## **INTRODUCTION TO FORM 23 – QUARTERLY MEDICATION HISTORY FORM**

This form has had four versions, 07/15/95, 01/15/96, 08/01/96 and 07/22/98. For purposes of the Public Use Data Set, the first two versions are the same and the last two are the same.

If the answer to question B1 was Yes, then information for each drug was recorded in Boxes B2, B3, etc... (depending on the number of different drugs). These data are provided in a repeating segment data set.

Whenever possible, blinded study medications which were later unblinded were retrospectively coded under the actual drug name. Similarly, when a new drug code was added, if that drug had previously been recorded under "other", it was retrospectively coded under the new code. Some drug codes were coded internally and were not on any of the original printed forms. Therefore, the final coding is reproduced here and the coding conventions on the forms have been deleted.

	Form \	/ersions
<b>Medication</b>	07/15/95, 01/15/96	08/01/96, 07/22/98
Antiretrovirals		
ritonavir (Norvir)	01	01
nelfinavir (Viracept)	02	02
adefovir (bis-Pom-PMEA)	03	03
delavirdine mesylate (Rescriptor)	04	04
didanosine (ddl, Videx)	05	05
hydroxyurea (Hydrea)	06	06
lamivudine (3TC, Epivir)	07	07
loviride	08	08
indinavir (Crixivan)	09	09
nevirapine (Viramune)	10	10
saquinavir (Invirase)	11	11
stavudine (d4T, Zerit)	12	12
zalcitabine (ddC, HIVID)	13	13
zidovudine (AZT, ZDV, Retrovir)	14	14
ABT-378	40	40
MKC-442	41	41
efavirenz (DMP-226, Sustiva)	42	42
saquinavir new formulation (Fortovase)	43	43
tipranavir (PNU140690)	44	44
abacavir (1592U89, Ziagen)	50	15
amprenavir (VX478, 141W94)	51	16
Other Antiretrovirals <sup>1</sup>	15	17

	Form	Versions
Medication	08/01/96,	08/01/96,
	07/22/98	07/22/98
Antivirals		
acyclovir (ACV, Zovirax)	16	18
CMV monoclonal antibodies	17	19
cidofovir (HPMPC, Visticle)	18	20
famciclovir (Famvir)	19	21
foscarnet (Foscavir)	20	22
oral ganciclovir (Cytovene)	21	23
IV ganciclovir	22	24
ganciclovir implant	23	25
valacyclovir (Valtrex)	24	26
intravitreal foscarnet	52	52
injections	02	02
intravitreal ganciclovir injections	53	53
Other Antivirals	25	27
Erythropoetin (EPO)		
erythropoetin (EPO)	26	28
Systemic Immunomodulators		
GM-CSF (Leukine)	27	29
interleukin 2	28	30
interferon alpha	29	31
(Roferon, Wellferon, Intron A)		
interferon beta (Betaseron)	30	32
interferon gamma (Actimmune)	31	33
i.v. immunoglobulin (IVIG)	32	34
thalidomide	33	35
Other systemic Immunomodulators	34	36
Systemic Corticosteroids		
Systemic Steroids > replacement dose	35	37
e.g. prednisone > 10 mg/day,		
hydrocortisone > 50 mg/day,		
dexamethasone > 1 mg/day)		
Systemic Steroids: replacement dose	36	38
e.g. prednisone $\leq 10$ mg/day,		
hydrocortisone $\leq$ 50 mg/day,		
dexamethasone ≤ 1 mg/day)		
Blinded study medications		
(in above categories)		
Blinded Study Medications <sup>2</sup>	37	39

<sup>1</sup> All "other antiretrovirals" were retrospectively recoded as one of the specific numbered antiretrovirals <sup>2</sup> When information was available, blinded medications were retrospectively recoded as one of the speci

<sup>2</sup> When information was available, blinded medications were retrospectively recoded as one of the specific numbered medications upon unblinding.

