Participant ID:		Date of Registration:	
Local ID:		Letters:	
Status:			
Site:			
Randomization ID:			
Treatment Assign Date:		Treatment Start Date:	

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: