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| **Serious Adverse Event Follow Up Reporting Form****Please submit this form to Nottingham University Hospitals NHS Trust Research and Innovation via e-mail to** **RDSAE@nuh.nhs.uk** |
|  |  |
| Please select one of the following options:[x]  **CTIMP (Clinical Trial of Investigational Medicinal Product)**[ ]  **CIMD (Clinical Investigation of Medical Device)**[ ]  **Other** |
| **DATE MUST BE ENTERED DD/MMM/YYYY****Time must be entered HH:MM** |
|  |
| **Section 1: Study Information** |
| **Study Title:** | MAnnitol for Cerebral oEdema after IntraCerebral Haemorrhage (MACE-ICH) |
| **Chief Investigator:** | Dr Kailash Krishnan | **Principal Investigator:** |  |
| **R&I Ref Number:** | 22SR001 | **EudraCT Number:** | 2022-000283-22 |
| **IRAS Number:** | 1004870 | **Site Address/Number:** |  |
|  |
| **Follow up Report Number:** |  | **Follow up Report Date:** |  | **SAE Reference Number:** |  |
|  |  |  |  |
| **Section 2: Participant Information** |

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

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| **Section 3: Event Follow Up Information** |
| **Changes to Event detailed in Initial SAE Report OR new additional event:**   | [ ]  Yes (*please add updated event below and complete causality assessment*)[ ] No |  |
| **Updated event** *(if applicable):* | 1) |
|  | 2) |
|  | 3) |
| **Description of Changes to the Event and Action Taken Since Previous Report:***Include dates. Do* ***NOT*** *use abbreviations* |  |
| **Event Outcome** |
| Fatal *(Give cause of death if known in event description)* | [ ]  | Date of death |  |
| Recovered/Resolved |[ ]  Date recovered |  |
| Recovered/Resolved with sequelae *(Give detail in event description)* |[ ]  Date recovered |  |
| On-going *(Give detail in event description)* |[ ]   |
| Unknown at time of report |[ ]   |
| **Updates to causality assessment if updated event:** |
| **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 |
| **^Section Completed by:** | NAME | SIGNATURE | DATE |
|  | *Name (PRINT)* | *Signature* | *Date* |
|  |
| **Section 4: Concomitant Medication Information** |
| **Participant has received Concomitant Medication** | [ ]  No  |
|  | [ ]  Yes *(Provide details below)*  |
| **Name of Medication** | **Indication(s) for Use** | **Dose (units)** | **Route of Administration** | **Date of First Administration** | **Date of Last Administration** |
|  |  |  |  |  |  |
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| **Continuation sheet attached** *(Tick if additional* ***concomitant medication*** *is listed on a separate sheet and indicate number of pages)* [ ]  |
| **Section 5: 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 6: Additional Information** |
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| **Section 7: Completion Details** |
| **Report Completed by:** |  |  |  |
|  | *Name (PRINT)* | *Signature* | *Date* |
| **PI Review:***(If not reporter)* |  |  |  |
|  | *Name (PRINT)* | *Signature* | *Date* |

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| **FOR SPONSOR USE ONLY** |
| **Initial Report Date:** |  |  |
| **Report Received by:** |  |  |  |
| *Name (PRINT)* | *Date* | *Time* |
| **Report Checked and Tracked by:** |  |  |  |
| *Name (PRINT)* | *Date* | *Time* |
| **Comments:** |  |
|  |  |  |  |  |
| **Assessment by R&I Clinical Research Physician:** |
| **Reference Safety Information Used for Expectedness Assessment (please also detail version):** |  |
| **Initial MedDRA Code:** |  |
| **MedDRA Code change required?** | [ ]  Yes (*please add event information below and complete causality assessment*)[ ] No |

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| **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.*  |
| **Further follow up required:** [ ]  Yes [ ]  No |

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| **Comments:** |  |
| **Assessment Completed by:** |  |  |  |
| *Name (PRINT)* | *Signature* | *Date* |