If a patient was continuing a medication since the previous quarterly visit, the "Start Date" for that medication, START\_DT, was to be coded with dashes in the date field. It is important to distinguish this type of missing value from a "true" missing value in which the start date of the medication was unknown. Both types of missing value are treated as missing for the date variable, but an additional variable, FRMBFOR, was added to distinguish between three situations, depending on whether or not medication was continuing from the previous visit and whether or not a start date was known:

- 1 = medication continuing from previous visit (START\_DT coded as missing)
- 2 = medication started since previous visit (START\_DT non-missing).
- . = start date unknown (START\_DT coded as missing)

## QUARTERLY MEDICATION HISTORY FORM -- FORM 23 – QxQ

Information requested in this form may be obtained through participant interview, medical record review, or both. We are interested in medicines taken since the last VATS Quarterly Visit. At Visit 03, "the last quarterly visit" pertains to the enrollment visit 00. For some medications, we are asking the dates started and ended, as well as the specific drug name. For others, we are only interested in a "yes" or "no" response.

#### SECTION A -- GENERAL INFORMATION

- A1. Affix the subject ID label. If label is not available, write the subject ID number in the space provided. If this is a multiple page form, affix an ID label or write the ID number on the top of each page in the space provided.
- A2. Enter the visit number. NOTE: Space to record the Quarterly Visit number has been added to the top of pages 2-4. It is not mandatory that this field be completed. However, for tracking purposes it is strongly recommended that this field be completed when revising\updating the form.
- A3. Enter the subject's first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If the subject does not have a middle name, enter the first initial in the first space provided, a "--" in the second space provided, and the last initial in the third space provided. If the person has a hyphenated last name or 2 last names, enter the initial of the first last name in the appropriate box. NOTE: Space to record the subject initials has been added to the top of pages 2-4. It is not mandatory that this field be completed. However, for tracking purposes it is strongly recommended that this field be completed when revising\updating the form.
- A5. Record the date that this form is completed.
- **A6.** Enter the initials of the person completing the form. Enter the first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If the person completing this form does not have a middle name, enter the first initial in the first space provided, a "--" in the second space provided, and the last initial in the third space provided. If the person has a hyphenated last name or 2 last names, enter the initial of the first last name in the appropriate box.

#### SECTION B: MEDICATION HISTORY

**B1.** Since the last quarterly visit, we would like to know if the participant has taken any of the following types (classifications) of medication, including as a part of a blinded study:

Antiretrovirals Antivirals Erythropoetin (EPO) Systemic immunomodulators Systemic corticosteroids

#### Form 23 – Quarterly Medication History Form – Introduction/ QXQ

If the participant has not taken any drugs that fall within these categories since the last quarterly visit, check the "No" box and proceed to Question C1. on page 3. If the participant did take one or more of the drug types listed, mark the "Yes" box and go to Question B2.

#### B2. through B8.

Please note: The drug codes in the examples below reflect the 8/1/96 and 7/22/98 versions. In the 7/15/95 and 1/15/96 versions the code for the same drug would be 36.

The drug code box located on page 1 lists the names of common medications within each of these drug classifications with a corresponding code.

Complete a separate question for each drug the participant has taken from any of the listed classifications, and for the same drug in the case of a > 7 day interruption in therapy, since the last quarterly visit. For example, assume this is visit 03 on 9/1/95 and the participant started taking 5 mg of Prednisone daily on 5/31/95, the day prior to an enrollment date of 6/1/95. Since enrollment, the participant discontinued therapy for a 10-day period, restarting on 8/20/95. The entries should be recorded as follows:

	a. Drug Code?	b. Date Started?	c. Still Taking?	d. Date Stopped?
B2.	8 IF 15, 25, 34, OR 37, SPECIFY ↓	<u>//</u>	1. Yes 2. No →	<u>_0_8/_1_0/_9</u> _5
	a. Drug Code?	b. Date Started?	c. Still Taking?	d. Date Stopped?
B3.	<u>_38</u> IF 15, 25, 34, OR 37, SPECIFY ↓	<u>_0_8/_2_0/_9_5</u>	X 1. Yes 2. No →	//

Each question has 4 parts: a, b, c and d.

For **part a** enter the 2-digit code that corresponds with each drug taken (unless drug is being taken as part of a blinded study; see\*). If participant is on combination therapy, list each medication separately, i.e., AZT and ddl combination therapy would be listed as code 14 in B2a. and code 05 in B3a. If participant is taking a medication from any of the categories which is not pre-coded, enter the corresponding category code for "other" and specify the name of the drug in the space provided. \*Code 37 (blinded medications) should be reserved for situations where the identity of the drug is blinded. This may not apply to all blinded treatments, for example blinded assignment of one of two doses of Zidovudine should be coded as Zidovudine, even though it is given as a blinded medication.

