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| R &I New image.PNG |
| **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): a feasibility trial |
| **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** |
| **Initials:** |  | **Participant Number:** |  |
|  |
| **Section 3: Event Follow Up Information** |
| **No Changes to Event detailed in Initial SAE Report**  |[ ]  **Changes to Event detailed in Initial SAE Report** |[ ]
| **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 |[ ]   |
|  |
| **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** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| **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** |
|  |
|  |
| **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:** |
| **Initial MedDRA Code:** |  | **MedDRA Code changed to:****(if required):** |  |
| **Comments:** |  |
| **Assessment Completed by:** |  |  |  |
| *Name (PRINT)* | *Signature* | *Date* |