

INTRODUCTION TO FORM 21

Sections C and D of this form were used as a mechanism for triggering further medical record abstraction (to be recorded on Form 22).

QUARTERLY MEDICAL HISTORY -- FORM 21

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.
- 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 -- MEDICAL HISTORY

Use patient self-report and other available medical records as sources for this form.

- B1.** This question serves as a prompt to obtain medical records and report any transfusions that may have occurred at a location other than the VATS site, and to complete the Transfusion Monitoring Form (Form 43), when appropriate.

B2 and B2a.

Ascertain whether or not the participant has **begun** any type of dialysis (i.e. hemo peritoneal) for pre-existing or newly diagnosed renal failure since the last quarterly visit. If yes, indicate whether the participant is currently on any type of dialysis.

- B3.** Ascertain and record whether or not participant has had an outbreak of herpes simplex or symptoms related to either oral or anogenital herpes at anytime in the last 30 days.

SECTION C -- HIV RELATED COMPLICATIONS

This section is used to ascertain history of HIV related complications since the last quarterly visit. Use patient self-report and any other available medical records as sources for this section. Any event coded "YES" or "DON'T KNOW" will require medical record abstraction.

C7. THROUGH C11.

Ascertain new diagnoses and progression of existing CMV disease. See protocol Section 7.4.1

SECTION D -- HOSPITALIZATIONS

- D1.** If the patient was hospitalized since the last quarterly visit, this will require a medical record abstraction of that hospitalization(s).

VIRAL ACTIVATION TRANSFUSION STUDY (VATS)
FORM 21 -- QUARTERLY MEDICAL HISTORY

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 / 1 5 / 9 5

A5. Today's date:

____ ____ / ____ ____ / ____ ____

A6. Initials of person completing form:

____ . ____ . ____ .

SECTION B -- MEDICAL HISTORY

B1. Since the last quarterly visit, has the patient had any blood products at a location other than the VATS site?

	1. Yes	➔
	2. No	

OBTAIN SIGNED MEDICAL RECORD RELEASE AND COMPLETE ONE NEW TRANSFUSION MONITORING FORM (FORM 43) FOR EACH EVENT.

B2. Since the last quarterly visit, has the patient developed renal failure requiring dialysis?

	1. Yes	➔
	2. No	

a.
 Is the patient on dialysis now?

	1. Yes
	2. No

B3. Has the patient had a symptomatic herpes simplex outbreak in the past 30 days?

	1. Yes
	2. No

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FORM
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(ENTER ID NUMBER OR AFFIX LABEL HERE ---->)

____ _ -- ____ _ -- ____ _

SECTION C -- HIV RELATED COMPLICATIONS (SELF REPORT)

Has the patient been diagnosed with any of the following since the last quarterly visit?

