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| **Serious Adverse Event Reporting Form (CTIMP and Other)***Please note for medical device trials, all SAEs whether related to the device or not should be reported on MEDDEV 2.7/3 reporting Excel spreadsheet. Please see SOP-RES-019 Adverse Event Reporting.*Please submit this form to Nottingham University Hospitals NHS Trust Research and Innovation via e-mail to RDSAE@nuh.nhs.uk |
|  |  |
|  |
| **Section 1: Study Information** |
| **Study Title:** | MAnnitol for Cerebral oEdema after IntraCerebral Haemorrhage (MACE-ICH) | **Site Address/Number:** | ENTER ADDRESS |
| **Chief Investigator:** | Dr Kailash Krishnan | **Principal Investigator:** | ENTER PI DETAILS |
| **R&I Ref Number:** | 22SR001 | **EudraCT Number:** | 2022-000283-22 |
| **REC Reference Number:** | 22/EM/0242 | **IRAS Number** | 1004870 |
|  |  |  |  |
| **Section 2: Participant Information** |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Initials:** |  | **Participant Number:** |  | **Age:** |  | **Sex:** | [ ]  Male [ ] Female |

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| --- |
|  |
| **Section 3: Event Information** |
| **Date of Report:** | DD/MMM/YYYY | **Date of Event Onset:** | DD/MMM/YYYY | **Date Site became aware:** | DD/MMM/YYYY | **Time Site Became Aware:** | HH:MM |
| **Event term:***If additional event terms are required please provide this in an appendix* | 1) |
| 2) |
| 3) |
| **Description of Event:***Specify diagnosis or cause of death if known;* ***otherwise*** *provide signs and symptoms, relevant tests/results. Do* ***NOT*** *use abbreviations* | ADD DESCRIPTION OF EVENT |
| **^Section Completed by:** | NAME | SIGNATURE | DATE |
| *Name (PRINT)* | *Signature* | *Date* |



|  |  |
| --- | --- |
| **Seriousness** | **Event Outcome** |
| Death | [ ]  | Fatal *(Give cause of death if known in event description)* | [ ]  | Date of death | DD/MMM/YYYY |
| Life threatening |[ ]  Recovered/Resolved |[ ]  Date recovered | DD/MMM/YYYY |
| Hospitalisation or prolongation of hospital stay | [ ]  | Recovered/Resolved with sequelae *(Give detail in event description)* |[ ]  Date recovered | DD/MMM/YYYY |
| Persistent or significant disability or incapacity | [ ]  | On-going *(Give detail in event description)* |[ ]   |
| Congenital abnormality or birth defect |[ ]  Unknown at time of report |[ ]   |
| Otherwise considered serious | [ ]  |  |
| **Event 1** |
| ***^To be completed by a medically qualified doctor only***  |
| **^Severity of Event:** |  | ***^*Causality** |  | **^Cause of Event:** *(Detail all possible and suspected causes, including relevant medical history)* |
| Mild |[ ]  Not related |[ ]  DETAIL CAUSE OF EVENT |
| Moderate |[ ]  Unlikely |[ ]   |
| Severe |[ ]  Possibly |[ ]   |
|  | Probably |[ ]   |
|  | Definitely |[ ]   |
| **Expectedness Assessment *(if possibly, probably, or definitely related):***[ ]  Expected[ ]  Unexpected |
| **Event 2** |
| ***^To be completed by a medically qualified doctor only***  |
| **^Severity of Event:** |  | ***^*Causality** |  | **^Cause of Event:** *(Detail all possible and suspected causes, including relevant medical history)* |
| Mild |[ ]  Not related |[ ]  DETAIL CAUSE OF EVENT |
| Moderate |[ ]  Unlikely |[ ]   |
| Severe |[ ]  Possibly |[ ]   |
|  | Probably |[ ]   |
|  | Definitely |[ ]   |
| **Expectedness Assessment *(if possibly, probably, or definitely related):***[ ]  Expected[ ]  Unexpected |
| **Event 3** |
| ***^To be completed by a medically qualified doctor only***  |
| **^Severity of Event:** |  | ***^*Causality** |  | **^Cause of Event:** *(Detail all possible and suspected causes, including relevant medical history)* |
| Mild |[ ]  Not related |[ ]  DETAIL CAUSE OF EVENT |
| Moderate |[ ]  Unlikely |[ ]   |
| Severe |[ ]  Possibly |[ ]   |
|  | Probably |[ ]   |
|  | Definitely |[ ]   |
| **Expectedness Assessment *(if possibly, probably, or definitely related):***[ ]  Expected[ ]  Unexpected |
| *If additional causality/expectedness assessments are required for additional event terms please provide this in an appendix* |
| **^Section Completed by:** | NAME | SIGNATURE | DATE |
|  | *Name (PRINT)* | *Signature* | *Date* |
|  |
| **Section 4: Study Medication Information (if applicable)** |
| **Participant has been Administered Study Medication** | [ ]  No *(Give reason i.e. screening) …………………………………………………..........................* |
|  | [ ]  Yes *(Provide details below)*  |
| **Name of Medication** | **Indication(s) for Use** | **Dose (units)** | **Route of Administration** | **Date of First Administration** | **Date of Last Administration** |
| MEDICATION | INDICATION | DOSE | ROUTE | DD/MMM/YYYY | DD/MMM/YYYY |
| MEDICATION | INDICATION | DOSE | ROUTE | DD/MMM/YYYY | DD/MMM/YYYY |
| MEDICATION | INDICATION | DOSE | ROUTE | DD/MMM/YYYY | DD/MMM/YYYY |
|  |
|  |
| **Section 5: Action Taken as Result of Event: (if applicable)** |
| None | [ ]  | *Details including new dose (units), date(s) of administration, duration:* |
| Dose changed | [ ]  | DETAIL ADDITIONAL INFORMATION |
| Medication interrupted | [ ]  |  |
| Medication discontinued | [ ]  |  |
| Treated with concomitant medication(s) | [ ]  |  |
| Other |  |  |
| Unknown at time of report | [ ]  | *Tick if* ***concomitant medication*** *is listed on a separate sheet and indicate number of pages* [ ]  **Pages:**  |
|  |  |  |
| **Section 6: Participant Status** |
| **Blind Broken:** | [ ]  Not Applicable | [ ]  Yes | [ ]  No |
| [ ]  Continuing in the trial |  |
| [ ]  Completed the trial | **Date of Completion:** |   |
| [ ]  Withdrawn from the trial | **Date of Withdrawal:** |   |
|  |
| **Section 7: Additional Information** |
| DETAIL ADDITIONAL INFORMATION |
|  |
| **Section 8: Completion Details** |
| **Report Completed by:** | NAME | SIGNATURE | DD/MMM/YYYY |
|  | *Name (PRINT)* | *Signature* | *Date* |
| **PI Review:***(If not reporter)* | NAME | SIGNATURE | DD/MMM/YYYY |
|  | *Name (PRINT)* | *Signature* | *Date* |
|  |
| **FOR SPONSOR USE ONLY** |
| **Report Received by:** | NAME | DD/MMM/YYYY | HH:MM |
|  | *Name (PRINT)* | *Date* | *Time* |
| **Report Checked and Tracked by:** | NAME | DD/MMM/YYYY | HH:MM |
|  | *Name (PRINT)* | *Date* | *Time* |
| **Comments:** | ANY COMMENTS |
|  |
| **Assessment by R&I Clinical Research Physician: (if applicable)** |
| **Reference Safety Information Used for Expectedness Assessment (please also detail version):** |  |
| **Event 1) MedDRA Code:** |
| **Event term** | **SOC** | **SOC code** | **LLT** | **LLT code** |
|  |  |  |  |  |
| **Causality Assessment:** | [ ]  Not Related (SAE) | **Expectedness Assessment:***(if related)* | [ ]  Expected (SAR) |
|  | [ ]  Related (SAR) |  | [ ]  Unexpected **(SUSAR)** |
| **Event 2) MedDRA Code:** |
| **Event term** | **SOC** | **SOC code** | **LLT** | **LLT code** |
|  |  |  |  |  |
| **Causality Assessment:** | [ ]  Not Related (SAE) | **Expectedness Assessment:***(if related)* | [ ]  Expected (SAR) |
|  | [ ]  Related (SAR) |  | [ ]  Unexpected **(SUSAR)** |
| **Event 3) MedDRA Code:** |
| **Event term** | **SOC** | **SOC code** | **LLT** | **LLT code** |
|  |  |  |  |  |
| **Causality Assessment:** | [ ]  Not Related (SAE) | **Expectedness Assessment:***(if related)* | [ ]  Expected (SAR) |
|  | [ ]  Related (SAR) |  | [ ]  Unexpected **(SUSAR)** |
| *If additional MedDRA terms and causality assessments are required, please provide this as an appendix.*  |
| **SAE Follow up required:** [ ]  Yes [ ]  No |
| **Comments:** |  |
| **Assessment Completed by:** |  |  |  |
|  | *Name (PRINT)* | *Signature* | *Date* |