|  |  |  |  |
| --- | --- | --- | --- |
| **JRESLOG0007- Adverse Events Log** | | | |
| **Version number:** | Version 8.0 | **Date:** | 06/08/2024 |
| **JRES Number & Short**  **Study Title:** |  | **Site Name & Number** |  |
| **EudraCT Number:** |  | **Principal Investigator (PI):** |  |

***Important Notes for Completing of this Log:***

***ALL AEs*** *should be recorded on this log unless otherwise agreed in the study protocol. Please continue to record AEs in source data and CRFs as well.*

*This Log must be kept on site for each trial and sent to the Sponsor/JRES at agreed intervals (as per monitoring plan). The JRES will send to the Chief Investigator for trend analysis. The CI will report any TSC or DMC subsequent findings and/or recommendations to the JRES governance team within 3 working days.*

**Causal Assessment:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1 = Definitely | 2 = Probably Related | 3 = Possibly related | 4 = Unlikely | 5 = Not related | 6= Not assessable |

*Please note: 1-3 qualifies an AE as an AR*

**Severity Grade:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 = Mild | 2 = Moderate | 3 = Severe | 4 = Potentially life threatening | 5 = Fatal |

*Please indicate a document you used to assess severity: Protocol, IB, IMPD or SmPC or use the following definitions*

**Mild** symptoms cause no or minimal interference with usual social and functional activities with intervention not indicated. The event is easily tolerated.

**Moderate** symptoms cause greater than minimal interference with usual social & functional activities with intervention indicated.

**Severe** symptoms cause an inability to perform usual social & functional activities with intervention or hospitalisation indicated.

**Potentially life-threatening** symptoms cause inability to perform basic self-care functions OR Medical or operative intervention indicated to prevent permanent impairment, persistent disability or death.

**Fatal** symptomsleading to death.

If severity could fall under either one of two grades, select the higher of the two grades.

|  |  |  |
| --- | --- | --- |
| **JRESLOG0007- Adverse Events Log** | | |
| **Study title:** | **Site Name & Number:** | **Principal Investigator (PI):** |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Subject ID** | **AE brief description** | **Does the event meet the criteria of an SAE?** | **If yes, state SAE reference no** | **Date of Onset (dd/mm/yyyy)** | **Date of Resolution**  **(dd/mm/yyyy)** | **Causal Assessment** | **Expected?** | **Severity Grade** | **Medication given to treat event?** | **Verified by PI (signature)** |
|  |  | Yes  No |  |  |  |  | Yes  No |  | Yes  No |  |
|  |  | Yes  No |  |  |  |  | Yes  No |  | Yes  No |  |
|  |  | Yes  No |  |  |  |  | Yes  No |  | Yes  No |  |
|  |  | Yes  No |  |  |  |  | Yes  No |  | Yes  No |  |
|  |  | Yes  No |  |  |  |  | Yes  No |  | Yes  No |  |
|  |  | Yes  No |  |  |  |  | Yes  No |  | Yes  No |  |
|  |  | Yes  No |  |  |  |  | Yes  No |  | Yes  No |  |

Date Log was sent to JRES (dd/mm/yyyy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_