For **part b** record the date the participant started the medication *only if the start date is after the last quarterly visit.* The start date only has to be listed once for medications the participant takes continuously over several visit intervals. Note in the example above, the Prednisone started prior to enrollment, has dashes (--) through the start date. For medications started or restarted since the last quarterly visit in which the exact day started is not known, enter the month and year and place dashes in the two boxes provided for the day. Estimate the month and/or year if participant cannot recall an exact start date and medical record documentation is not available.

For **part c** indicate whether or not participant is still taking the medication.

For **part d**, if the participant is no longer taking the medication, record the date the drug was stopped.

The form allows room for recording up to 7 medications from these categories. If additional space is needed, copy page 2 as many times as necessary, record the additional medications and attach the extra pages to the end of this form. There is no need to alter page or question numbers.

### SECTION C -- MEDICATION HISTORY

## C1. through C6.

Check the appropriate box indicating whether or not the participant has taken any of the categories of drugs listed at any time since the last quarterly visit. Please keep in mind that the example lists in each category are not meant to be all inclusive.

Questions C1. and C3. below were added only to the 7/22/98 version to explain blinded study medications.

- C1. If the patient is on or has been on PCP prophylaxis at any time since the last quarterly visit, check "Yes" and proceed to question C2. If the patient is not on or has not been on PCP prophylaxis since the last quarterly visit, check "No" and proceed to question C2. If the patient is enrolled in a blinded study and you are unable to determine whether or not the patient is receiving PCP prophylaxis check "Don't know" and provide the identifying information for the study, such as the ACTG study number, and the name of the medication vs. placebo administered for the study in the space provided. NOTE: Should the patient be on a blinded or open-label, non-placebo controlled study for PCP (i.e. randomized to 1 of 2 or more active PCP medications), "Yes" should be checked.
- **C3.** If the patient is on or has been on MAC prophylaxis/treatment at any time since the last quarterly visit, check "Yes" and proceed to question C4. If the patient is not on or has not been on MAC prophylaxis/treatment since the last quarterly visit, check "No" and proceed to question C4. If the patient is enrolled in a blinded study and you are unable to determine whether or not the patient is receiving MAC prophylaxis/treatment check "Don't know" and provide the identifying information for the study, such as the ACTG study number, and the name of the medication vs. placebo administered for the study in the space provided. NOTE: Should the patient be on a blinded or open-label, non-placebo controlled study for MAC (i.e. randomized to 1 of 2 or more active MAC medications), "Yes" should be checked.

### **SECTION D -- VACCINES**

### D1. and D2.

Check the appropriate boxes regarding participant's receipt of influenza and pneumococcal vaccines *since the last quarterly visit.* If either was received since the last quarterly visit, record the date, or at least month and year, the participant received the vaccine.

### D3. OTHER VACCINES

Either through self-report or medical record review, indicate whether the participant received other vaccines since *the last quarterly visit*. If yes, record the name of the vaccine(s) and the date received. If more than 2 other vaccines were received, copy this page to record additional information in D3 and attach to the form.

VIRAL ACTIVATION TRANSFUSION STUDY (VATS) FORM 23 QUARTERLY MEDICATION HISTORY FORM			
SECT	ION A GENERAL INFORMATION		
A1.	Subject ID: (ENTER ID NUMBER OR AFFIX LABEL AT THE RIGHT)	·	
A2.	Visit number:		
A3.	Subject initials:	··	
A4.	Form version:	<u>0</u> <u>1</u> / <u>1</u> <u>5</u> / <u>9</u> <u>6</u>	
A5.	Today's date:	/ /	
A6.	Initials of person completing form:		
<u>SECT</u>	ION B MEDICATION HISTORY		
B1.	Since the last quarterly visit, has the patient received any of the following drugs?	1. Yes 2. No $\rightarrow$ SKIP TO SECTION C	
Use	multiple entries (i.e. B2, B3) to indicate multiple st given drug. Date Started required only if drug started		
	a. Drug Code? b. Date Started?	c. Still Taking? d. Date Stopped?	
B2.	IF 15, 25, 34, OR 37, SPECIFY V	1. Yes 2. No →//	
B3.	IF 15, 25, 34, OR 37, SPECIFY V	1. Yes 2. No →//	
B4.	IF 15, 25, 34, OR 37, SPECIFY V	1. Yes 2. No →//	
B5.	IF 15, 25, 34, OR 37, SPECIFY	1. Yes 2. No →//	
ATTACH COPIES OF THIS PAGE IF ADDITIONAL SPACE IS REQUIRED.			

