

INTRODUCTION TO FORM 25 – QUARTERLY OPHTHALMOLOGIC EXAM REPORT

Although ophthalmologic exams were required every 6 months (plus when indicated due to symptoms), Form 25 was to be completed at every quarterly visit.

QUARTERLY OPHTHALMOLOGIC EXAM REPORT -- FORM 25 QxQ

This form is to be completed for all participants at every follow-up quarterly visit. Results of the VATS required eye exams at 06, 12, 18, etc. are to be abstracted onto this form, once available. Though the exam may not be performed for a few weeks after the VATS quarterly visit, record the visit number that the exam was due, in the space provided at A2. Ascertain through medical record review and/or self report, whether the participant has had any other eye exams since his/her last quarterly visit. This includes exams resulting from previous referrals or from symptomatic out-patient/in-patient visits occurring since the last quarterly visit and unrelated to the VATS study. Attempts should be made to obtain, and review and record results of, all eye exams performed while a participant continues in the VATS. It is assumed that one Form 25 can accommodate a summary of all exams performed between visits. Space for up to four exam dates is available for noting new CMV disease diagnoses and/or progression requiring changes in therapy in either or both eyes. If for some reason, this is not sufficient, an additional form 25 should be completed and attached.

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 -- LESIONS

- B1. After querying the participant and reviewing medical records, indicate if any eye exams were performed since the last quarterly visit, or if an exam is being scheduled as part of the current study visit. If an exam is due at this visit, the rest of this form should be completed once the results of the exam are available.

If the response to this question is "No," the form is complete.

- B2. After reviewing the ophthalmologist's exam(s) findings, record whether or not CMV disease was present on any exam done since the last quarterly visit. If the response is "No" for both eyes, this form is completed. If the response is "Yes" for either or both eyes, indicate for both the left and right eyes, whether or not the ophthalmologist noted the CMV disease as new or pre-existing.

B2a. Record the date of the most recent eye exam. (*This question is only in the 8/01/96 version.*)

B3. AND B4.

If CMV disease is only present in one eye, complete these questions only for the eye affected. Otherwise, complete a response for both eyes. For example, if there was no CMV retinitis in the left eye ("No" at B2b.), B3b. and B4b. should be left blank for the left eye.

B3. Only complete for the appropriate eye or eyes and only if CMV disease was noted as pre-existing at Question B2. We are interested in knowing whether CMV progression, requiring a change in therapy, was indicated by the ophthalmologist's report. If "yes," record the date(s) progression was noted/therapy change ordered in B4, under the appropriate eye or eyes.

B4. This question is to be completed if any new CMV disease was found on any exam performed between visits OR if progression of pre-existing disease required a change in therapy. Record the appropriate dates, i.e., date of new diagnosis or progression/change in therapy under the appropriate eye(s).

**VIRAL ACTIVATION TRANSFUSION STUDY (VATS)
FORM 25 -- QUARTERLY OPHTHALMOLOGIC EXAM REPORT**

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 8 / 0 1 / 9 6
- A5. Today's date: _____ / _____ / _____
- A6. Initials of person completing form: _____

SECTION B -- LESIONS

- B1. Were there any ophthalmological exams triggered by "current" clinic study visit, or any since last quarterly visit, that have not been reported?
 1. Yes
 2. No → **STOP. FORM COMPLETE.**
- B2. Is CMV disease present?

a. <u>Right Eye</u> <input type="checkbox"/> 1. Yes, new disease <input type="checkbox"/> 2. Yes, pre-existing <input type="checkbox"/> 3. No	b. <u>Left Eye</u> <input type="checkbox"/> 1. Yes, new disease <input type="checkbox"/> 2. Yes, pre-existing <input type="checkbox"/> 3. No
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- B2a. Date of most recent eye exam _____ / _____ / _____

If B2=3 (NO) for both right and left eyes, STOP. FORM COMPLETE.

If B2=1 (YES, NEW DISEASE) OR If B2=2 (YES, PRE-EXISTING) for right and/or left eye, complete appropriate questions below.

- B3. If B2=2 (pre-existing disease), has pre-existing lesion(s) progressed requiring a change in therapy?

a. <u>Right Eye</u> <input type="checkbox"/> 1. Yes <input type="checkbox"/> 2. No	b. <u>Left Eye</u> <input type="checkbox"/> 1. Yes <input type="checkbox"/> 2. No
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- B4. If B2=1 (new disease) **and/or** If B3=1 (progression of pre-existing disease), give all appropriate dates of diagnosis and/or progression.

a1. _____ / _____ / _____ a2. _____ / _____ / _____ a3. _____ / _____ / _____ a4. _____ / _____ / _____	b1. _____ / _____ / _____ b2. _____ / _____ / _____ b3. _____ / _____ / _____ b4. _____ / _____ / _____
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END OF FORM

QUARTERLY OPHTHALMOLOGIC EXAM REPORT – CODEBOOK FM25DATA CODEBOOK

PUB_ID ----- SUBJECT ID
 type: numeric (float)
 range: [1,530] units: 1
 unique values: 398 coded missing: 0 / 2528
 mean: 266.383
 std. dev: 156.519
 percentiles: 10% 25% 50% 75% 90%
 43 132 271.5 402 486

VISNUM ----- A2.VISIT NUMBER
 type: string (str2)
 unique values: 15 coded missing: 0 / 2528
 tabulation: Freq. Value
 373 "03"
 312 "06"
 280 "09"
 259 "12"
 238 "15"
 213 "18"
 194 "21"
 162 "24"
 141 "27"
 121 "30"
 95 "33"
 74 "36"
 39 "39"
 20 "42"
 7 "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
 type: numeric daily date (long)
 range: [12979,13362] units: 1
 or equivalently: [15jul1995,01aug1996] units: days
 unique values: 2 coded missing: 0 / 2528
 tabulation: Freq. Value
 230 12979 15jul1995
 2298 13362 01aug1996

