Adverse Event Log

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| N° | Adverse Event Description | Start Date  (DD/MMM/YYYY) | End Date  (DD/MMM/YYYY) | Is the event an SAE?  If yes, criteria 1 | Severity 2 | Causality assessment 3 | Causality assessed by (initials & date) | Action taken with trial treatment 4 | Outcome 5 |
|  |  |  |  | Yes – criteria n°:  No |  |  |  |  |  |
|  |  |  |  | Yes – criteria n°:  No |  |  |  |  |  |
|  |  |  |  | Yes – criteria n°:  No |  |  |  |  |  |
|  |  |  |  | Yes – criteria n°:  No |  |  |  |  |  |
|  |  |  |  | Yes – criteria n°:  No |  |  |  |  |  |
|  |  |  |  | Yes – criteria n°:  No |  |  |  |  |  |
|  |  |  |  | Yes – criteria n°:  No |  |  |  |  |  |
| 1: 1= Death, 2 = Life threatening, 3 = Hospitalisation, 4 = Persistent or significant disability/incapacity, 5 = Congenital abnormality/birth defect, 6 = Other  2: 1= Mild, 2 = Moderate, 3= Severe  3: 1= Possibly related, 2 = Probably related, 3 = Definitely related  4: 1=Dose modification, 2=Discontinuation of the IMP, 3= Not applicable, 4 = Treatment continued without change  5: 1=Resolved, 2=Resolved with sequelae, 3= On-going, 4= Unknown at present, 5= Fatal | | | | | | | | | |