	<u>Yes</u>		<u>No</u>		<u>Don't know</u>	
C1. Bacteremia, catheter related	<input type="checkbox"/>	1. Yes	<input type="checkbox"/>	2. No	<input type="checkbox"/>	3. D/K
C2. Bacteremia, non-catheter related	<input type="checkbox"/>	1. Yes	<input type="checkbox"/>	2. No	<input type="checkbox"/>	3. D/K
C3. Cervical cancer, invasive only	<input type="checkbox"/>	1. Yes	<input type="checkbox"/>	2. No	<input type="checkbox"/>	3. D/K
C4. Coccidioidomycosis, disseminated or extrapulmonary	<input type="checkbox"/>	1. Yes	<input type="checkbox"/>	2. No	<input type="checkbox"/>	3. D/K
C5. Cryptococcosis, extrapulmonary	<input type="checkbox"/>	1. Yes	<input type="checkbox"/>	2. No	<input type="checkbox"/>	3. D/K
C6. Cryptosporidiosis, chronic intestinal (>1 mo's duration).....	<input type="checkbox"/>	1. Yes	<input type="checkbox"/>	2. No	<input type="checkbox"/>	3. D/K
C7. Cytomegalovirus, eye.....	<input type="checkbox"/>	1. Yes	<input type="checkbox"/>	2. No	<input type="checkbox"/>	3. D/K
C8. Cytomegalovirus, central nervous system	<input type="checkbox"/>	1. Yes	<input type="checkbox"/>	2. No	<input type="checkbox"/>	3. D/K
C9. Cytomegalovirus, upper GI	<input type="checkbox"/>	1. Yes	<input type="checkbox"/>	2. No	<input type="checkbox"/>	3. D/K
C10. Cytomegalovirus, lower GI	<input type="checkbox"/>	1. Yes	<input type="checkbox"/>	2. No	<input type="checkbox"/>	3. D/K
C11. Cytomegalovirus, other	<input type="checkbox"/>	1. Yes	<input type="checkbox"/>	2. No	<input type="checkbox"/>	3. D/K
C12. Histoplasmosis, disseminated or extrapulmonary	<input type="checkbox"/>	1. Yes	<input type="checkbox"/>	2. No	<input type="checkbox"/>	3. D/K
C13. Kaposi's sarcoma (lung, lymphedema)	<input type="checkbox"/>	1. Yes	<input type="checkbox"/>	2. No	<input type="checkbox"/>	3. D/K
C14. Lymphoma, Non-Hodgkins.....	<input type="checkbox"/>	1. Yes	<input type="checkbox"/>	2. No	<input type="checkbox"/>	3. D/K
C15. Lymphoma, primary, of brain	<input type="checkbox"/>	1. Yes	<input type="checkbox"/>	2. No	<input type="checkbox"/>	3. D/K
C16. Mycobacterium avium complex or M. kansasii, disseminated or extrapulmonary	<input type="checkbox"/>	1. Yes	<input type="checkbox"/>	2. No	<input type="checkbox"/>	3. D/K
C17. Mycobacterium tuberculosis, any site (pulmonary or extrapulmonary)	<input type="checkbox"/>	1. Yes	<input type="checkbox"/>	2. No	<input type="checkbox"/>	3. D/K
C18. Mycobacterium, other species or unidentified species, disseminated or extrapulmonary	<input type="checkbox"/>	1. Yes	<input type="checkbox"/>	2. No	<input type="checkbox"/>	3. D/K
C19. Pneumocystis carinii pneumonia.....	<input type="checkbox"/>	1. Yes	<input type="checkbox"/>	2. No	<input type="checkbox"/>	3. D/K
C20. Progressive multifocal leukoencephalopathy (PML)	<input type="checkbox"/>	1. Yes	<input type="checkbox"/>	2. No	<input type="checkbox"/>	3. D/K
C21. Toxoplasmosis of the brain	<input type="checkbox"/>	1. Yes	<input type="checkbox"/>	2. No	<input type="checkbox"/>	3. D/K
C22. Other serious bacterial infection (normally sterile	<input type="checkbox"/>	1. Yes	<input type="checkbox"/>	2. No	<input type="checkbox"/>	3. D/K
site, e.g., meningitis, abscess)						

FOR EACH CONDITION REPORTED AS "YES" OR "DON'T KNOW" IN SECTION C, COMPLETE A NEW ENTRY ON FORM 22, IN SECTION B, -- QUARTERLY MEDICAL RECORD ABSTRACTION FORM. OBTAIN SIGNED MEDICAL RECORD RELEASES IF NECESSARY.

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(ENTER ID NUMBER OR AFFIX LABEL HERE ---->)

____ -- ____ -- ____

SECTION D -- HOSPITALIZATIONS

D1. Was the patient hospitalized
since his/her last quarterly visit?

1. Yes

2. No



**OBTAIN SIGNED MEDICAL
RECORD RELEASE,
IF REQUIRED.**

IF PATIENT HAS BEEN HOSPITALIZED SINCE LAST STUDY VISIT, COMPLETE FORM 22, ABSTRACTING HOSPITAL RECORD FOR ANY OF THE HIV RELATED COMPLICATIONS LISTED IN SECTION C. REPORT ALL NEW DEFINITIVE AND PRESUMPTIVE DIAGNOSES ON FORM 22 -- QUARTERLY MEDICAL RECORD ABSTRACTION FORM.

END OF FORM

QUARTERLY MEDICAL HISTORY – FM21DATA CODEBOOK

PUB_ID ----- SUBJECT ID
 type: numeric (float)
 range: [1,530] units: 1
 unique values: 373 coded missing: 0 / 2128
 mean: 265.293
 std. dev: 155.664
 percentiles: 10% 25% 50% 75% 90%
 43 133 271 400 484

VISNUM ----- A2.VISIT NUMBER
 type: string (str2)
 unique values: 15 coded missing: 0 / 2128
 tabulation: Freq. Value
 341 "03"
 291 "06"
 256 "09"
 218 "12"
 193 "15"
 171 "18"
 153 "21"
 126 "24"
 104 "27"
 90 "30"
 80 "33"
 58 "36"
 27 "39"
 14 "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: [12979,12979] units: 1
 unique values: 1 coded missing: 0 / 2128
 tabulation: Freq. Numeric Label
 2128 12979 07/15/95

