Protocol # TN10 - Anti-CD3 Prevention

Participant ID:		Date of Registration:	
Local ID:		Letters:	
Status:			
Site:			

Adverse Event Reporting Form

Initial Report

* These fields are required in order to SAVE the form

A. INTERVIEW INFORMATION

Adverse event report date	(DD MMM YYYY) *

B. ADVERSE EVENT REPORT

Adverse event occurrence date	(DD MMM YYYY) *
Is this a primary or secondary event?	Primary Secondary* (required only for initial report) If secondary event, enter primary Adverse Event ID:

C. EVENT DESCRIPTION

Event Category	*Help
Event Supra-term "Type of Event"	*
Event Select "Site or Modifier"	* (required only if options are present in drop down list)
Severity	*

Note:The adverse event electronic case report form for this protocol is only completed for all adverse events greater than or equal to Grade 2 of the NCI CTCAE. All adverse events grade 1 and above must be documented in the source.

Event Details "Description"	*
Location of event treatment	Other

D. EVENT ASSESSMENT

Expected (per the IB or package insert with the exception of observational studies)	Yes No*

Causality (by reporter)	▼ *
Was the adverse event associated with any of the following? (check all that apply)	☐ Development of a congenital anomaly or birth defect ☐ Development of a permanent, serious, disabling or incapacitating condition ☐ Death ☐ Hospitalization or prolonged hospitalization ☐ Life threatening ☐ Is another condition which investigators judge to represent significant hazards
Patient status (at time of report):	▼ *
Adverse event resolved date	▼ (DD MMM YYYY)
Date of death	▼ (DD MMM YYYY)
Additional comments	

E. Study Drug Activity

Study Drug Start Date (DD MMM YYYY)	Study Drug Stop Date (DD MMM YYYY)
▼	▼
▼	▼
▼	▼

Add

Did the event/reaction abate after stopping drug?	○ Yes ○ No ○ Not Applicable
Did the event/reaction reappear after reintroduction?	○ Yes ○ No ○ Not Applicable

F. CONCOMITANT MEDICATIONS

* If applicable, please ensure the concomitant medications log was updated prior to adverse event submission.

REPORTER INFORMATION

Reporter User ID	

Save Draft | Submit for Review | Print | Close Window

Details of Initial and Previous Follow-up Reports: