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| **SERIOUS ADVERSE EVENT REPORTING FORM** |

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| **Study information** | |
| **Protocol title:** |  |
| **Clinical Trials Registry ID/number:** |  |
| **Sponsor Name:** |  |
| **Site Name:** |  |
| **Investigator Name:** |  |
| **e-mail:** |  |
| **Phone number:** |  |

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| **Report details** | | | | |
| **Type of report** |  | Initial | | |
|  | Follow-up (FU) | If FU, add FU No.: |  |
| **Date site was first made aware of SAE** |  | | | |
| **Date of report completion** |  | | | |

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| **Subject information** | | | | | | |
| **Subject trial ID** |  | | **Gender:** |  | Male | |
|  | Female | |
| **Height (cm)** |  | **Weight (kg)** |  | **Age at time of onset (years)** | |  |

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| **Serious Adverse Event information** | | | | | | |
| **Event term**  (List one event per line)  *Provide final diagnosis, if known (signs and symptoms/procedures can be documented in Event Description section* | **Onset date**  *DD-MM-YYYY* | **Category**   1. Death 2. Life-threatening 3. Hospitalization 4. Involved persistence or significant disability or incapacity 5. Congenital anomaly. Other important medical conditions 6. Other | **Causality relationship to IP**   1. Not related 2. Unlikely related 3. Possibly related 4. Probably related 5. Definitely related 6. Not assessable | **Action taken regarding treatment**   1. None 2. Treatment modification 3. Treatment discontinued 4. Medical Intervention 5. Hospitalization 6. Other (specify) | **Outcome**   1. Resolved 2. Recovered with minor sequelae 3. Recovered with major sequelae 4. Ongoing/continuing treatment 5. Condition worsening 6. Death | **Resolution date**  *DD-MM-YYYY* |
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| **Investigational Product information** | | | | | | | |
| **IP and dose subject was receiving (mark)** | | | | **Frequency** | | **Route** | |
|  | <insert IP name and dose> | | |  | Once daily |  | |
|  | <insert IP name and dose> | | |  | Twice daily |
|  | <insert IP name and dose> | | |
| **Start date** | | **Ongoing** | | **End date** | | **Date of last dose of IP** | |
|  | |  | Yes |  | |  | |
|  | No |  | IP not started (*screening*) |

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| **Action taken with IP in response to SAE** | | | | | |
|  | Dose not changed | **Dechallenge / Rechallenge**  complete if dose reduced / drug withdrawn | | | |
|  | Dose reduced |
|  | Dose Increased |
|  | Drug withdrawn |  | Yes | No | Unknown |
|  | Unknown | Did event stop after discontinuation? |  |  |  |
|  | Not applicable | Did event reappear after restart? |  |  |  |

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| **Non-Investigational Product information** | | | | | | |
| **Medication** | **Dose** | **Frequency** | **Route** | **Start date** | **Ongoing:**  *Yes (Y)*  *No (N)* | **End date** |
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| **Concomitant Medication** | | | | | | |
| **Medication** | **Dose** | **Frequency** | **Route** | **Start date** | **Ongoing:**  *Yes (Y)*  *No (N)* | **End date** |
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| **Relevant Medical History** | | | | | | |
| **Medication** | **Dose** | **Frequency** | **Route** | **Start date** | **Ongoing:**  *Yes (Y)*  *No (N)* | **End date** |
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| **Treatment given for management of SAE** | | | | | | |
| **Medication** | **Dose** | **Frequency** | **Route** | **Start date** | **Ongoing:**  *Yes (Y)*  *No (N)* | **End date** |
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| **Any relevant tests / laboratory data? □ Yes / □ No**  *(If yes, please specify below and continue on separate sheet if necessary or attach print outs)* |
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| **Any relevant medical history / concurrent conditions? □ Yes / □ No**  *(If yes, please specify below and continue on separate sheet if necessary or attach print outs)* |
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| **Summary Description of the event** |
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| **Outcome**  *(on recovery and any sequelae, include specific tests and/or treatment and their results)* |
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| **Signature of person making the assessment**  *Delegated health professional* |  | Print Name |  | Date of assessment |  |
| **Signature of person completing the form if different to person above** |  | Print Name |  | Date of report |  |