**Serious Adverse Events (SAE) Reporting**

**Patient Trial Number**

|  |
| --- |
|  |

**SAE Diagnosis:**

|  |
| --- |
|  |

**SAE Types**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Death |  | Result in disability and incapability |
|  | Life Threatening |  | Others (Please Specify) |
|  | Prolongation of Hospitalisation |

**SAE Description and Treatment:**

|  |
| --- |
|  |

**Principal/ Investigator Suspected Relationship of SAE to Study Treatment:**

|  |  |
| --- | --- |
|  | Not Related |
|  | Unlikely |
|  | Possible |
|  | Probably |
|  | Definitely |

**SAE Onset Date: \_\_\_\_\_\_/\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_ (DD/ MM/ YYYY)**

**SAE Resolution Date: \_\_\_\_\_\_/\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_ (DD/ MM/ YYYY)**

**Death Date: \_\_\_\_\_\_/\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_ (DD/ MM/ YYYY)**

**Outcome:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Unknown/  Lost to Follow Up |  |  | |
|  | Unresolved |  |  | |
|  | Resolved |  |  | |
|  | Resolved with Sequels | Please Specify |  | |
|  | Death | Cause of Death |  | |
| Autopsy |  | Report Attached |
|  | Not Done |

**Action Taken with Study Protocol:**

|  |  |
| --- | --- |
|  | None |
|  | Recruitment Manoeuvre or PUMP manoeuvre changed/ Temporary discontinued |
|  | Termination of Recruitment Manoeuvre or PUMP |

**Additional Notes:**

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**Investigator’s Signature:**

**Investigator’s Name:**

**Date: \_\_\_\_\_\_/\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_**