

## INTRODUCTION TO FORM 5 – BASELINE 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.

<b>Medication</b>	<b>Form Versions</b>	
	07/15/95, 01/15/96	08/01/96, 07/22/98
<b>Antiretrovirals</b>		
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

<b>Medication</b>	<b>Form Versions</b>	
	08/01/96, 07/22/98	08/01/96, 07/22/98
<b>Antivirals</b>		
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
<b>Erythropoetin (EPO)</b>		
erythropoetin (EPO)	26	28
<b>Systemic Immunomodulators</b>		
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
<b>Systemic Corticosteroids</b>		
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
<b>Blinded study medications (in above categories)</b>		
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 specific numbered medications upon unblinding.

**BASELINE MEDICATION HISTORY FORM -- FORM 5 QxQ**

Information requested in this form may be obtained through participant interview, medical record review, or both. We are primarily interested in medicines taken in the past month, i.e., 30 days prior to the participant's VATS enrollment visit. 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.** At the baseline visit, this question will always be completed in advance by the Medical Coordinating Center. Since this form is **only** used at the baseline visit, this number will always be "00".
- 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.
- 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.** In the 30 days prior to this 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

If the participant has not taken any drugs that fall within these categories in the last 30 days, 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 in the last 30 days. For example, assume the participant has been taking 5 mg of Prednisone every other day for the last 3 months, but discontinued therapy for a 10-day period, restarting the day prior to an enrollment date of 6/1/95. The entries should be recorded as follows:

	a. Drug Code?	b. Date Started?	c. Still Taking?	d. Date Stopped?
B2.	<u>  3  </u> <u>  8  </u> IF 15, 25, 34, OR 37, SPECIFY ↓ <div style="border: 1px solid black; height: 20px; width: 100%; margin-top: 5px;"></div>	<u>  0  </u> <u>  3  </u> / <u>  -</u> <u>  -</u> / <u>  9  </u> <u>  5  </u>	<input type="checkbox"/> 1. Yes <input checked="" type="checkbox"/> 2. No →	<u>  0  </u> <u>  5  </u> / <u>  2  </u> <u>  1  </u> / <u>  9  </u> <u>  5  </u>

	a. Drug Code?	b. Date Started?	c. Still Taking?	d. Date Stopped?
B3.	<u>  3  </u> <u>  8  </u> IF 15, 25, 34, OR 37, SPECIFY ↓ <div style="border: 1px solid black; height: 20px; width: 100%; margin-top: 5px;"></div>	<u>  0  </u> <u>  5  </u> / <u>  3  </u> <u>  1  </u> / <u>  9  </u> <u>  5  </u>	<input checked="" type="checkbox"/> 1. Yes <input type="checkbox"/> 2. No →	<u>  -</u> <u>  -</u> / <u>  -</u> <u>  -</u> / <u>  -</u> <u>  -</u>

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

For **part a** enter the 2-digit code that corresponds with each drug taken (if 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** enter the original date the participant started the medication. If the exact day 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. Attach copies of page 2 if additional space is required.

**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 in the last 30 days*. 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 taken PCP prophylaxis in the last 30 days, check "Yes" and proceed to question C2. If the patient is not on or has not been on PCP prophylaxis in the last 30 days, 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 taken/received MAC prophylaxis/treatment in the last 30 days, check “Yes” and proceed to question C4. If the patient is not on or has not been on MAC prophylaxis/treatment in the last 30 days, 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 *in the last 3 months*. If either was received in the last 3 months, record the date, or at least month and year the participant received the vaccine.

- D3.** Either through self-report or medical record review, indicate whether the participant received other vaccines *in the last 3 months*. 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 5 -- BASELINE MEDICATION HISTORY**

**SECTION A -- GENERAL INFORMATION**

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

\_\_\_\_ - \_\_\_\_ - \_\_\_\_

A2. Visit number:

0 0

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. In the last 30 days, 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.**

a. Drug Code?

b. Date Started?

c. Still Taking?

d. Date Stopped?

B2.

\_\_\_\_  
IF 15, 25, 34, OR 37, SPECIFY ↓

\_\_\_\_

1. Yes

2. No →

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

**Use multiple entries (i.e. B2, B3...) to indicate multiple start/stop dates or interruptions > 7 days for a given drug.**

a. Drug Code?

b. Date Started?

c. Still Taking?

d. Date Stopped?

