ADVERSE EVENT REPORTING FORM (For Pharma Products)

Reporter's Details	
Name	**Occupation**
Address	**Contact no.**
E mail ID:	
Is reporter also the patient	Yes ❑ No ❑

Patient's Details	
Initials	[__I__I__]* *first letter of first, middle and last name
Gender	Male ❑ Female ❑
Height (cm)	**Weight (kg)**
Date of Birth (DD-MM-YY) **Or** **Age**	[__I__]-[__I__]-[__I__] Or [__I__] or [__I__] / [__I__] / [__I__] Years Months / Weeks / Days

Concomitant conditions		
Condition	**Start Date**	**Stop Date**
Relevant family history:		

Suspected Drug(s)						
Name (Brand / or Generic name) with dosage form & strength	Batch / lot no.	Indication (Reason for use or prescribed for)	Daily dose (specify units – e.g., mg, ml, mg/kg) & regimen	Route used	Duration of Therapy	
					Start date	Stop date

Concomitant medication						
Name (Brand / or Generic name) with dosage form & strength	Batch / lot no.	Indication (Reason for use or prescribed for)	Daily dose (specify units – e.g., mg, ml, mg/kg) & regimen	Route used	Duration of Therapy	
					Start date	Stop date

Details (all available) of the Event(s) reported as Suspected Adverse EVENT			
Full description of the event along with body site/system involved			
Severity of event:	Mild ❑	Moderate ❑	Severe ❑
Mild = No interference with usual activities; Moderate = Significant interference with usual activities; Severe = Prevents usual activities			

Criteria for reporting the event as an SAE
The adverse event resulted in (please tick as applicable):
❑ Death
❑ A life threatening experience
❑ Inpatient hospitalization or prolongation of existing hospitalization *
❑ A persistent or significant disability/incapacity
❑ A congenital anomaly/birth defect
❑ Any other important medical event (Which as per PI opinion can be considered serious)

If patient was hospitalized / hospitalization prolonged, enter details below			
Admission date [__I__]-[__I__]-[__I__] D D M M Y Y	Discharge date [__I__]-[__I__]-[__I__] D D M M Y Y	Still in hospital: Yes ❑ No ❑	Discharge summary attached Yes ❑ No ❑
Event Start date [__I__]-[__I__]-[__I__]	Event Stop date [__I__]-[__I__]-[__I__]	Event ongoing at final contact Yes ❑ No ❑	
Did the patient received any treatment for the adverse event? Yes ❑ No ❑ If yes, please provide details here			
Event abated after use stopped or dose reduced	Yes ❑	No ❑	Not Applicable ❑
Event reappeared after reintroduction	Yes ❑	No ❑	Not Applicable ❑
Relevant diagnostic test results and laboratory data:			
Outcome	Resolved with no sequelae ❑	Resolved with sequelae ❑ Date of Resolution _____	
Ongoing at final contact ❑	Death ❑	Unknown ❑	

In case of death

Please mention cause of death

a. Immediate cause or condition resulting in death:

_____

_____

b. Other conditions, if any, leading to cause listed on 'a' line:

_____

_____

Was autopsy performed? Yes ❑ No ❑
If yes, please attach the autopsy report.

Causal relationship to the drug	Certain ❑	Probable/ Likely ❑	Possible ❑
	Unlikely ❑	Conditional/ Unclassified ❑	Unassessible/ Unclassifiable ❑

Any other relevant information to facilitate the assessment of the case:

Reporter's Signature

_____

Name

_____ _____

Signature **Date**