SECTION C -- MEDICATION HISTORY Including blinded studies with active controls, since the last quarterly has the visit participant taken any medications in the categories listed below for indications listed?

C1.	PCP prophylaxis	1. Yes
	(For example TMP-SMX, dapsone, pentamidine, atovaquone, clindamycin/primaquine)	2. No
C2.	PCP treatment	1. Yes
	(For example TMP-SMX, dapsone, pentamidine, atovaquone, clindamycin/primaquine)	2. No
C3.	MAC prophylaxis/treatment	1. Yes
	(For example rifabutin, clarithromycin, ethambutol, ciprofloxacin, clofazimine, rifampin, amikacin, azithromycin)	2. No
C4.	Systemic chemotherapy for malignancies	1. Yes
		2. No
C5.	Treatment for wasting	1. Yes
	(For example marinol, megesterol, testosterone, growth hormone)	2. No
C6.	Total parenteral nutrition (TPN)	1. Yes
		2. No

## **SECTION D: VACCINES**

Has the patient received any of the following vaccines since the last quarterly visit?

D2. Pneumococcal vaccine:

D3.	Other	vaccine(	s	):	
00.	0.1101	10001101	<u> </u>	<i>,</i> .	

1. Yes 2. No
1. Yes 2. No
1. Yes 2. No

→

→

→

a. Date of pneumococcal vaccine:
/ /

\_ / \_\_\_ \_\_ / \_\_\_ \_

a. Date of flu vaccine:

•	a1. Name of vaccine:
	b1. Date of vaccine:
	//
	a2. Name of vaccine:
	b2. Date of vaccine:
	//

## END OF FORM

	VIRAL ACTIVATION TRAN FORM 23 QUARTERLY ME	
<u>SECT</u>	ION A GENERAL INFORMATION	
A1.	Subject ID: (ENTER ID NUMBER OR AFFIX LABEL AT THE RIG	GHT)
A2.	Visit number:	
A3.	Subject initials:	··
A4.	Form version:	_0 _7 / _2 _2 / _9 _8_
A5.	Today's date:	/ /
A6.	Initials of person completing form:	
<u>SECT</u>	ION B MEDICATION HISTORY	
B1.	Since the last quarterly visit, has the patient received any of the following drugs?	1. Yes         2. No       → SKIP TO SECTION C
Use I		tiple start/stop dates or interruptions > 7 days for a
	given Date Started required only if drug st	
	a. Drug Code? b. Date Started?	? c. Still Taking? d. Date Stopped?
B2.	IF 17, 27, 36, OR 39, SPECIFY	1. Yes 2. No →//
B3.	IF 17, 27, 36, OR 39, SPECIFY	1. Yes 2. No →//
B4.	IF 17, 27, 36, OR 39, SPECIFY	1. Yes 2. No →//
B5.	IF 17, 27, 36, OR 39, SPECIFY	1. Yes 2. No →//
	ATTACH COPIES OF THIS PAGE IF	ADDITIONAL SPACE IS REQUIRED

<u>SECTION C – MEDICATION HISTORY</u> Including blinded studies with active controls, since the last quarterly visit has the participant taken any medications in the categories listed below for indications listed?

C1.	PCP prophylaxis		Γ	1. Yes
	(For example TMP-SMX, dapsone, pentamidir clindamycin/primaquine)	ne, atovaquone,		2. No
				3. Don't know, placebo-controlled blinded study ↓
			-	
				(Specify the study & name of medication vs. placebo)
C2.	PCP treatment			1. Yes
	(For example TMP-SMX, dapsone, pentamidir clindamycin/primaquine)	ne, atovaquone,		2. No
C3.	MAC prophylaxis/treatment			1. Yes
	(For example rifabutin, clarithromycin, ethambutol,			2. No
	ciprofloxacin, clofazimine, rifampin, amikacin,	azithromycin)	<u> </u>	3. Don't know, placebo-controlled
				blinded study V
			_	
			-	
				(Specify the study & name of medication vs. placebo)
C4.	Systemic chemotherapy for malignancies			1. Yes
				2. No
C5.	Treatment for wasting		<b>—</b>	1. Yes
00.	(For example marinol, megesterol, testosterone, growth			2. No
	hormone)	, 0	L	
C6.	Total parenteral nutrition (TPN)			1. Yes
				2. No
	<b>FION D: VACCINES</b> the patient received any of the following vaccines	since the last q	uarter	'ly visit?
D1.	Flu vaccine:	1. Yes	→	a. Date of flu vaccine:
		2. No		/ /
D2.	Pneumococcal vaccine:	1. Yes	→	a. Date of pneumococcal vaccine:

