

ADVERSE EVENT REPORTING FORM (In Confidence)



A. PATIENT INFORMATION

1. Patient Initials:

2. Country: _____

3. Sex: M F

4. Age at time of event: years OR

5. Date of Birth: (dd/mm/yyyy)

6. Weight: Kg

B. ADVERSE EVENT

1. Do you consider the adverse event to be serious? Yes No

2. If yes, please indicate why the adverse event is considered to be serious: (Check all that apply)

Death (dd/mm/yyyy) Disability or Permanent damage Life-threatening Congenital anomaly / birth defect

Hospitalization - initial or prolonged Other important medical events

If patient died, cause of death and post mortem findings: _____

(Please attach autopsy findings and hospital discharge summaries as required)

3. If the adverse event is not serious, indicate intensity of the adverse reaction: Mild Moderate Severe

4. Date of onset of event: (dd/mm/yyyy) 5. If event stopped, date: (dd/mm/yyyy)

Time (if available) : (hh/mm)

Time (if available) : (hh/mm)

6. Describe event: (Full description of reaction(s), including body site and severity as well as description of signs and symptoms. Whenever possible, describe a specific diagnosis for the reaction)

7. Information on recovery and any sequelae: Recovered Recovering Recovered with sequelae
Not recovered Fatal Unknown

Other: _____

8. Setting where event occurred:

Hospital Out-Patient Home Nursing Home

9. Relevant tests / laboratory data, including dates:

10. Other relevant history, including preexisting medical conditions: (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic / renal dysfunction, etc.)

11. Treatment of adverse event:

