



4776

CAMUS Clinical Trial Post Week 72 Follow-up Form (CAM97)

A. Report Date
 / /
 mm dd yyyy

B. Participant ID
 S

C. Page Number
 1

D. Visit Number
 8 0

E. Staff ID

1. Date of Week 72 Visit / /
 mm dd yyyy

Circle the appropriate number

- | | Yes | No |
|--|---------------------------|---------------------------|
| 2. Was the participant on study drug at Week 72?
⇒ If no, at which study week did the participant discontinue study drug? | 1
<input type="text"/> | 2
<input type="text"/> |
| 3. Was contact made within 30 days of the Week 72 visit?
⇒ If yes, Date of Contact | 1
<input type="text"/> | 2
<input type="text"/> |
| 4. Was an abnormal and clinically significant lab value report at Week 72?
⇒ If yes, please complete #5
If no, please skip #5 and proceed to #6 | 1 | 2 |
| 5. For each lab test, please indicate whether or not it was abnormal and clinically significant at Week 72, resolution status, and relationship to study drug. | | |

Lab	Abnormal and clinically Significant at Week 72		Resolved		Date of Resolution			Relationship to Study Drug (1-Unrelated; 2-Unlikely; 3-Possible; 4-Probable; 5-Definite)
	Yes	No	Yes	No	mm	dd	yyyy	
Complete Blood Count:								
(a) Leukocyte count (WBC):	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
(b) Erythrocyte count (RBC):	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
(c) Hemoglobin:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
(d) Hematocrit:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
(e) Platelet count:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
Serum Chemistries:								
(a) Sodium:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
(b) Potassium:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
(c) Chloride:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
(d) Bicarbonate:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
(e) Glucose:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
(f) Creatinine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
(g) ALT (SGPT):	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
(h) AST (SGOT):	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
(i) GGT:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
Electrocardiogram	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>



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6. Was a serum PSA sample collected at Week 72? Yes No
1 2

⇒ If yes, please record the PSA result: . ng/ml

⇒ If no, proceed to #7

7. Was a urinalysis done at Week 72? 1 2

⇒ If yes, record the results below

⇒ If no, proceed to #8

(a) pH: .

	<i>0</i>	<i>trace</i>	<i>1+</i>	<i>2+</i>	<i>3+</i>	<i>4+</i>
(b) Glucose	1	2	3	4	5	6
(c) Blood	1	2	3	4	5	6
(d) Ketones	1	2	3	4	5	6
(e) Protein	1	2	3	4	5	6
(f) Leukocyte esterase	1	2	3	4	5	6

8. Did any other AE or SAE occur within 30 days of the Week 72 Visit? 1 2
 ⇒ If yes, please complete a CAM81 (AE) or CAM82 (SAE) form.