

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.

Medication	Form Versions	
	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 ¹	15	17

Medication	Form Versions	
	08/01/96, 07/22/98	08/01/96, 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 injections	52	52
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 (Roferon, Wellferon, Intron A)	29	31
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 e.g. prednisone > 10 mg/day, hydrocortisone > 50 mg/day, dexamethasone > 1 mg/day)	35	37
Systemic Steroids: replacement dose e.g. prednisone ≤ 10 mg/day, hydrocortisone ≤ 50 mg/day, dexamethasone ≤ 1 mg/day)	36	38
Blinded study medications (in above categories)		
Blinded Study Medications ²	37	39

¹ All “other antiretrovirals” were retrospectively recoded as one of the specific numbered antiretrovirals

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

Form 23 – Quarterly Medication History Form – Introduction/ QXQ

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.	<input type="text" value="3"/> <input type="text" value="8"/> <small>IF 15, 25, 34, OR 37, SPECIFY ↓</small> <input style="width: 350px; height: 20px;" type="text"/>	<input type="text" value="-"/> <input type="text" value="-"/> / <input type="text" value="-"/> <input type="text" value="-"/> / <input type="text" value="-"/> <input type="text" value="-"/>	<input type="checkbox"/> 1. Yes <input checked="" type="checkbox"/> 2. No →	<input type="text" value="0"/> <input type="text" value="8"/> / <input type="text" value="1"/> <input type="text" value="0"/> / <input type="text" value="9"/> <input type="text" value="5"/>

	a. Drug Code?	b. Date Started?	c. Still Taking?	d. Date Stopped?
B3.	<input type="text" value="3"/> <input type="text" value="8"/> <small>IF 15, 25, 34, OR 37, SPECIFY ↓</small> <input style="width: 350px; height: 20px;" type="text"/>	<input type="text" value="0"/> <input type="text" value="8"/> / <input type="text" value="2"/> <input type="text" value="0"/> / <input type="text" value="9"/> <input type="text" value="5"/>	<input checked="" type="checkbox"/> 1. Yes <input type="checkbox"/> 2. No →	<input type="text" value=""/> <input type="text" value=""/> / <input type="text" value=""/> <input type="text" value=""/> / <input type="text" value=""/> <input type="text" value=""/>

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 ddI 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**

SECTION A -- GENERAL INFORMATION

- A1. Subject ID: (ENTER ID NUMBER OR AFFIX LABEL AT THE RIGHT) _____ - _____ - ____
- A2. Visit number: __ __
- A3. Subject initials: __ . __ . __ .
- A4. Form version: _0_1_ / _1_5_ / _9_6_
- A5. Today's date: __ __ / __ __ / __ __
- A6. Initials of person completing form: __ . __ . __ .

SECTION 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 multiple entries (i.e. B2, B3...) to indicate multiple start/stop dates or interruptions > 7 days for a given drug.
Date Started required only if drug started since the last quarterly visit.**

	a. Drug Code?	b. Date Started?	c. Still Taking?	d. Date Stopped?
B2.	<div style="border: 1px solid black; padding: 2px; width: 100%;"> _____ <small>IF 15, 25, 34, OR 37, SPECIFY ↓</small> </div>	<div style="border: 1px solid black; padding: 2px; width: 100%;"> __ __ / __ __ / __ __ </div>	<input type="checkbox"/> 1. Yes <input type="checkbox"/> 2. No →	<div style="border: 1px solid black; padding: 2px; width: 100%;"> __ __ / __ __ / __ __ </div>
B3.	<div style="border: 1px solid black; padding: 2px; width: 100%;"> _____ <small>IF 15, 25, 34, OR 37, SPECIFY ↓</small> </div>	<div style="border: 1px solid black; padding: 2px; width: 100%;"> __ __ / __ __ / __ __ </div>	<input type="checkbox"/> 1. Yes <input type="checkbox"/> 2. No →	<div style="border: 1px solid black; padding: 2px; width: 100%;"> __ __ / __ __ / __ __ </div>
B4.	<div style="border: 1px solid black; padding: 2px; width: 100%;"> _____ <small>IF 15, 25, 34, OR 37, SPECIFY ↓</small> </div>	<div style="border: 1px solid black; padding: 2px; width: 100%;"> __ __ / __ __ / __ __ </div>	<input type="checkbox"/> 1. Yes <input type="checkbox"/> 2. No →	<div style="border: 1px solid black; padding: 2px; width: 100%;"> __ __ / __ __ / __ __ </div>
B5.	<div style="border: 1px solid black; padding: 2px; width: 100%;"> _____ <small>IF 15, 25, 34, OR 37, SPECIFY ↓</small> </div>	<div style="border: 1px solid black; padding: 2px; width: 100%;"> __ __ / __ __ / __ __ </div>	<input type="checkbox"/> 1. Yes <input type="checkbox"/> 2. No →	<div style="border: 1px solid black; padding: 2px; width: 100%;"> __ __ / __ __ / __ __ </div>

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, megestrol, 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?

