

INTRODUCTION TO FORM 4 – BASELINE CMV HISTORY MEDICAL RECORD ABSTRACTION

These data are the result of medical record abstraction for CMV diagnoses prior to baseline. Form 4 was only to be completed if triggered by certain responses on Form 3. Note that CMV retinitis diagnosed within 28 days after baseline (Form 7) was also considered a “baseline” diagnosis but may not appear on Form 4.

BASELINE CMV HISTORY MEDICAL RECORD ABSTRACTION – FORM 4 QxQ

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 -- CMV DISEASE HISTORY

The prompts on Form 3 will lead to completion of Form 4 if there is a known history of CMV disease or if the history is uncertain but there are other suggestions of CMV disease.

- B1.** This question provides a way to skip most of the form if no evidence of CMV was found in the medical record. If none is found, record source of information in **B1a**. STOP.

If any CMV diagnosis is found, complete B2. through B6. (and possibly B7. through B10., if required).

B2. THROUGH B10.

These questions provide a space to document specific sites of CMV disease. Each question has 3 parts: a, b & c.

For **part a**, record the code corresponding to the most reliable source of information. Generally speaking, a medical record is considered more reliable than physicians report. Discuss with your Clinical Center PI if there is a question.

For **part b**, if there are both definitive and presumptive diagnoses, code as definitive. Criteria for definitive diagnosis are given in the protocol, Section 7.3. It is not necessary to document all diagnoses of progression of CMV retinitis, just whether there has ever been a diagnosis. If no diagnosis of a particular site is found, such as no history of upper GI disease, enter code 03 (no diagnosis found) and go to the next question.

For **part c**, give the first date of diagnosis of the most definitive diagnosis. For example, if there was a presumptive diagnosis and a definitive diagnosis in a single site, code 01 (definitive) in part b and give the date of the definitive diagnosis in part c.

Note that the protocol (Section 7.4.2) distinguishes upper and lower GI. Upper GI extends from the mouth to the proximal duodenum. Lower GI is everything distal to the proximal duodenum.

IF THE INCIDENCE OF CMV IN SPECIFIC SITES LISTED IN QUESTIONS B2 THROUGH B6 ARE NOT SEARCHED/RESEARCHED, ENTER “04” FOR SOURCE, AND “03” FOR DIAGNOSIS CONFIRMATION.

B7. THROUGH B10.

Complete as needed if record of CMV disease is found at a site not mentioned in B2 through B6. Specify the site and complete parts b and c for each additional site entered.

VIRAL ACTIVATION TRANSFUSION STUDY (VATS)
FORM 4 -- BASELINE CMV HISTORY MEDICAL RECORD ABSTRACTION

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 / _ 1 _ 5 / _ 9 _ 5
- A5. Today's date: _ _ _ / _ _ _ / _ _ _
- A6. Initials of person completing form: _ . _ . _ .

SECTION B -- CMV DISEASE HISTORY

SOURCE OF INFORMATION CODES

If more than one source reports diagnosis, record the most reliable.

01= Medical Record
 02= Physician's Report
 03= Other Source
 04= No Source Available

DIAGNOSIS CONFIRMATION CODES

If more than one source confirms diagnosis, but reports conflict regarding definitive or presumptive, record definitive.

01= Definitive
 02= Presumptive
 03= No Diagnosis Found

B1. Was any evidence of CMV disease found (other than seropositivity)?

1. Yes
 2. No



a. Source of information:

STOP. FORM COMPLETE.