B3.

\_\_\_\_  
IF 15, 25, 34, OR 37, SPECIFY ↓

\_\_\_\_

1. Yes

2. No →

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

B4.

\_\_\_\_  
IF 15, 25, 34, OR 37, SPECIFY ↓

\_\_\_\_

1. Yes

2. No →

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

B5.

\_\_\_\_  
IF 15, 25, 34, OR 37, SPECIFY ↓

\_\_\_\_

1. Yes

2. No →

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

B6.

\_\_\_\_  
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, in the last 30 days has the 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 in the last 3 months?

- 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 → a1. Name of vaccine:   
 2. No   
 b1. Date of vaccine:   
 a2. Name of vaccine:   
 b2. Date of vaccine:

**END OF FORM**

**VIRAL ACTIVATION TRANSFUSION STUDY (VATS)  
FORM 5 -- BASELINE MEDICATION HISTORY**

**SECTION A -- GENERAL INFORMATION**

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

A2. Visit number: \_0\_ \_0\_

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. In the last 30 days, 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.

a. Drug Code?	b. Date Started?	c. Still Taking?	d. Date Stopped?
B2. <span style="border: 1px solid black; padding: 2px;">_____</span> <small>IF 17, 27, 36, OR 39, SPECIFY</small> ↓ <span style="border: 1px solid black; height: 20px; width: 100%;"></span>	<span style="border: 1px solid black; padding: 2px;">_ _ / _ _ / _ _</span>	<input type="checkbox"/> 1. Yes <input type="checkbox"/> 2. No →	<span style="border: 1px solid black; padding: 2px;">_ _ / _ _ / _ _</span>
B3. <span style="border: 1px solid black; padding: 2px;">_____</span> <small>IF 17, 27, 36, OR 39, SPECIFY</small> ↓ <span style="border: 1px solid black; height: 20px; width: 100%;"></span>	<span style="border: 1px solid black; padding: 2px;">_ _ / _ _ / _ _</span>	<input type="checkbox"/> 1. Yes <input type="checkbox"/> 2. No →	<span style="border: 1px solid black; padding: 2px;">_ _ / _ _ / _ _</span>
B4. <span style="border: 1px solid black; padding: 2px;">_____</span> <small>IF 17, 27, 36, OR 39, SPECIFY</small> ↓ <span style="border: 1px solid black; height: 20px; width: 100%;"></span>	<span style="border: 1px solid black; padding: 2px;">_ _ / _ _ / _ _</span>	<input type="checkbox"/> 1. Yes <input type="checkbox"/> 2. No →	<span style="border: 1px solid black; padding: 2px;">_ _ / _ _ / _ _</span>
B5. <span style="border: 1px solid black; padding: 2px;">_____</span> <small>IF 17, 27, 36, OR 39, SPECIFY</small> ↓ <span style="border: 1px solid black; height: 20px; width: 100%;"></span>	<span style="border: 1px solid black; padding: 2px;">_ _ / _ _ / _ _</span>	<input type="checkbox"/> 1. Yes <input type="checkbox"/> 2. No →	<span style="border: 1px solid black; padding: 2px;">_ _ / _ _ / _ _</span>

**ATTACH COPIES OF THIS PAGE IF ADDITIONAL SPACE IS REQUIRED**



**SECTION C -- MEDICATION HISTORY**

Including blinded studies with active controls, in the last 30 days has the 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  
 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, pentamidine, atovaquone, clindamycin/primaquine)  2. No  
 3. Don't know, placebo-controlled blinded study ↓  
  
 (Specify the study & name of medication vs. placebo)

C3. MAC prophylaxis/treatment  1. Yes  
 (For example rifabutin, clarithromycin, ethambutol, ciprofloxacin, clofazimine, rifampin, amikacin, azithromycin)  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  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 in the last 3 months?