EXAMTRIG ----- B1.EXAMS TRIGGERED AND NOT REPORTED

type: numeric (float)
 label: EXAMTRIG
 range: [1,2] units: 1
 unique values: 2 coded missing: 13 / 2528

tabulation:	Freq.	Numeric	Label
	983	1	1:Yes
	1532	2	2:No

CMV_RT ----- B2a.CMV DISEASE RIGHT EYE

type: numeric (float)
 label: CMV_RT
 range: [1,3] units: 1
 unique values: 3 coded missing: 1548 / 2528

tabulation:	Freq.	Numeric	Label
	20	1	1:Yes, new disease
	154	2	2:Yes, pre-existing
	806	3	3:No

CMV_LEFT ----- B2b.CMV DISEASE LEFT EYE

type: numeric (float)
 label: CMV_LEFT
 range: [1,3] units: 1
 unique values: 3 coded missing: 1548 / 2528

tabulation:	Freq.	Numeric	Label
	29	1	1:Yes, new disease
	175	2	2:Yes, pre-existing
	776	3	3:No

EYEEEXAM ----- B2a.DATE OF MOST RECENT EYE EXAM

type: numeric (float)
 range: [17,1294] units: 1
 unique values: 527 coded missing: 1659 / 2528

mean: 489.881
 std. dev: 292.976

percentiles:	10%	25%	50%	75%	90%
	164	238	423	706	925

EYEEEXAM:

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).

EYEEEXAMZ ----- DATE IMPUTATION INDICATOR -- EYEEEXAM
 type: numeric (float)
 label: EYEEEXAMZ

range: [1,2] units: 1
 unique values: 2 coded missing: 0 / 2528

tabulation:	Freq.	Numeric	Label
	2527	1	Date not imputed
	1	2	15th of month imputed

EYEEEXAMZ:

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.

PROGRESR ----- B3a.PROGRESSED RIGHT EYE
 type: numeric (float)
 label: PROGRESR

range: [1,2] units: 1
 unique values: 2 coded missing: 2374 / 2528

tabulation:	Freq.	Numeric	Label
	20	1	1:Yes
	134	2	2:No

PROGRESL ----- B3b.PROGRESSED LEFT EYE
 type: numeric (float)
 label: PROGRESL

range: [1,2] units: 1
 unique values: 2 coded missing: 2353 / 2528

tabulation:	Freq.	Numeric	Label
	20	1	1:Yes
	155	2	2:No

DX_RT1 ----- B4a1.DATE OF DIAGNOSIS RIGHT EYE
 type: numeric (float)

range: [7,700] units: 1
 unique values: 36 coded missing: 2488 / 2528

mean: 194.725
 std. dev: 165.406

percentiles:	10%	25%	50%	75%	90%
	28	84	154.5	282.5	382

DX_RT1:

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).

DX_RT1Z ----- DATE IMPUTATION INDICATOR -- DX_RT1
 type: numeric (float)
 label: DX_RT1Z

range: [1,2] units: 1
 unique values: 2 coded missing: 0 / 2528

tabulation:	Freq.	Numeric	Label
	2527	1	Date not imputed
	1	2	15th of month imputed

DX_RT1Z:

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.

DX_LEFT1 ----- B4b1.DATE OF DIAGNOSIS LEFT EYE
 type: numeric (float)

range: [7,1120] units: 1
 unique values: 45 coded missing: 2479 / 2528

mean: 236.531
 std. dev: 230.706

percentiles:	10%	25%	50%	75%	90%
	35	89	155	325	609

DX_RT2 ----- B4a2.DATE OF DIAGNOSIS RIGHT EYE
 type: numeric (float)

range: [46,295] units: 1
 unique values: 7 coded missing: 2521 / 2528

tabulation:	Freq.	Value
	1	46
	1	62
	1	155
	1	208
	1	233
	1	271
	1	295

DX_RT2:

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).

DX_LEFT2 ----- B4b2.DATE OF DIAGNOSIS LEFT EYE
 type: numeric (float)

range: [62,721] units: 1
 unique values: 8 coded missing: 2520 / 2528

tabulation:	Freq.	Value
	1	62
	1	85
	1	147
	1	197
	1	208
	1	271
	1	346
	1	721

DX_LEFT2:

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).

DX_RT3 ----- B4a3.DATE OF DIAGNOSIS RIGHT EYE
 type: numeric (float)

range: [197,197] units: 1
 unique values: 1 coded missing: 2527 / 2528

tabulation:	Freq.	Value
	1	197

DX_RT3:

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).

DX_LEFT3 ----- B4b3.DATE OF DIAGNOSIS LEFT EYE
 type: numeric (float)

range: [364,364] units: 1
 unique values: 1 coded missing: 2527 / 2528

tabulation:	Freq.	Value
	1	364

DX_LEFT3:

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).

DX_RT4 ----- B4a4.DATE OF DIAGNOSIS RIGHT EYE
type: numeric (float)
range: [.,.] units: .
unique values: 0 coded missing: 2528 / 2528
tabulation: Freq. Value

DX_RT4:
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).

DX_LEFT4 ----- B4b4.DATE OF DIAGNOSIS LEFT EYE
type: numeric (float)
range: [384,384] units: 1
unique values: 1 coded missing: 2527 / 2528
tabulation: Freq. Value
1 384

DX_LEFT4:
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).