B2. CMV: Eye Disease

- a. Source of information: _ _ _ (If 03, specify source: _____)
- b. Diagnosis confirmation: _ _ _
- c. If Confirmation=01 or 02, Date of diagnosis: _ _ _ / _ _ _ / _ _ _

B3. CMV: Central Nervous System (CNS)

- a. Source of information: _ _ _ (If 03, specify source: _____)
- b. Diagnosis confirmation: _ _ _
- c. If Confirmation=01 or 02, Date of diagnosis: _ _ _ / _ _ _ / _ _ _

B4. CMV: Upper GI Disease

- a. Source of information: _ _ _ (If 03, specify source: _____)
- b. Diagnosis confirmation: _ _ _
- c. If Confirmation=01 or 02, Date of diagnosis: _ _ _ / _ _ _ / _ _ _

B5. CMV: Lower GI Disease

- a. Source of information: _ _ _ (If 03, specify source: _____)
- b. Diagnosis confirmation: _ _ _
- c. If Confirmation=01 or 02, Date of diagnosis: _ _ _ / _ _ _ / _ _ _

SOURCE OF INFORMATION CODES

If more than one source reports diagnosis, record the most reliable.

- 01= Medical Record
- 02= Physician's Report
- 03= Other Source
- 04= No Source Available

DIAGNOSIS CONFIRMATION CODES

If more than one source confirms diagnosis, but reports conflict regarding definitive or presumptive, record definitive.

- 01= Definitive
- 02= Presumptive
- 03= No Diagnosis Found

B6. CMV: Viremia Only

- a. Source of information: ___ ___ (If 03, specify source: _____)
- b. Diagnosis confirmation: ___ ___
- c. If Confirmation=01 or 02, Date of diagnosis: ___ ___ / ___ ___ / ___ ___

IF OTHER SITE(S) INVOLVED, COMPLETE QUESTIONS BELOW AS REQUIRED. OTHERWISE, STOP. FORM COMPLETE.

B7. CMV: Other site:

(Specify site: _____)

- a. Source of information: ___ ___ (If 03, specify source: _____)
- b. Diagnosis confirmation: ___ ___
- c. If Confirmation=01 or 02, Date of diagnosis: ___ ___ / ___ ___ / ___ ___

B8. CMV: Other site:

(Specify site: _____)

- a. Source of information: ___ ___ (If 03, specify source: _____)
- b. Diagnosis confirmation: ___ ___
- c. If Confirmation=01 or 02, Date of diagnosis: ___ ___ / ___ ___ / ___ ___

B9. CMV: Other site:

(Specify site: _____)

- a. Source of information: ___ ___ (If 03, specify source: _____)
- b. Diagnosis confirmation: ___ ___
- c. If Confirmation=01 or 02, Date of diagnosis: ___ ___ / ___ ___ / ___ ___

B10. CMV: Other site:

(Specify site: _____)

- a. Source of information: ___ ___ (If 03, specify source: _____)
- b. Diagnosis confirmation: ___ ___
- c. If Confirmation=01 or 02, Date of diagnosis: ___ ___ / ___ ___ / ___ ___

END OF FORM

BASELINE CMV HISTORY MEDICAL RECORD ABSTRACTION – FM04DATA CODEBOOK

PUB_ID ----- SUBJECT ID

type: numeric (float)

range: [3,531] units: 1

unique values: 166 coded missing: 0 / 166

mean: 272.657

std. dev: 157.49

percentiles:	10%	25%	50%	75%	90%
	52	140	283.5	402	491

VISNUM ----- A2.VISIT NUMBER

type: string (str2)

unique values: 1 coded missing: 0 / 166

tabulation:	Freq.	Value
	166	"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: [12979,12979] units: 1

unique values: 1 coded missing: 0 / 166

tabulation:	Freq.	Numeric	Label
	166	12979	07/15/95

CMV_DIS ----- B1.EVIDENCE OF CMV DISEASE

type: numeric (float)

label: CMV_DIS

range: [1,2] units: 1

unique values: 2 coded missing: 0 / 166

tabulation:	Freq.	Numeric	Label
	118	1	1:Yes
	48	2	2:No

CMVSOURC ----- B1a.CMV SOURCE OF INFORMATION (B1.a.)
 type: numeric (float)
 label: CMVSOURC
 range: [1,4] units: 1
 unique values: 4 coded missing: 118 / 166
 tabulation: Freq. Numeric Label
 42 1 01:Medical Record
 2 2 02:Physician's Report
 3 3 03:Other Source
 1 4 04:No Source Available