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**

## BASELINE MEDICATION HISTORY FORM – FM05DATA

PUB\_ID ----- SUBJECT ID

type: numeric (float)

range: [1,531] units: 1  
 unique values: 528 coded missing: 0 / 528

mean: 266.491  
 std. dev: 153.568

percentiles:	10%	25%	50%	75%	90%
	53	133.5	266.5	399.5	479

VISNUM ----- A2.VISIT NUMBER

type: string (str2)

unique values: 1 coded missing: 0 / 528

tabulation:	Freq.	Value
	528	"00"

VISNUM:

1. Since this form is only used at baseline visit (QU 00), this variable is always coded as 00.

FORM\_V ----- A4.FORM VERSION DATE

type: numeric (float)  
 label: FORM\_V

range: [12979,14082] units: 1  
 unique values: 4 coded missing: 0 / 528

tabulation:	Freq.	Numeric	Label
	162	12979	07/15/95
	137	13163	01/15/96
	227	13362	08/01/96
	2	14082	07/22/98

COMP\_D ----- A5.DATE FORM COMPLETED (TODAY'S DATE)

type: numeric (float)

range: [-3,315] units: 1  
 unique values: 35 coded missing: 0 / 528

mean: 3.25947  
 std. dev: 19.5188

percentiles:	10%	25%	50%	75%	90%
	0	0	0	1	6

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.RECEIVED ANY OF FOLLOWING MEDS

type: numeric (float)  
 label: RECVMEDS

range: [1,2] units: 1  
 unique values: 2 coded missing: 0 / 528

tabulation:	Freq.	Numeric	Label
	436	1	1:Yes
	92	2	2:No

PCP\_PROP ----- C1.PCP PROPHYLAXIS

type: numeric (float)  
 label: PCP\_PROP

range: [1,2] units: 1  
 unique values: 2 coded missing: 0 / 528

tabulation:	Freq.	Numeric	Label
	463	1	1:Yes
	65	2	2:No

PCPSPEC ----- C1.PCP SPECIFY STUDY NAME

type: string (str60), but longest is str0

unique values: 0 coded missing: 528 / 528

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: 528 / 528

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

type: numeric (float)  
 label: PCP\_TX

range: [1,2] units: 1  
 unique values: 2 coded missing: 0 / 528

tabulation:	Freq.	Numeric	Label
	70	1	1:Yes
	458	2	2:No

MAC\_PROP ----- C3.MAC PROPHYLAXIS OR TREATMENT

type: numeric (float)  
label: MAC\_PROP

range: [1,2] units: 1  
unique values: 2 coded missing: 0 / 528

tabulation:	Freq.	Numeric	Label
	243	1	1:Yes
	285	2	2:No

MAC\_SPEC ----- C3.MAC SPECIFY STUDY NAME

type: string (str60), but longest is str0

unique values: 0 coded missing: 528 / 528

tabulation: Freq. Value

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 str0

unique values: 0 coded missing: 528 / 528

tabulation: Freq. Value

MAC\_SPE2:

1. Value corresponds to study drug if question MAC\_PROP=3 (i.e., question C3=3)

CHEMO ----- C4.SYSTEMIC CHEMOTHERAPY

type: numeric (float)  
label: CHEMO

range: [1,2] units: 1  
unique values: 2 coded missing: 0 / 528

tabulation:	Freq.	Numeric	Label
	37	1	1:Yes
	491	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 / 528

tabulation:	Freq.	Numeric	Label
	123	1	1:Yes
	405	2	2:No

TPN ----- C6.TOTAL PARENTERAL NUTRITION

type: numeric (float)  
label: TPN

range: [1,2] units: 1  
unique values: 2 coded missing: 0 / 528

tabulation:	Freq.	Numeric	Label
	13	1	1:Yes
	515	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 / 528

tabulation:	Freq.	Numeric	Label
	56	1	1:Yes
	471	2	2:No

FLU\_DATE ----- D1a.DATE OF FLU VACCINE

type: numeric (float)

range: [-388,1] units: 1  
unique values: 42 coded missing: 472 / 528

mean: -62.6607  
std. dev: 60.1792

percentiles:	10%	25%	50%	75%	90%
	-116	-82.5	-50	-29	-8

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: [1,3] units: 1  
unique values: 3 coded missing: 0 / 528

tabulation:	Freq.	Numeric	Label
	522	1	Date not imputed
	4	2	15th of month imputed
	2	3	July 1 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 / 528  
  
 tabulation: Freq. Numeric Label  
               32          1 1:Yes  
               495         2 2:No

