


Adverse Event CRA Orientation Presentation Case Studies Answer Sheet

Case 1

For Demonstration Purposes Only: Not Actual Patient Data


CALGB: 49907 ADVERSE EVENT (AE) FORM

47948

INSTRUCTIONS: Complete and submit this form as required by the protocol. Information in the upper right box must be completed for this form to be accepted. For optimal accuracy use black ink. Mark an X in the appropriate box for fields with a choice. Print text in capital letters. Avoid contact with the edges of the boxes. If data are amended, circle amended items and check the "Yes" box. If submitting by mail, retain a copy for your records and send the original to the CALGB Statistical Center, Data Operations. If submitting by fax, use an original form for maximum clarity in transmission and fax to 919-416-4990.

CALGB Form		C-719	
CALGB Study No.		4	9
CALGB Patient ID		4	5
CTC adverse event report begin date		0	6
CTC adverse event report end date		0	6
Are data amended?		<input type="checkbox"/> Yes	

Patient Initials M, F, C
Last, First Middle

Patient Hospital Number 2489742

Institution/Affiliate ST FRANCIS

Participating Group _____

Participating Group Protocol No. _____

Participating Group Patient ID _____

Was an AdEERS Report filed based on an event reported below? No Yes STAT USE ONLY

EXPECTED ADVERSE EVENTS				Report any other AE grades 3-5 only noted during this time period. (Report secondary malignancies other than AML/MDS here.)			
MedDRA code*	CTC adverse event term	CTC AE* grade*	CTC AE* Attribution Code*	MedDRA code*	CTC adverse event term	CTC AE* grade*	CTC AE* Attribution Code*
10018876	Hemoglobin (Hgb)	0 0		1 0 0 1 2 1 7 4	DEHYDRATION	0 3	4
10024285	Leukocytes (total WBC)	0 0		1 0 0 0 0 0 8 5	ABDOMINAL PAIN	0 3	4
10035528	Platelets	0 0					
10002646	Anorexia	0 0					
10016256	Fatigue	0 2	3				
10025222	Lymphedema	0 0					
10042128	Mucositis	0 0					
10028813	Nausea	0 0					
10016288	Neutropenic fever	0 0					
10012457	Skin Rash	0 0					
10047706	Vomiting	0 0					
10024772	Hand-foot syndrome**	0 0					
10012745	Diarrhea	0 3	4				
10005483	Creatinine	0 0					

***CODING INSTRUCTIONS:** Use NCI CTCAE v2.0 to determine the grade for each adverse event (AE) except Hand-foot syndrome. If a particular category was not evaluated or not applicable, code grade = -1. DO NOT USE THE CALGB EXPANDED COMMON TOXICITY CRITERIA.

***ATTRIBUTION CODES:** 1 = unrelated, 2 = unlikely, 3 = possible, 4 = probable, 5 = definite

*The CTC with MedDRA codes included is on the CALGB Web site at <http://www.calgb.org>.

*AE is defined as adverse event.

**See protocol for grading of Hand-foot syndrome (Sec. 12.8).

Completed by: JANE SMITH (Last name, First name)

Date form completed: 0 2 / 2 8 / 2 0 0 8
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Case 2

The AML should NOT be reported via AdEERS. It should be reported using the NCI/CTEP AML/MDS Report form and the C-1001.

Case 3

Neither requires AdEERS submission- only study specific AE forms.

Case 4

Both are expected events.

Neither requires AdEERS submission- only study specific AE forms.