COMP_D ----- A5.DATE FORM COMPLETED

type: numeric (float)
 range: [50,1380] units: 1
 unique values: 786 coded missing: 0 / 2128
 mean: 464.598
 std. dev: 308.549
 percentiles: 10% 25% 50% 75% 90%
 101 199.5 392 666 934

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)

BLD_PROD ----- B1.RECVD BLD NON-VATS SITE SINCE LST QRT

type: numeric (float)
 label: BLD_PROD
 range: [1,2] units: 1
 unique values: 2 coded missing: 0 / 2128
 tabulation: Freq. Numeric Label
 49 1 1:Yes
 2079 2 2:No

REN_FAIL ----- B2.RENAL FAIL REQ DIAL SINCE LST VISIT

type: numeric (float)
 label: REN_FAIL
 range: [1,2] units: 1
 unique values: 2 coded missing: 0 / 2128
 tabulation: Freq. Numeric Label
 18 1 1:Yes
 2110 2 2:No

DIALYSIS ----- B2a.ON DIALYSIS NOW

type: numeric (float)
 label: DIALYSIS
 range: [1,2] units: 1
 unique values: 2 coded missing: 2110 / 2128
 tabulation: Freq. Numeric Label
 12 1 1:Yes
 6 2 2:No

H_SIMPLX ----- B3. HAD HERPES SIMP OUTBREAK IN 30 DAYS

type: numeric (float)
 label: H_SIMPLX

range: [1,2] units: 1
 unique values: 2 coded missing: 8 / 2128

tabulation:	Freq.	Numeric	Label
	148	1	1:Yes
	1972	2	2:No

BACT_CTH ----- C1.BACTEREMIA CATHETER RELATED

type: numeric (float)
 label: BACT_CTH

range: [1,3] units: 1
 unique values: 3 coded missing: 0 / 2128

tabulation:	Freq.	Numeric	Label
	48	1	1:Yes
	2079	2	2:No
	1	3	3:Don't Know

BACT_NCA ----- C2.BACTEREMIA NON-CATHETER RELATED

type: numeric (float)
 label: BACT_NCA

range: [1,3] units: 1
 unique values: 3 coded missing: 0 / 2128

tabulation:	Freq.	Numeric	Label
	23	1	1:Yes
	2104	2	2:No
	1	3	3:Don't Know

CERVCANC ----- C3.CERVICAL CANCER INVASIVE ONLY

type: numeric (float)
 label: CERVCANC

range: [2,2] units: 1
 unique values: 1 coded missing: 0 / 2128

tabulation:	Freq.	Numeric	Label
	2128	2	2:No

COCCIDIO ----- C4.COCCIDIOIDOMYCOSIS DISSEM OR EXTRAP
 type: numeric (float)
 label: COCCIDIO

range: [2,2] units: 1
 unique values: 1 coded missing: 0 / 2128

tabulation:	Freq.	Numeric	Label
	2128	2	2:No

CRYPTOCO ----- C5.CRYPTOCOCCOSIS EXTRAPULMONARY
 type: numeric (float)
 label: CRYPTOCO

range: [1,2] units: 1
 unique values: 2 coded missing: 0 / 2128

tabulation:	Freq.	Numeric	Label
	2	1	1:Yes
	2126	2	2:No

CRYPTOSP ----- C6.CRYPTOSPORIDIOSIS CHRONIC INTEST
 type: numeric (float)
 label: CRYPTOSP

range: [1,2] units: 1
 unique values: 2 coded missing: 0 / 2128

tabulation:	Freq.	Numeric	Label
	3	1	1:Yes
	2125	2	2:No

CMV_EYE ----- C7.CMV EYE
 type: numeric (float)
 label: CMV_EYE

range: [1,3] units: 1
 unique values: 3 coded missing: 0 / 2128

tabulation:	Freq.	Numeric	Label
	71	1	1:Yes
	2055	2	2:No
	2	3	3:Don't Know

CMV_CNS ----- C8.CMV CENTRAL NERVOUS SYSTEM

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    type: numeric (float)
    label: CMV_CNS

    range: [1,3]                units: 1
unique values: 3                coded missing: 0 / 2128

    tabulation: Freq.  Numeric  Label
                  6         1  1:Yes
                  2121      2  2:No
                  1         3  3:Don't Know
    
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CMV_UGI ----- C9.CMV UPPER GI

```

    type: numeric (float)
    label: CMV_UGI

    range: [1,3]                units: 1
unique values: 3                coded missing: 0 / 2128

    tabulation: Freq.  Numeric  Label
                  10         1  1:Yes
                  2115      2  2:No
                  3         3  3:Don't Know
    
```