\_ / \_\_ / \_\_ \_

2. No

D3. Other vaccine(s):

1. Yes
2. No

→	a1. Name of vaccine:
	b1. Date of vaccine:
	/ /
	a2. Name of vaccine:
	b2. Date of vaccine:
	/ /

END OF FORM

**QUARTERLY MEDICATION HISTORY FORM – FM23DATA CODEBOOK** 

PUB_ID					- SUBJECT ID
type:	numeric (fl	loat)			
range:	[1,530]		מוו	its: 1	
	[_,]				
unique values:	373	c	oded miss:	ing: 0 / 2	132
	265.396				
std. dev:	155.718				
percentiles:	10%	25%	50%	75%	90%
-	43	133	271	400.5	484
VISNUM	string (sti			A2.	VISIT NUMBER
cype:	SCIING (SCI	)			
unique values:	15	c	oded miss:	ing: 0 / 2	132
tabulation:	Freq. Valu				
	342 "03"				
	291 "06' 255 "09'				
	255 "09"				
	193 "15"				
	172 "18"				
	153 "21'				
	125 "24'	•			
	104 "27"	•			
	90 "30"				
	80 "33'				
	58 "36'				
	28 "39"				
	15 "42' 6 "45'				
	o "45"	-			
VI CNUM.					

VISNUM:

 This form is only used at quarterly visits (QU 03, QU 06, QU 09, etc.). Therefore, this variable is always coded as 03, 06, 09, etc.

#### Codebook – Form 23 – Quarterly Medication History Form – Dataset: FM23DATA

FORM\_V ------ A4.FORM VERSION DATE type: numeric (float) label: FORM\_V range: [12979,14082] units: 1 values: 4 coded missing: 0 / 2132 unique values: 4 tabulation: Freq. Numeric Label 
 54
 12979
 07/15/95

 173
 13163
 01/15/100
 1243 13362 08/01/96 662 14082 07/22/98 COMP D ----- A5.DATE FORM COMPLETED (TODAY'S DATE) type: numeric (float) 

 range:
 [50,1380]
 units:
 1

 values:
 791
 coded missing:
 0 / 2132

 unique values: 791 mean: 465.184 std. dev: 309.161 percentiles: 10% 25% 50% 75% 90% 103 199.5 392.5 665.5 935 COMP\_D: 1. This variable has been coded as the number of days since Randomization (Negative values indicate dates before Randomization; positive values indicate dates subsequent to Randomization) RECVMEDS ------ B1.RECEIVE MEDS SINCE LAST VISIT type: numeric (float) label: RECVMEDS range: [1,2] units: 1 unique values: 2 coded missing: 1 / 2132 tabulation: Freq. Numeric Label 2063 1 1:Yes 68 2 2:No PCP PROP ----- C1.PCP PROPHYLAXIS TAKEN type: numeric (float) label: PCP\_PROP units: 1 coded missing: 0 / 2132 range: [1,2] unique values: 2 tabulation: Freq. Numeric Label 1849 1 1:Yes 1 1:Yes 2 2:No 283

PCPSPEC ----- C1.PCP SPECIFY STUDY NAME type: string (str60), but longest is str0 unique values: 0 coded missing: 2132 / 2132 tabulation: Freq. Value PCPSPEC: 1. Value corresponds to study name if PCP\_PROP=3 (i.e., question C1=3) PCPSPEC2 ----- C1.PCP SPECIFY NAME OF MED VS. PLACEBO type: string (str60), but longest is str0 unique values: 0 coded missing: 2132 / 2132 tabulation: Freq. Value PCPSPEC2: 1. Value corresponds to study drug if question PCP\_PROP=3 (i.e., question C1=3) PCP\_TX ----- C2.PCP TREATMENT TAKEN type: numeric (float) label: PCP\_TX range: [1,2] units: 1 coded missing: 0 / 2132 unique values: 2 tabulation: Freq. Numeric Label 78 1 1:Yes 2054 2 2:No MAC PROP ----- C3.MAC PROPHYLAXIS OR TREATMENT type: numeric (float) label: MAC\_PROP range: [1,3] units: 1 coded missing: 8 / 2132 unique values: 3 tabulation: Freq. Numeric Label 1023 1 1:Yes 1072 2 2:No 3 3:Don't Know 29 MAC SPEC ----- C3.MAC SPECIFY STUDY NAME type: string (str60), but longest is str8 unique values: 1 coded missing: 2103 / 2132 tabulation: Freq. Value 29 "ACTG 362" warning: variable has embedded blanks

