InQuest Quest for ethical research...	**APPENDIX-II** **ADVERSE EVENT REPORTING FORM**	**UNIQUE MEDICAL INQUIRY / CASE REPORT NUMBER:** _____ (to be filled by PV officials)

Reporter Details			
Name		**Phone #**	
Address		**Fax #**	
		Email id	
City		**Preferred method to contact**	Phone / Fax / Email
State		**Consent to contact Reporter**	Yes / No
Country		**Consent to contact Patient**	Yes / No
Qualification		Health Care Professional / Non HCP	

Patient Details			
Patient Initials		**Gender (M / F)**	
DOB (DD/MMM/YYYY)		**Age at the time of event (years)**	
Weight (kgs)		**Height (cms)**	
Ethnicity / Race			

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Suspected Drug(s)	
Generic name of the drug	

Sr. No.	Suspect Drug Name	Strength	Dosage from	Route	Dosage	Frequency	Indication	Start date, Time	Stop date, time	Action Taken*
1										
2										

*** Action Taken: 0 - Ongoing; 1 - Dose reduced; 2 - Temporarily stopped; 3 - Drug Withdrawn; 4 - Not Applicable, 5- Unknown**

Other Drug Details										
Sr. No.	**Past / Concomitant Drug**	**Trade name (Generic name)**	**Strength**	**Dosage from**	**Route**	**Dosage**	**Frequency**	**Indication**	**Start date, Time**	**Stop date, time**
1										
2										
3										

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4										

Details of Suspected Adverse Drug Reactions

Sr. No.	Adverse Event (Verbatim)	Severity*	Serious (Y/N)	Seriousness Criteria~	Onset Date of Event	Causality¥	Start date, Time	Stop date, time	Outcome±
1									
2									
3									
4									
5									
6									
7									
8									
9									

* 1 - Mild; 2 - Moderate; 3 – Severe
~ 1 - Fatal; 2 - Life-Threatening; 3 - Hospitalization or prolongation of hospitalization; 4 - Persistent or significant disability or Incapacity; 5 - Congenital Anomaly; 6 - Other IME
¥ 1 - Definite; 2 - Probable; 3 - Possible; 4 - Unlikely; 5 – Unclassifiable, 6 - Unasseccible
± 1 - Resolved; 2 - Resolved with sequelae; 3 - Resolving; 4 - Ongoing; 5 – Unknown

Location where SAE event occurred		
	Other (Please specify)* -	

* 1 - Hospital; 2 - Home; 3 - Nursing home; 4 - Ambulatory Surgical Facility; 5 - Outpatient treatment facility; 6 - Outpatient diagnostic facility; 7 - Other (Please specify)

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In case of Hospitalization	
Date of Admission	
Date of Discharge	

For Fatal Outcome			
Date of Death		**Time Of Death**	
Autopsy Report		**Death Certificate**	
Cause(s) of Death			

Laboratory Tests Performed				
Sr. No.	**Test Name**	**Date of Test performed**	**Result**	**Reference Range**
1				
2				
3				
4				
5				

6				

Medical History / Concurrent Conditions				
Sr. No.	**Description**	**Type***	**Start Date**	**Stop Date**
1				
2				
3				
*	**1 - Past History (Surgical procedures); 2 - Concurrent Condition**			

Full description of reaction(s) including body site and severity. In addition, description of reported signs and symptoms