- D1. Flu vaccine: 1. Yes → a. Date of flu vaccine:
 2. No 2. No _____ / _____ / _____
- D2. Pneumococcal vaccine: 1. Yes → a. Date of pneumococcal vaccine:
 2. No 2. No _____ / _____ / _____
- D3. Other vaccine(s): 1. Yes → a1. Name of vaccine:
 2. No 2. No _____
 b1. Date of vaccine:
 _____ / _____ / _____
 a2. Name of vaccine:

 b2. Date of vaccine:
 _____ / _____ / _____

END OF FORM

**VIRAL ACTIVATION TRANSFUSION STUDY (VATS)
FORM 23 -- QUARTERLY MEDICATION HISTORY FORM**

SECTION A -- GENERAL INFORMATION

- A1. Subject ID: (ENTER ID NUMBER OR AFFIX LABEL AT THE RIGHT)
- 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:

SECTION 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 multiple entries (i.e. B2, B3...) to indicate multiple start/stop dates or interruptions > 7 days for a given drug.
Date Started required only if drug started since the last quarterly visit.

a. Drug Code?	b. Date Started?	c. Still Taking?	d. Date Stopped?
B2. <input type="text"/> IF 17, 27, 36, OR 39, SPECIFY ↓ <input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1. Yes <input type="checkbox"/> 2. No →	<input type="text"/>
B3. <input type="text"/> IF 17, 27, 36, OR 39, SPECIFY ↓ <input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1. Yes <input type="checkbox"/> 2. No →	<input type="text"/>
B4. <input type="text"/> IF 17, 27, 36, OR 39, SPECIFY ↓ <input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1. Yes <input type="checkbox"/> 2. No →	<input type="text"/>
B5. <input type="text"/> IF 17, 27, 36, OR 39, SPECIFY ↓ <input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1. Yes <input type="checkbox"/> 2. No →	<input type="text"/>

ATTACH COPIES OF THIS PAGE IF ADDITIONAL SPACE IS REQUIRED

SECTION C – MEDICATION HISTORY

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

(For example TMP-SMX, dapsone, pentamidine, atovaquone, clindamycin/primaquine)

1. Yes

2. No

3. Don't know, placebo-controlled blinded study ↓

(Specify the study & name of medication vs. placebo)

C2. PCP treatment

(For example TMP-SMX, dapsone, pentamidine, atovaquone, clindamycin/primaquine)

1. Yes

2. No

C3. MAC prophylaxis/treatment

(For example rifabutin, clarithromycin, ethambutol, ciprofloxacin, clofazimine, rifampin, amikacin, azithromycin)

1. Yes

2. No

3. Don't know, placebo-controlled blinded study ↓

(Specify the study & name of medication vs. placebo)

C4. Systemic chemotherapy for malignancies

1. Yes

2. No

C5. Treatment for wasting

(For example marinol, megestrol, testosterone, growth hormone)

1. Yes

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?

D1. Flu vaccine:

1. Yes

2. No

→

a. Date of flu vaccine:

__ __ / __ __ / __ __

D2. Pneumococcal vaccine:

1. Yes

2. No

→

a. Date of pneumococcal vaccine:

__ __ / __ __ / __ __

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 (float)

range: [1,530] units: 1

unique values: 373 coded missing: 0 / 2132

mean: 265.396

std. dev: 155.718

percentiles: 10% 25% 50% 75% 90%

43 133 271 400.5 484

VISNUM ----- A2.VISIT NUMBER

type: string (str2)

unique values: 15 coded missing: 0 / 2132

tabulation: Freq. Value

342	"03"
291	"06"
255	"09"
220	"12"
193	"15"
172	"18"
153	"21"
125	"24"
104	"27"
90	"30"
80	"33"
58	"36"
28	"39"
15	"42"
6	"45"

VISNUM:

1. 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.

