| **AE No.** | **Event term** | **Date of onset** | **Date of awareness** | **End date or ongoing at study end** | **Intensity**1 | **Causality with IMP/IMD/intervention/study procedures2** | **SAE?** (Y/N) | **Comment / action taken** | **Outcome**3 | **Assessment done by** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  | Initials:  Date: |
|  |  |  |  |  |  |  |  |  |  | Initials:  Date: |
|  |  |  |  |  |  |  |  |  |  | Initials:  Date: |
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| --- | --- | --- | --- | --- | --- |
| **1) Intensity:** | | **2) Causality with IMP/IMD/intervention/study procedures:** | | **3) Outcome:** | |
| **1** | Mild | **1** | Definite | **1** | Resolved |
| **2** | Moderate | **2** | Probable | **2** | Resolved with sequelae |
| **3** | Severe | **3** | Possible | **3** | Death |
| **4** | Life-threatening | **4** | Unlikely | **4** | Not resolved at death |
| **5** | Fatal | **5** | Not related | **5** | Ongoing at study end |