

INTRODUCTION TO FORM 7 – BASELINE OPHTHALMOLOGIC EXAM REPORT

The allowable window for the baseline visit ophthalmologic exam was expanded from ± 3 weeks to ± 4 weeks as documented in Communications Memorandum #013 (Chapter 2.Doc). Retinitis diagnosed within 28 days after randomization was considered to be present at baseline for purposes of analyses.

BASELINE OPHTHALMOLOGIC EXAM REPORT -- FORM 7 QxQ

All participants are required to have a direct and indirect dilated eye exam performed by an experienced ophthalmologist within the three weeks prior to or following enrollment. Results of the retinal exam are to be obtained, reviewed and recorded on this form by the VATS Clinical Coordinator or his/her designate. This form is not intended to be used by the ophthalmologist for recording results of an entire direct and indirect dilated exam.

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: LESIONS

- B1.** After reviewing the ophthalmologist's exam findings, record whether or not any retinal lesions were seen on exam. If none were seen, check the "No" box and this form is complete. If retinal lesions were seen in one or both eyes, check the "Yes" box and continue.
- B2.** Indicate, for both the left and right eyes, whether or not the ophthalmologist noted the presence of CMV retinitis. If the response is "No" for both eyes, this form is completed. If the response is "Yes" for either or both eyes, complete corresponding question(s) in B3.
- B3.** Indicate whether the CMV retinitis is active or not, according to the ophthalmologist's report, for any eye with retinitis. For example, if there was no CMV retinitis in the left eye ("No" at B2b.), leave B3b blank. If CMV retinitis was present in the right eye ("Yes" at B2a.), record whether or not the disease is active in B3a.

**VIRAL ACTIVATION TRANSFUSION STUDY (VATS)
FORM 7 -- BASELINE OPHTHALMOLOGIC EXAM REPORT**

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: _ _ . _ _ . _ _ .
- A7. Date of baseline ophthalmologic exam: _ _ _ / _ _ _ / _ _ _

SECTION B -- LESIONS

- B1. Were any retinal lesions seen? 1. Yes
 2. No ➔ **STOP. FORM COMPLETE.**
- B2. CMV retinitis?
- | | | |
|---------------------------------|---------------------------------|---------------------------------|
| | a. <u>Right Eye</u> | b. <u>Left Eye</u> |
| <input type="checkbox"/> 1. Yes | <input type="checkbox"/> 1. Yes | <input type="checkbox"/> 1. Yes |
| <input type="checkbox"/> 2. No | <input type="checkbox"/> 2. No | <input type="checkbox"/> 2. No |

**IF B2a AND/OR B2b = YES, COMPLETE APPROPRIATE QUESTIONS IN B3 BELOW.
IF BOTH B2a AND B2b = NO, END.**

- B3. Is the CMV retinitis active?
- | | | |
|---------------------------------|---------------------------------|---------------------------------|
| | a. <u>Right Eye</u> | b. <u>Left Eye</u> |
| <input type="checkbox"/> 1. Yes | <input type="checkbox"/> 1. Yes | <input type="checkbox"/> 1. Yes |
| <input type="checkbox"/> 2. No | <input type="checkbox"/> 2. No | <input type="checkbox"/> 2. No |

END OF FORM

BASELINE OPHTHALMOLOGIC EXAM REPORT – FM07DATA CODEBOOK

PUB_ID ----- SUBJECT ID
 type: numeric (float)
 range: [1,530] units: 1
 unique values: 408 coded missing: 0 / 408
 mean: 267.27
 std. dev: 154.152
 percentiles: 10% 25% 50% 75% 90%
 51 126.5 273.5 396.5 481

VISNUM ----- A2.VISIT NUMBER
 type: string (str2)
 unique values: 1 coded missing: 0 / 408
 tabulation: Freq. Value
 408 "00"

VISNUM:

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

FORM_V ----- A3.FORM VERSION
 type: numeric (float)
 label: FORM_V
 range: [12979,12979] units: 1
 unique values: 1 coded missing: 0 / 408
 tabulation: Freq. Numeric Label
 408 12979 07/15/95

OPHTH_DT ----- A7.OPHTHALMOLOGIC EXAM DATE
 type: numeric (float)
 range: [-358,130] units: 1
 unique values: 101 coded missing: 8 / 408
 mean: 9.495
 std. dev: 30.1963
 percentiles: 10% 25% 50% 75% 90%
 -15 0 8 21 36.5

OPHTH_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)

LESIONS ----- B1.ANY RETINAL LESIONS SEEN

type: numeric (float)
 label: LESIONS

range: [1,2] units: 1
 unique values: 2 coded missing: 9 / 408

tabulation:	Freq.	Numeric	Label
	165	1	1:Yes
	234	2	2:No

CMV_RT ----- B2a.CMV RETINITIS - RIGHT EYE

type: numeric (float)
 label: CMV_RT

range: [1,2] units: 1
 unique values: 2 coded missing: 243 / 408

tabulation:	Freq.	Numeric	Label
	57	1	1:Yes
	108	2	2:No

CMV_LEFT ----- B2b.CMV RETINITIS - LEFT EYE

type: numeric (float)
 label: CMV_LEFT

range: [1,2] units: 1
 unique values: 2 coded missing: 244 / 408

tabulation:	Freq.	Numeric	Label
	62	1	1:Yes
	102	2	2:No

RCMV_ACT ----- B3a.CMV RETINITIS ACTIVE - RIGHT EYE

type: numeric (float)
 label: RCMV_ACT

range: [1,2] units: 1
 unique values: 2 coded missing: 351 / 408

tabulation:	Freq.	Numeric	Label
	38	1	1:Yes
	19	2	2:No

LCMV_ACT ----- B3b.CMV RETINITIS ACTIVE - LEFT EYE

type: numeric (float)
 label: LCMV_ACT

range: [1,2] units: 1
 unique values: 2 coded missing: 346 / 408

tabulation:	Freq.	Numeric	Label
	28	1	1:Yes
	34	2	2:No