

**SERIOUS**

**ADVERSE EVENT REPORT**

**FORM**

**FORM 3.1**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Principal Investigator: | | Protocol No.: | IRB Reference No:   |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  | - |  |  |  |  | - |  |  | | |
| Study Title: | | | | |
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| Name of the study medicine/device: | |  |  | | --- | --- | |  | initial | |  | |  | Follow-up | |   Report Date: | | | Onset date: |
| Sponsor: | | | Date of first use: |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Subject’s initial/number: | Age: | | |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | MALE |  |  | FAMALE | |
| Subject’s history: | Laboratory findings: | | |
| SAE: | Treatment: | | |
|  | |  |  |  |  |  | | --- | --- | --- | --- | --- | |  |  | resolved |  | On-going |   Outcome: | | |
| Seriousness: | | Relation to 🔾 Drug 🔾 Study | |
| |  | | --- | |  | |  | Death | |  | |  | Life Threatening | | | |  | |  | Hospitalization -🔾 initial 🔾 prolong | | | | |  | |  | Disability / Incapacity | | | |  | |  | Congenital Anomaly | | |  | |  | Other | | | |  | | --- | |  | |  | Not related | |  | |  | Possibly | | |  | |  | Probably | | | |  | |  | Definitely related | | | | |  | |  | Unknown | | | | | | |
| Changes of the protocol recommended?  Changes to the informed consent form recommended? | | |  |  |  |  | | --- | --- | --- | --- | |  | No |  | Yes , attach proposal | |  | |  | No |  | Yes , attach proposal | | |
| Reviewed by: Date:    Comment: Action: | | | |
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