MAC\_SPEC: 1. Value corresponds to study name if MAC\_PROP=3 (i.e., question C3=3) MAC\_SPE2 ----- C3.MAC SPECIFY NAME OF MED VS. PLACEBO type: string (str60), but longest is str23 unique values: 1 coded missing: 2103 / 2132 tabulation: Freq. Value 29 "AZITHROMYCIN VS PLACEBO" warning: variable has embedded blanks MAC\_SPE2: 1. Value corresponds to study drug if question MAC\_PROP=3 (i.e., question C3=3) CHEMO ----- C4.CHEMOTHERAPY type: numeric (float) label: CHEMO range: [1,2] units: 1 unique values: 2 coded missing: 0 / 2132 tabulation: Freq. Numeric Label 1 1:Yes 124 2008 2 2:No TX\_WASTE ----- C5.TREATMENT FOR WASTING type: numeric (float) label: TX\_WASTE 

 range:
 [1,2]
 units:
 1

 unique values:
 2
 coded missing:
 0 / 2132

 tabulation: Freq. Numeric Label 1 1:Yes 416 1716 2 2:No TPN ----- C6.TOTAL PARENTERAL NUTRITION type: numeric (float) label: TPN units: 1 range: [1,2] coded missing: 0 / 2132 unique values: 2 tabulation: Freq. Numeric Label 40 1 1:Yes 2092 2 2:No

#### Codebook – Form 23 – Quarterly Medication History Form – Dataset: FM23DATA

FLU\_VACC ----- D1.FLU VACCINE type: numeric (float) label: FLU\_VACC range: [1,2] units: 1 unique values: 2 coded missing: 1 / 2132 tabulation: Freq. Numeric Label 
 282
 1
 1:Yes

 1849
 2
 2:No
 FLU DATE ----- Dla. FLU VACCINE DATE type: numeric (float) range: [0,1155] coded missing: 1850 / 2132 units: 1 unique values: 233 mean: 421.511 std. dev: 295.544 10% 25% 50% 75% 90% 68 180 378.5 601 895 percentiles: FLU DATE: 1. This variable has been coded as the number of days since Randomization (Negative values indicate dates before Randomization; positive values indicate dates subsequent to Randomization) FLU DATZ ----- DATE IMPUTATION INDICATOR -- FLU DATE type: numeric (float) label: FLU\_DATZ range: [1,2]
unique values: 2 units: 1 coded missing: 0 / 2132 tabulation: Freq. Numeric Label 2117 1 Date not imputed 15 2 15th of month imputed FLU DATZ: 1. Indicator of whether the associated date variable is (1) complete (or entirely missing), or (2) incomplete with day of month missing, or (3) incomplete with day and month of year missing. PNEUMO\_V ----- D2.PNEUMOCOCCAL VACCINE type: numeric (float)
label: PNEUMO\_V range: [1,2] values: 2 units: 1 unique values: 2 coded missing: 1 / 2132 tabulation: Freq. Numeric Label 5911:Yes207222:No