FORM_V ----- A4.FORM VERSION DATE

type: numeric (float)
 label: FORM_V

 range: [12979,14082] units: 1
 unique values: 4 coded missing: 0 / 2132

 tabulation: Freq. Numeric Label
 54 12979 07/15/95
 173 13163 01/15/96
 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
 unique values: 791 coded missing: 0 / 2132

 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

 range: [1,2] units: 1
 unique values: 2 coded missing: 0 / 2132

 tabulation: Freq. Numeric Label
 1849 1 1:Yes
 283 2 2:No

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 ----- D1a. FLU VACCINE DATE

type: numeric (float)

range: [0,1155] units: 1
 unique values: 233 coded missing: 1850 / 2132

mean: 421.511
 std. dev: 295.544

percentiles:	10%	25%	50%	75%	90%
	68	180	378.5	601	895

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] units: 1
 unique values: 2 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] units: 1
 unique values: 2 coded missing: 1 / 2132

tabulation:	Freq.	Numeric	Label
	59	1	1:Yes
	2072	2	2:No

PNEUM_DT ----- D2a.PNEUMOCOCCAL VACCINE DATE
 type: numeric (float)
 range: [13,948] units: 1
 unique values: 55 coded missing: 2073 / 2132
 mean: 333.271
 std. dev: 264.548
 percentiles: 10% 25% 50% 75% 90%
 49 121 229 518 779

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
 range: [1,2] units: 1
 unique values: 2 coded missing: 0 / 2132
 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

VAC_DT1Z:

- 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

unique values: 8

coded missing: 2124 / 2132

tabulation:	Freq.	Value
	1	161
	1	433
	1	677
	1	735
	1	779
	1	861
	1	902
	1	1045

VACC_DT2:

- 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)

QUARTERLY MEDICATION HISTORY FORM – FM23DATB CODEBOOK

PUB_ID ----- SUBJECT ID
 type: numeric (float)
 range: [1,530] units: 1
 unique values: 362 coded missing: 0 / 8176
 mean: 266.908
 std. dev: 153.781
 percentiles: 10% 25% 50% 75% 90%
 43 141 272 400 484

VISNUM ----- A2.VISIT NUMBER
 type: string (str2)
 unique values: 15 coded missing: 0 / 8176
 tabulation: Freq. Value
 1216 "03"
 1097 "06"
 1003 "09"
 888 "12"
 745 "15"
 669 "18"
 606 "21"
 479 "24"
 401 "27"
 361 "30"
 310 "33"
 225 "36"
 105 "39"
 48 "42"
 23 "45"

VISNUM:

1. 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.

DRUGCODE ----- B2a.DRUG CODE
 type: numeric (float)
 range: [1,53] units: 1
 unique values: 43 coded missing: 0 / 8176
 mean: 12.8878
 std. dev: 9.70731
 percentiles: 10% 25% 50% 75% 90%
 2 7 11 14 26

DRUGCODE:

1. Drug codes differ across form versions (see documentation file FM23.doc).

START_DT ----- B2b.DATE STARTED DRUG

type: numeric (float)
 range: [0,1258] units: 1
 unique values: 586 coded missing: 6115 / 8176
 mean: 296.087
 std. dev: 285.202
 percentiles: 10% 25% 50% 75% 90%
 22 72 190 454 786

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] units: 1
 unique values: 3 coded missing: 0 / 8176
 tabulation: Freq. Numeric Label
 8112 1 Date not imputed
 62 2 15th of month imputed
 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
 range: [1,2] units: 1
 unique values: 2 coded missing: 6 / 8176
 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).

CONTINUE ----- B2c.STILL TAKING DRUG

type: numeric (float)
 label: CONTINUE

range: [1,2] units: 1
 unique values: 2 coded missing: 0 / 8176

tabulation:	Freq.	Numeric	Label
	6545	1	1:Yes
	1631	2	2:No

STOP_DT ----- B2d.DATE STOPPED TAKING DRUG

type: numeric (float)

range: [-2,1343] units: 1
 unique values: 558 coded missing: 6555 / 8176

mean: 349.37
 std. dev: 292.45

percentiles:	10%	25%	50%	75%	90%
	36	104	271	535	812

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 ----- DATE IMPUTATION INDICATOR -- STOP_DT

type: numeric (float)
 label: STOP_DTZ

range: [1,3] units: 1
 unique values: 3 coded missing: 0 / 8176

tabulation:	Freq.	Numeric	Label
	8085	1	Date not imputed
	90	2	15th of month imputed
	1	3	July 1 imputed

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