Adverse Event Log

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| N° | Adverse Event Description | Start Date(DD/MMM/YYYY) | End Date(DD/MMM/YYYY) | Is the event an SAE?If yes, criteria\* | Severity\*\* | Causality assessment \*\*\* | Action takenwith trial treatment\*\*\*\* | Outcome\*\*\*\*\* |
|  |  | \_\_ \_\_ /\_\_ \_\_ /\_\_ \_\_ \_\_ \_\_ | \_\_ \_\_ /\_\_ \_\_ /\_\_ \_\_ \_\_ \_\_ | [ ]  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= Death, 2 = Life threatening, 3 = Hospitalisation, 4 = Medically significant, 5 = Congenital abnormality/birth defect\*\* 1= Mild, 2 = Moderate, 3= Severe\*\*\* 1= Possibly related, 2 = Probably related, 3 = Definitely related\*\*\*\* 1=Dose modification, 2=Discontinuation of the IMP, 3= Not applicable, 4 = Treatment continued without change\*\*\*\*\* 1=Resolved, 2=Resolved with sequelae, 3= On-going, 4= Unknown at present, 5= Fatal |