PNEUM\_DT ----- D2a.PNEUMOCOCCAL VACCINE DATE type: numeric (float) units: 1 coded missing: 2073 / 2132 range: [13,948] unique values: 55 mean: 333.271 std. dev: 264.548 25% 10% 25% 49 121 50% 75% 90% 229 518 779 percentiles: 90% PNEUM DT: 1. This variable has been coded as the number of days since Randomization (Negative values indicate dates before Randomization; positive values indicate dates subsequent to Randomization) PNEUM\_DZ ----- DATE IMPUTATION INDICATOR -- PNEUM\_DT type: numeric (float) label: PNEUM\_DZ units: 1 coded missing: 0 / 2132 range: [1,2] unique values: 2 tabulation: Freq. Numeric Label 2131 1 Date not imputed 1 2 15th of month imputed PNEUM DZ: 1. Indicator of whether the associated date variable is (1) complete (or entirely missing), or (2) incomplete with day of month missing, or (3) incomplete with day and month of year missing. OTH VACC ----- D3.OTHER VACCINE type: numeric (float) label: OTH\_VACC range: [1,2] units: 1 unique values: 2 coded missing: 1 / 2132 tabulation: Freq. Numeric Label 52 1 1:Yes 2079 2 2:No

VACCSPC1 ----- D3a1.SPECIFY OTHER VACCINE 1 type: string (str30), but longest is str19 unique values: 18 coded missing: 2080 / 2132 tabulation: Freq. Value 1 "DPT" 1 "HAVRIX- HEPATITIS A" 3 "HEP A" 2 "HEP A VACCINE" 2 "HEP B" 1 "HEP B VACCINE" 1 "HEP. A VACCINE" 13 "HEPATITIS A" 2 "HEPATITIS A VACCINE" 7 "HEPATITIS B" 1 "HEPATITIS B-" "MENINGIOCOCAL" 1 1 "TD" 1 "TETANAS (TD)" 11 "TETANUS" 1 "TETANUS BOOSTER" 1 "TETNAS" 2 "TETNUS" warning: variable has embedded blanks VACC DT1 ----- D3a2.OTHER VACCINE 1 DATE type: numeric (float) range: [21,1259] units. 1 coded missing: 2080 / 2132 unique values: 52 mean: 615.865 std. dev: 358.367 75% 5. 50% percentiles: 10% 25% 90% 277 642 890.5 131 VACC DT1: 1. This variable has been coded as the number of days since Randomization (Negative values indicate dates before Randomization; positive values indicate dates subsequent to Randomization) VAC DT1Z ----- DATE IMPUTATION INDICATOR -- VACC DT1 type: numeric (float) label: VAC\_DT1Z range: [1,2] units: 1 coded missing: 0 / 2132 unique values: 2 tabulation: Freq. Numeric Label 2130 1 Date not imputed 2 15th of month imputed 2

VAC\_DT1Z: 1. Indicator of whether the associated date variable is (1) complete (or entirely missing), or (2) incomplete with day of month missing, or (3) incomplete with day and month of year missing. VACCSPC2 ----- D3b1.SPECIFY OTHER VACCINE 2 type: string (str30), but longest is str13 unique values: 6 coded missing: 2124 / 2132 tabulation: Freq. Value 1 "HEP A" 1 "HEP B VACCINE" 2 "HEPATITIS A" 2 "HEPATITIS B" 1 "TETANUS" 1 "TETNUS" warning: variable has embedded blanks VACC\_DT2 ----- D3b2.OTHER VACCINE DATE 2 type: numeric (float) range: [161,1045] units: 1 coded missing: 2124 / 2132 unique values: 8 tabulation: Freq. Value 1 161 1 433 1 677 735 1 779 1 861 1 1 902 1045 1

VACC\_DT2:

1. This variable has been coded as the number of days since Randomization (Negative values indicate dates before Randomization; positive values indicate dates subsequent to Randomization)

PUB ID						SUBJECT ID
—		c (float				BODOECI ID
_	[1,530	]			nits: 1	
unique values:	362			coded miss	sing: 0 /	8176
mean: std. dev:	266.90 153.78					
percentiles:			25% 141	50% 272		
VISNUMtype:	string				A:	2.VISIT NUMBER
unique values:	15			coded miss	sing: 0 /	8176
<pre>tabulation: VISNUM: 1. This form is only Therefore, this vanishing</pre>	1216 1097 1003 888 745 669 606 479 401 361 310 225 105 48 23	"03" "06" "09" "12" "15" "18" "21" "24" "27" "30" "33" "36" "39" "42" "45" quarter	-			
	LIADIC .	is aiway	5 0000	a as 05, 00	, 0, есс	•
DRUGCODE						B2a.DRUG CODE
type:	numerio	c (float	)			
range: unique values:	[1,53] 43			un coded miss	nits: 1 sing: 0 /	8176
mean: std. dev:						
percentiles:	:	10% 2	25% 7	50% 11	75% 14	90% 26
DRUGCODE: 1. Drug codes differ FM23.doc).	across :	form ver	sions	(see docume	entation f	ile

# QUARTERLY MEDICATION HISTORY FORM – FM23DATB CODEBOOK

START\_DT ----- B2b.DATE STARTED DRUG type: numeric (float) range: [0,1258] units: 1 coded missing: 6115 / 8176 unique values: 586 mean: 296.087 std. dev: 285.202 50% ७๖<sub>ಌ</sub> ^ 454 75% yu. 786 10% 25% percentiles: 90% 190 72 22 START DT: 1. This variable has been coded as the number of days since Randomization (Negative values indicate dates before Randomization, positive values indicate dates subsequent to Randomization). START\_DZ ----- DATE IMPUTATION INDICATOR -- START\_DT type: numeric (float) label: START\_DZ range: [1,3]
unique values: 3 units: 1 coded missing: 0 / 8176 tabulation: Freq. Numeric Label 1 Date not imputed 8112 2 15th of month imputed 62 2 3 July 1 imputed START DZ: 1. Indicator of whether the associated date variable is (1) complete (or entirely missing), or (2) incomplete with day of month missing, or (3) incomplete with day and month of year missing. FRMBEFOR ----- MED CONTINUING FROM PREV VISIT type: numeric (float) label: FRMBEFOR units: 1 coded missing: 6 / 8176 range: [1,2] unique values: 2 tabulation: Freq. Numeric Label 6109 1 Continuing 2061 2 Started since previous FRMBEFOR:

1. Created variable to distinguish between whether the medication is continuing from a previous visit versus medication started since previous visit (see documentation file FM23.doc).

#### Codebook – Form 23 – Quarterly Medication History Form – Dataset: FM23DATB

CONTINUE					B2c.STILL	TAKING DRUG
	type:	numeric (floa	t)			
		CONTINUE	,			
	100011	001111101				
		[1 0]			ts: 1	
	range:					
	unique values:	2		coded missin	ng: 0/8	176
	tabulation:	Freq. Numer		abel		
		6545	1 1	:Yes		
		1631	2 2	:NO		
STOP DT -				B2d.DA	TE STOPPED	TAKING DRUG
STOP_DT ·	 type:			B2d.DA	TE STOPPED	TAKING DRUG
STOP_DT ·		numeric (floa		B2d.DA	IE STOPPED	TAKING DRUG
STOP_DT ·	type:	numeric (floa				TAKING DRUG
STOP_DT ·	type: range:	numeric (floa [-2,1343]		unit	ts: 1	
STOP_DT ·	type:	numeric (floa [-2,1343]			ts: 1	
STOP_DT -	type: range: unique values:	numeric (floa [-2,1343] 558		unit	ts: 1	
STOP_DT -	type: range: unique values:	numeric (floa [-2,1343]		unit	ts: 1	
STOP_DT ·	type: range: unique values:	numeric (floa [-2,1343] 558 349.37		unit	ts: 1	
STOP_DT ·	type: range: unique values: mean:	numeric (floa [-2,1343] 558 349.37		unit	ts: 1	
STOP_DT ·	type: range: unique values: mean: std. dev:	numeric (floa [-2,1343] 558 349.37 292.45	t)	unit coded missin	ts: 1 ng: 6555	/ 8176
STOP_DT ·	type: range: unique values: mean:	numeric (floa [-2,1343] 558 349.37 292.45	t) 25	unit	ts: 1 ng: 6555	/ 8176

STOP\_DT:

1. This variable has been coded as the number of days since Randomization (Negative values indicate dates before Randomization, positive values indicate dates subsequent to Randomization).

STOP\_DTZ ----- INDICATOR -- STOP\_DT type: numeric (float) label: STOP\_DTZ range: [1,3] units: 1 coded missing: 0 / 8176 unique values: 3 tabulation: Freq. Numeric Label 8085 1 Date not imputed 90 2 15th of month imputed 3 July 1 imputed 1 STOP\_DTZ: 1. Indicator of whether the associated date variable is (1) complete (or entirely missing), or (2) incomplete with day of month missing, or (3) incomplete with day and month of year missing. DRUGSPEC ----- B2a.DRUG SPECIFY type: string (str30) unique values: 71 coded missing: 8063 / 8176 examples: "" .... .... .... warning: variable has embedded blanks