirin & Interferon alfa-2b)

093 ___ Rifabutin (mycobutin)

139 ___ Rifadin (rifampin)

169 ___ Sporanox (itraconazole)

230 ___ Terazol (terconazole)

198 ___ Valtrex (valacyclovir)

247 ___ Vfend (voriconazole)

152 ___ Zithromax (azithromycin)

146 ___ Zovirax (acyclovir)

i. PARTICIPANT HAS **NOT TAKEN ANY** MEDS IN C1a, C1b OR C1c1 (SECT. D)
PARTICIPANT HAS TAKEN **AT LEAST ONE** MED IN C1a, C1b OR C1c2

END F22MEDS4

PLEASE COMPLETE DRUG FORM 2 FOR EACH MEDICATION MARKED ABOVE IN QUESTION C1a – C1c. IF NO MEDICATIONS ARE MARKED, GO TO SECTION D.

d. ENTER THE TOTAL NUMBER OF NON-ANTIRETROVIRAL MEDICATIONS THE PARTICIPANT REPORTED TAKING IN QUESTIONS C1a, C1b and C1c:

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SECTION D. HEPATITIS MEDICATION HISTORY

START F22MEDS9

D1. PROMPT: HAND PARTICIPANT RESPONSE CARD D4a.

a. Since your (MONTH) study visit, have you taken any of the following medications for Hepatitis B or C?

- 242 ___ Pegylated interferon (PEGASYS or Peginterferon alfa-2a)
(PEG-Intron or Peginterferon alfa-2b)
- 058 ___ Ribavirin (Virazole, Rebetrol, Copegus)
- 235 ___ Rebetron (Ribavirin and interferon alfa-2b)
- 204 ___ Epivir (lamivudine, 3-TC)
- 234 ___ Viread (tenofovir, bis-POC-PMPA)
- 224 ___ Hespera (adefovir, Preveon, bis-POM PMPA, GS 840)
- 239 ___ Emtriva (emtricitabine, Coviracil, FTC)
- 253 ___ Truvada (Viread + Emtriva)
- 709 ___ Baraclude (entecavir, BMS-200475)
- 710 ___ Tyzeka (telbivudine)
- 713 ___ Victrelis (boceprevir)
- 714 ___ Incivek (telaprevir)
- 715 ___ Olysio (simeprevir)
- 716 ___ Sovaldi (sofosubir)

Specify name of "other" antiviral:
Specify name of "other" antiviral:

→ Drug Code: |_|_|_|_|

→ Drug Code: |_|_|_|_|

b. PARTICIPANT HAS **NOT TAKEN ANY** MEDS IN D1a.....1 (SECT. E)
 PARTICIPANT HAS TAKEN **AT LEAST ONE** MED IN D1a.....2

END F22MEDS9

**PLEASE COMPLETE DRUG FORM 3 FOR EACH
 MEDICATION MARKED ABOVE IN QUESTION D1a.**

c. ENTER THE TOTAL NUMBER OF HEPATITIS MEDICATIONS THE
 PARTICIPANT REPORTED TAKING IN QUESTION D1a:

|_|_|

SECTION E. OTHER PRESCRIPTION MEDICATION USE

E1. Since your (MONTH) study visit, have you received any of the following vaccinations?

	<u>YES</u>	<u>NO</u>	<u>DON'T KNOW</u>
a. Hepatitis A	1	2	-8
b. Hepatitis B	1	2	-8
c. Pneumovax.....	1	2	-8
d. Varicella (chicken pox)	1	2	-8
e. Tetanus	1	2	-8
f. HPV (human papillomavirus).....	1	2	-8
g. Herpes Zoster (shingles).....	1	2	-8

PROMPT: IF ODD-NUMBERED VISIT (E.G., 31, 33, ETC.), SKIP TO QUESTION E11.

E2. During the last flu season, did you get the **regular** flu vaccine?

YES	1
NO.....	2

E11. **PROMPT: HAND PARTICIPANT RESPONSE CARD D4h.**

Since your (MONTH) study visit, have you taken any of the following hormone replacement therapies (hormones, estrogen, progesterone) for more than one month? These therapies could have been taken in the form of a pill, cream, or patch worn on the skin. Please do not include any hormones taken only to prevent pregnancy; we will discuss those later in the interview.

ESTROGEN: Premarin, Estrace, Estratab, Menest, Ogen, Cenestin, Estraderm, Climara, Menostar, Estrasorb, Alora, Enjuvia, Evamist, Femring, Vivelle-Dot

PROGESTERONE: Provera, Cycrin, Amen, Prometrium, Micronor, Nor-QD

COMBINATION ESTROGEN/PROGESTERONE: Premphase, Prempro, Combipatch, Angeliq, Activella, Prefest

OTHER HRT: Tamoxifen, Raloxifene, testosterone patch or cream, Estratest (combination estrogen/testosterone), birth control pills, Norplant, Ortho Evra (birth control patch), NuvaRing (a vaginal ring containing hormone)

YES	1
NO.....	2 (E12a)

a. INTERVIEWER: BASED ON PARTICIPANT RESPONSE IN E11, CODE BELOW THE TYPE OF HRT PARTICIPANT REPORTED ABOVE:

ESTROGEN.....	1
PROGESTERONE	2
COMBINATION	3
OTHER HRT	4

SPECIFY: _____

b. What are the main reasons you are taking hormone replacement therapy? Is it for:

	<u>YES</u>	<u>NO</u>
i. Menopause related symptoms (the change, hot flashes, vaginal dryness, sweating).....	1	2
ii. Depression, anxiety or emotional distress	1	2
iii. Replacement after hysterectomy or removal of ovaries	1	2
iv. Osteoporosis, or to prevent or treat bone loss.....	1	2
v. Prevention of heart disease	1	2
vi. Irregular menstrual periods (spotting)	1	2
vii. Other reason	1	2 (E12a)

SPECIFY: _____

E12a. Since your (MONTH) study visit, have you taken any medication for blood pressure or your heart, (such as Amiodarone, Quinidine, Verapamil, hydrochlorothiazide, etc.)? **SHOW PARTICIPANT RESPONSE CARD D4b. IF “YES,” RECORD MEDICATION IN QUESTION E13a.**

YES.....1
NO.....2

E12b. (Since your (MONTH) study visit), have you taken any medication to lower your cholesterol, triglyceride, or blood lipid level, (such as Lipitor, Pravachol, Zocor, etc.)? **SHOW PARTICIPANT RESONSE CARD D4c. IF “YES,” RECORD MEDICATION IN QUESTION E13a.**

YES.....1
NO.....2

E12c. (Since your (MONTH) study visit), have you taken any medication to lower your blood sugar, such as insulin injections or any oral medications? **SHOW PARTICIPANT RESPONSE CARD D4d. IF “YES,” RECORD MEDICATION IN QUESTION E13a.**

YES.....1
NO.....2

E12d. (Since your (MONTH) study visit), have you taken any medication to prevent or treat osteoporosis or fracture, such as bisphosphonates [alendronate (Fosamax), risedronate (Actonel, Atelvia), zoledronic acid (Reclast), ibandronate (Boniva)], estrogen, raloxifene (Evista), teriparatide (Forteo), denosumab (Prolia), or calcitonin (Fortical, Miacalcin)? **SHOW PARTICIPANT RESPONSE CARD D4e. IF “YES,” RECORD MEDICATION IN QUESTION E13a.**

YES.....1
NO.....2

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E12e. (Since your (MONTH) study visit), have you taken any medication for seizures, (such as Tegretol, Dilantin, Phenobarbital, Depakote, etc.)? **SHOW PARTICIPANT RESPONSE CARD D4f. IF “YES,” RECORD MEDICATION IN QUESTION E13a.**

YES.....1
NO.....2

E12f. (Since your (MONTH) study visit), have you taken any medication for psychological conditions or depression, (such as Zyprexa, Zoloft, Celexa, etc.)? **SHOW PARTICIPANT RESPONSE CARD D4g. IF “YES,” RECORD MEDICATION IN QUESTION E13a.**

YES.....1
NO.....2

E12g. (Since your (MONTH) study visit), have you taken any medication for HIV lipodystrophy or body fat changes related to HIV, such as growth hormones or steroids? **SHOW PARTICIPANT RESPONSE CARD D4i. IF “YES,” RECORD MEDICATION IN QUESTION E13a.**

YES.....1
NO.....2

E12h. (Since your (MONTH) study visit), have you taken any medication for breathing or lung problems, (such as Singulair, monteleukast, Accolate, zafirlukast, Zyflo, zileutin, Theodur, theophylline, Slo-phyllin, Slo-bid, Aerolate, or albuterol)? **SHOW PARTICIPANT RESPONSE CARD D4k. IF “YES,” RECORD MEDICATION IN QUESTION E13a.**

YES.....1
NO.....2

E12i. Since your (MONTH) study visit, have you taken any other **prescribed** medications **not** previously mentioned? **IF “YES,” RECORD MEDICATION IN QUESTION E13a.**

YES.....1
NO.....2

E13. ENTER THE TOTAL NUMBER OF OTHER PRESCRIPTION MEDICATIONS RECORDED IN THE F22MEDS6 SECTION:

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

PROMPT: IF E13 = 0, SKIP TO SECTION F. IF E13 ≥ 1, LIST MEDICATIONS IN COLUMN “a” AND COMPLETE COLUMNS “b” AND “c” FOR EACH MEDICATION.

