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**Adverse Event Reporting (AER) Form**

**INSTITUTIONAL ETHICS COMMITTEE (IEC)**

**PROJET DETAILS**

|  |  |
| --- | --- |
| **IEC Reference Code** |  |
| **Study Title** |  |
| **Name of Principal / Co-Investigator(s)** |  |

**Patient and reaction information**

**1. PARTICULARS OF PATIENT**

Name of patient

Age Weight (kg) Patient address

Sex Male Race

Female

Pregnant Yes No Not applicable

Relevant Medical History

**2. ADVERSE EVENT**

Reason for reporting:

|  |  |  |
| --- | --- | --- |
| Requires or prolongs hospitalization | Life threatening | Death |
| Permanently disabling or incapacitating | Congenital anomaly | Overdose |
| Other (Please Specify) |  |  |

**3. Details**

|  |  |  |
| --- | --- | --- |
| Date: |  | Comments: |
| Physician: | Ward/OPD: |   |
| Intervention: | Details of intervention: |   |
| Date of intervention started: | Date of reaction: |   |
| Diagnosis for use (Indications): |   |
| Relevant medical history and concurrent drug therapy: |   |
| Description of AE (use reverse side if necessary):   | 1. |   |
| 2. |   |
| 3. |   |
| 4. |   |
| Outcomes attributed to AE:    | 1. |   |
| 2. |   |
| 3. |   |
| 4. |   |
| Severity code: | SevereModerateMinorIncidental |   |
| Reported initiated by: | Date report initiated:  |  Signature: |

 **GUIDELINES TO FILL UP ADVERSE EVENT REPORTING (AER) FORM**

***An adverse event is considered “Serious”, if it:***

• Is life threatening

• Results in permanent disability

• Results in hospitalization

• Is associated with death

• Prolongation of hospitalization

• Causes a birth defect

• Causes malignancy

• Causes a relevant organ toxicity

• Is an overdose resulting in clinically relevant signs and / or symptoms

***An adverse event can be a manifestation of various etiologies such as***

• Complication of an underlying disease

• Intercurrent disease

• Coincidental accident

• Drug associated effect

 • Concomitant medication