EYESOURC ----- B2a.SOURCE OF INFO - CMV EYE DISEASE
 type: numeric (float)
 label: EYESOURC
 range: [1,3] units: 1
 unique values: 3 coded missing: 48 / 166
 tabulation: Freq. Numeric Label
 108 1 01:Medical Record
 8 2 02:Physician's Report
 2 3 03:Other Source

EYESPEC ----- B2a.SPEC OTHER SOURCE - CMV EYE DISEASE
 type: string (str25), but longest is str21
 unique values: 2 coded missing: 164 / 166
 tabulation: Freq. Value
 1 "PT'S REPORT"
 1 "TALKED WITH PHYSICIAN"
 warning: variable has embedded blanks

EYE_CONF ----- B2b.DX CONFIRMATION - CMV EYE DISEASE
 type: numeric (float)
 label: EYE_CONF
 range: [1,3] units: 1
 unique values: 3 coded missing: 48 / 166
 tabulation: Freq. Numeric Label
 79 1 01:Definitive
 10 2 02:Presumptive
 29 3 03:No Diagnosis Found

CNS_CONF ----- B3b.DIAGNOSIS CONFIRMATION - CMV CNS

type: numeric (float)
label: CNS_CONF

range: [1,3] units: 1
unique values: 3 coded missing: 48 / 166

tabulation:	Freq.	Numeric	Label
	6	1	01:Definitive
	3	2	02:Presumptive
	109	3	03:No Diagnosis Found

CNSDX_DT ----- B3c.DATE OF DIAGNOSIS - CMV CNS

type: numeric (float)

range: [-208,-2] units: 1
unique values: 8 coded missing: 157 / 166

tabulation:	Freq.	Value
	1	-208
	1	-113
	1	-88
	1	-35
	1	-22
	2	-15
	1	-7
	1	-2

CNSDX_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)

UGISOURC ----- B4a.SOURCE OF INFO - CMV UPP GI DISEASE

type: numeric (float)
label: UGISOURC

range: [1,4] units: 1
unique values: 3 coded missing: 48 / 166

tabulation:	Freq.	Numeric	Label
	113	1	01:Medical Record
	2	2	02:Physician's Report
	3	4	04:No Source Available

UGISPEC ----- B4a.SPECIFY OTHER SOURCE - CMV UPPER GI

type: string (str25), but longest is str0

unique values: 0 coded missing: 166 / 166

tabulation:	Freq.	Value
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UGI_CONF ----- B4b.DIAGNOSIS CONFIRM - CMV UPPER GI

type: numeric (float)

label: UGI_CONF

range: [1,3] units: 1
 unique values: 2 coded missing: 48 / 166

tabulation:	Freq.	Numeric	Label
	13	1	01:Definitive
	105	3	03:No Diagnosis Found

UGIDX_DT ----- B4c.DATE OF DIAGNOSIS - CMV UPPER GI

type: numeric (float)

range: [-1186,2] units: 1
 unique values: 13 coded missing: 153 / 166

tabulation:	Freq.	Value
	1	-1186
	1	-961
	1	-514
	1	-280
	1	-198
	1	-141
	1	-139
	1	-136
	1	-74
	1	-69
	1	-51
	1	0
	1	2

UGIDX_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)

LGISOURC ----- B5a.SOURCE OF INFO - CMV LOW GI DISEASE

type: numeric (float)

label: LGISOURC

range: [1,4] units: 1
 unique values: 4 coded missing: 48 / 166

tabulation:	Freq.	Numeric	Label
	111	1	01:Medical Record
	3	2	02:Physician's Report
	1	3	03:Other Source
	3	4	04:No Source Available

LGISPEC ----- B5a.SPECIFY OTHER SOURCE - CMV LOWER GI
 type: string (str25)
 unique values: 1 coded missing: 165 / 166
 tabulation: Freq. Value
 1 "PATHOLOGY REPORT-COMPUTER"
 warning: variable has embedded blanks