PNEUM\_DT ----- D2a.DATE OF PNEUMOCOCCAL VACCINE

type: numeric (float)  
  
 range: [-329,0] units: 1  
 unique values: 28 coded missing: 496 / 528  
  
 mean: -53.0313  
 std. dev: 58.6045  
  
 percentiles:       10%      25%      50%      75%      90%  
                       -89      -81     -39.5     -20      -8

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 / 528  
  
 tabulation: Freq. Numeric Label  
               524          1 Date not imputed  
               4              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 VACCINES

type: numeric (float)  
 label: OTH\_VACC  
  
 range: [1,2] units: 1  
 unique values: 2 coded missing: 1 / 528  
  
 tabulation: Freq. Numeric Label  
               6          1 1:Yes  
               521         2 2:No

VACCSPC1 ----- D3a1.OTHER VACCINE 1

type: string (str30), but longest is str22

unique values: 4                      coded missing: 522 / 528

tabulation:	Freq.	Value
	2	"HEPATITIS B"
	1	"LEDERLE PUROGENATED TD"
	2	"TETANUS"
	1	"TETANUS TD"

warning: variable has embedded blanks

VACC\_DT1 ----- D3b1.DATE OF OTHER VACCINE 1

type: numeric (float)

range: [-80,-7]                      units: 1  
unique values: 5                      coded missing: 523 / 528

tabulation:	Freq.	Value
	1	-80
	1	-44
	1	-36
	1	-15
	1	-7

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  
unique values: 2                      coded missing: 0 / 528

tabulation:	Freq.	Numeric	Label
	527	1	Date not imputed
	1	2	15th of month imputed

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 ----- D3a2.OTHER VACCINE 2

type: string (str30), but longest is str4

unique values: 1                      coded missing: 527 / 528

tabulation:	Freq.	Value
	1	"-1-1"



## BASELINE MEDICATION HISTORY FORM – FM05DATB

PUB\_ID ----- SUBJECT ID

type: numeric (float)

range: [1,530]

units: 1

unique values: 435

coded missing: 0 / 1137

mean: 269.215

std. dev: 151.583

percentiles:	10%	25%	50%	75%	90%
	61	140	271	402	483

VISNUM ----- A2.VISIT NUMBER

type: string (str2)

unique values: 1

coded missing: 0 / 1137

tabulation:	Freq.	Value
	1137	"00"

VISNUM:

1. Since this form is only used at baseline visit (QU 00), this variable is always coded as 00.

DRUGCODE ----- B2a.DRUG CODE

type: numeric (float)

range: [1,53]

units: 1

unique values: 36

coded missing: 0 / 1137

mean: 14.1715

std. dev: 8.58294

percentiles:	10%	25%	50%	75%	90%
	7	7	13	16	26

DRUGCODE:

1. Drug codes differ across form versions (see documentation file FM05.doc).

START\_DT ----- B2b.DATE STARTED TAKING DRUG

type: numeric (float)

range: [-2841,11]

units: 1

unique values: 394

coded missing: 8 / 1137

mean: -211.385

std. dev: 367.572

percentiles:	10%	25%	50%	75%	90%
	-542	-215	-88	-31	-11

## 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 / 1137

tabulation:	Freq.	Numeric	Label
	1042	1	Date not imputed
	79	2	15th of month imputed
	16	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.

## CONTINUE ----- B2c.STILL TAKING DRUG

type: numeric (float)  
 label: CONTINUE  
  
 range: [1,2] units: 1  
 unique values: 2 coded missing: 0 / 1137

tabulation:	Freq.	Numeric	Label
	875	1	1:Yes
	262	2	2:No

## STOP\_DT ----- B2d.DATE STOPPED TAKING DRUG

type: numeric (float)  
  
 range: [-33,26] units: 1  
 unique values: 40 coded missing: 875 / 1137  
  
 mean: -7.22137  
 std. dev: 8.92437  
  
 percentiles:      10%      25%      50%      75%      90%  
                      -20      -13      -5      -1      0

## 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: [1,2]

units: 1

unique values: 2

coded missing: 0 / 1137

tabulation:	Freq.	Numeric	Label
	1133	1	Date not imputed
	4	2	15th of month 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.SPECIFY OTHER DRUG NAME

type: string (str30), but longest is str25

unique values: 28

coded missing: 1105 / 1137

examples: ""  
 ""  
 ""  
 ""

warning: variable has embedded blanks