PROMPT: PHOTOCOPY PAGE 14 AND INSERT IF PARTICIPANT REPORTS USING MORE THAN 10 OTHER PRESCRIPTION MEDICATIONS.

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START F22MEDS6

a. Specify Drug Name	b. Have you taken this in the past 5 days? YES NO	c. INTERVIEWER, RECORD HERE HOW USE OF THIS MEDICATION WAS REPORTED.
Name of drug:	1 2	Self report..... 1 Participant brought written list to visit.....2 Participant brought medication bottles to visit.....3 Participant brought pharmacy record to visit4 Record obtained directly from pharmacy.....5 Other6 SPECIFY:
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a. Specify Drug Name	b. Have you taken this in the past 5 days? YES NO	c. INTERVIEWER, RECORD HERE HOW USE OF THIS MEDICATION WAS REPORTED.
Name of drug:	1 2	Self report..... 1 Participant brought written list to visit..... 2 Participant brought medication bottles to visit..... 3 Participant brought pharmacy record to visit 4 Record obtained directly from pharmacy 5 Other 6 SPECIFY: _____
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END F22MEDS6

SECTION F. ALTERNATIVE/COMPLEMENTARY MEDICATION USE

F1. In addition to standard medication therapies, we are interested in collecting information on complementary and alternative therapies.

PROMPT: HAND PARTICIPANT RESPONSE CARD D5.

- a. Since your (MONTH) study visit, have you used any complementary or alternative medications that you take by mouth either as a pill or liquid, that you apply to your skin, or that you insert in your rectum or vagina. Please include any enzyme therapies, flower remedies, herbs, homeopathic remedies and nutritional supplements such as vitamins or minerals you may have taken. Do not include commercial herbal tea preparations (i.e., tea bags), but please include tea remedies made from fresh bulk herbs.

YES 1
 NO 2 **(GO TO G3)**

- b. Please name those complementary and alternative medications that you have taken.

PROMPT: CIRCLE THE DRUG CODE FOR CAM NAMED. SPECIFY THOSE NOT LISTED UNDER "OTHER" AND FILL IN THE THREE-DIGIT DRUG CODE FROM DRUG LIST 3.

START F22MEDS5

Treatments		i. Frequency of Use		ii. Currently Taking		iii. MAIN Reason for Taking
		Every or Almost Every Day	Only as Needed	YES	NO	
602	Acidophilus	1	2	1	2	_ _ _
607	B-complex	1	2	1	2	_ _ _

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Treatments	i. Frequency of Use		ii. Currently Taking		iii. MAIN Reason for Taking	
	Every or Almost Every Day	Only as Needed	YES	NO		
608	B-vitamins (B1 thiamine, B2 riboflavin, B5 pantothenic acid, B6 pyridoxine, B12)	1	2	1	2	□□□
612	C-vitamins (rosehips)	1	2	1	2	□□□
646	Calcium	1	2	1	2	□□□
615	Chinese herbs in combination	1	2	1	2	□□□
196	Co-enzyme Q-10	1	2	1	2	□□□
657	D-vitamins	1	2	1	2	□□□
619	E-vitamins	1	2	1	2	□□□
620	Echinacea (with or without goldenseal)	1	2	1	2	□□□
623	Folic Acid	1	2	1	2	□□□
624	Garlic	1	2	1	2	□□□
652	Glucosamine/Chondroitin	1	2	1	2	□□□
641	Iron	1	2	1	2	□□□
630	Multi- or Prenatal vitamins / Minerals	1	2	1	2	□□□
633	Omega-3 Type or Fish Oils	1	2	1	2	□□□
640	Zinc	1	2	1	2	□□□
□□□□	Specify:	1	2	1	2	□□□
□□□□	Specify:	1	2	1	2	□□□
□□□□	Specify:	1	2	1	2	□□□
□□□□	Specify:	1	2	1	2	□□□

PROMPT: HAND PARTICIPANT RESPONSE CARD D6. REASONS FOR TAKING COMPLEMENTARY/ALTERNATIVE MEDICATIONS:

- | | |
|--|---|
| 01 = to treat or reduce side effects from “standard” medications | 08 = to gain weight |
| 02 = to boost immune system | 09 = to lose weight |
| 03 = to prevent opportunistic and general infections | 10 = it was prescribed by my medical provider |
| 04 = to treat HIV infection | 11 = for bone health |
| 05 = for general health | 12 = for heart health |
| 06 = they are beneficial without causing side effects | 13 = for prevention of memory loss |
| 07 = standard HIV medications don’t work | 14 = for treatment of menopause |
| 99 = other | |

END F22MEDS5

c. ENTER THE TOTAL NUMBER OF ALTERNATIVE/COMPLEMENTARY MEDICATIONS THE PARTICIPANT REPORTED TAKING IN QUESTION F1b: □□□

G3. TIME MODULE ENDED: □□□□ : □□□□ AM 1
 PM 2