LGI_CONF ----- B5b.DIAGNOSIS CONFIRM - CMV LOWER GI
 type: numeric (float)
 label: LGI_CONF
 range: [1,3] units: 1
 unique values: 3 coded missing: 48 / 166
 tabulation: Freq. Numeric Label
 18 1 01:Definitive
 2 2 02:Presumptive
 98 3 03:No Diagnosis Found

LGIDX_DT ----- B5c.DATE OF DIAGNOSIS - CMV LOWER GI
 type: numeric (float)
 range: [-852,8] units: 1
 unique values: 19 coded missing: 146 / 166
 tabulation: Freq. Value
 1 -852
 1 -707
 1 -686
 1 -422
 1 -380
 1 -310
 1 -294
 1 -243
 1 -206
 1 -161
 1 -140
 1 -131
 1 -84
 1 -69
 1 -48
 2 -35
 1 -6
 1 -3
 1 8

LGIDX_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)

LGIDX_DZ ----- DATE IMPUTATION INDICATOR -- LGIDX_DT

type: numeric (float)
 label: LGIDX_DZ
 range: [1,2] units: 1
 unique values: 2 coded missing: 0 / 166
 tabulation: Freq. Numeric Label
 165 1 Date not imputed
 1 2 15th of month imputed

LGIDX_DZ:

- 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.

VIRSOURC ----- B6a.SOURCE OF INFO - CMV VIREMIA

type: numeric (float)
 label: VIRSOURC
 range: [1,4] units: 1
 unique values: 3 coded missing: 48 / 166
 tabulation: Freq. Numeric Label
 113 1 01:Medical Record
 2 2 02:Physician's Report
 3 4 04:No Source Available

VIRSPEC ----- B6a.SPECIFY OTHER SOURCE - CMV VIREMIA

type: string (str25), but longest is str0
 unique values: 0 coded missing: 166 / 166
 tabulation: Freq. Value

VIR_CONF ----- B6b.DIAGNOSIS CONFIRMATION - CMV VIREMIA

type: numeric (float)
 label: VIR_CONF
 range: [1,3] units: 1
 unique values: 2 coded missing: 48 / 166
 tabulation: Freq. Numeric Label
 9 1 01:Definitive
 109 3 03:No Diagnosis Found

VIRDX_DT ----- B6c.DATE OF DIAGNOSIS - CMV VIREMIA

type: numeric (float)

range: [-305,-2]

units: 1

unique values: 8

coded missing: 157 / 166

tabulation:	Freq.	Value
	1	-305
	1	-229
	1	-68
	1	-31
	1	-21
	1	-16
	2	-6
	1	-2

VIRDX_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)

OTHSOURC ----- B7a.SOURCE OF INFO - OTHER CMV SITE
 type: numeric (float)
 label: OTHSOURC
 range: [1,1] units: 1
 unique values: 1 coded missing: 0 / 13
 tabulation: Freq. Numeric Label
 13 1 01:Medical Record

SOURCSPC ----- B7a.SOURCE OF INFO - OTHER CMV SITE
 type: string (str25), but longest is str0
 unique values: 0 coded missing: 13 / 13
 tabulation: Freq. Value

OTH_CONF ----- B7b.DIAGNOSIS CONFIRM - OTHER CMV SITE
 type: numeric (float)
 label: OTH_CONF
 range: [1,2] units: 1
 unique values: 2 coded missing: 0 / 13
 tabulation: Freq. Numeric Label
 12 1 01:Definitive
 1 2 02:Presumptive

OTHDX_DT ----- B7c.DATE OF DIAGNOSIS - OTHER CMV SITE
 type: numeric (float)
 range: [-463,8] units: 1
 unique values: 13 coded missing: 0 / 13
 tabulation: Freq. Value
 1 -463
 1 -216
 1 -142
 1 -98
 1 -82
 1 -61
 1 -42
 1 -20
 1 -16
 1 -10
 1 -9
 1 -3
 1 8

OTHDX_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)