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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 | | | | |
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| **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 |
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| **Section 2: Participant Information** | | | | |

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| **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* | |



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| **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 | | |
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| **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:** | | | | | | | |  | | | | | | | | | | |
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| **Section 7: Additional Information** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| DETAIL ADDITIONAL INFORMATION | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **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** | |
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| **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* | | | | | | | |