CMV_LGI ----- C10.CMV LOWER GI

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    type: numeric (float)
    label: CMV_LGI

    range: [1,3]                units: 1
unique values: 3                coded missing: 0 / 2128

    tabulation: Freq.  Numeric  Label
                  9         1  1:Yes
                  2116      2  2:No
                  3         3  3:Don't Know
    
```

CMV_OTH ----- C11.CMV OTHER

```

    type: numeric (float)
    label: CMV_OTH

    range: [1,3]                units: 1
unique values: 3                coded missing: 0 / 2128

    tabulation: Freq.  Numeric  Label
                  5         1  1:Yes
                  2121      2  2:No
                  2         3  3:Don't Know
    
```

HISTOPL ----- C12.HISTOPLAMOSIS

type: numeric (float)
label: HISTOPL

range: [1,3] units: 1
unique values: 3 coded missing: 0 / 2128

tabulation:	Freq.	Numeric	Label
	4	1	1:Yes
	2121	2	2:No
	3	3	3:Don't Know

KAPOSI ----- C13.KAPOSI'S SARCOMA LUNG, LYMPHEDEMA

type: numeric (float)
label: KAPOSI

range: [1,2] units: 1
unique values: 2 coded missing: 0 / 2128

tabulation:	Freq.	Numeric	Label
	6	1	1:Yes
	2122	2	2:No

LYMPHNON ----- C14.LYMPHOMA NON-HODGKINS

type: numeric (float)
label: LYMPHNON

range: [1,3] units: 1
unique values: 3 coded missing: 0 / 2128

tabulation:	Freq.	Numeric	Label
	6	1	1:Yes
	2121	2	2:No
	1	3	3:Don't Know

LYMPHBRN ----- C15.LYMPHOMA PRIMARY OF BRAIN

type: numeric (float)
label: LYMPHBRN

range: [1,2] units: 1
unique values: 2 coded missing: 0 / 2128

tabulation:	Freq.	Numeric	Label
	4	1	1:Yes
	2124	2	2:No

MYCOAVIU ----- C16.MAC OR M. KANSASII DISSEM OR EXTRAP
 type: numeric (float)
 label: MYCOAVIU

range: [1,3] units: 1
 unique values: 3 coded missing: 0 / 2128

tabulation:	Freq.	Numeric	Label
	33	1	1:Yes
	2093	2	2:No
	2	3	3:Don't Know

MYCOTUBR ----- C17.MYCOBACTERIUM TUBERCULOSIS ANY SITE
 type: numeric (float)
 label: MYCOTUBR

range: [1,3] units: 1
 unique values: 3 coded missing: 0 / 2128

tabulation:	Freq.	Numeric	Label
	5	1	1:Yes
	2121	2	2:No
	2	3	3:Don't Know

MYCO_OTH ----- C18.MYCOBACTERIUM OTH/UNIDENT SPECIES
 type: numeric (float)
 label: MYCO_OTH

range: [2,3] units: 1
 unique values: 2 coded missing: 0 / 2128

tabulation:	Freq.	Numeric	Label
	2127	2	2:No
	1	3	3:Don't Know

PCP ----- C19.PNEUMOCYSTIS CARINII PNEUMONIA
 type: numeric (float)
 label: PCP

range: [1,3] units: 1
 unique values: 3 coded missing: 0 / 2128

tabulation:	Freq.	Numeric	Label
	23	1	1:Yes
	2103	2	2:No
	2	3	3:Don't Know

PML ----- C20.PROG MULTIFOCAL LEUKOENCEPHALOPATHY

type: numeric (float)
 label: PML

 range: [1,2] units: 1
 unique values: 2 coded missing: 0 / 2128

 tabulation: Freq. Numeric Label
 1 1 1:Yes
 2127 2 2:No

TOXOPLAS ----- C21.TOXOPLASMOSIS OF THE BRAIN

type: numeric (float)
 label: TOXOPLAS

 range: [1,2] units: 1
 unique values: 2 coded missing: 0 / 2128

 tabulation: Freq. Numeric Label
 1 1 1:Yes
 2127 2 2:No

BACT_INF ----- C22.OTHER SERIOUS BACTERIAL INFECTION

type: numeric (float)
 label: BACT_INF

 range: [1,3] units: 1
 unique values: 3 coded missing: 0 / 2128

 tabulation: Freq. Numeric Label
 24 1 1:Yes
 2103 2 2:No
 1 3 3:Don't Know

PT_HOSP ----- D1.PT HOSPITALIZED SINCE LAST QRT VISIT

type: numeric (float)
 label: PT_HOSP

 range: [1,2] units: 1
 unique values: 2 coded missing: 0 / 2128

 tabulation: Freq. Numeric Label
 448 1 1:Yes
 1680 2 2:No