**SERIOUS ADVERSE EVENT (SAE) REPORTINGFORM**

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| **Study Information:-** |
| **Study Title:** |  |
| **NBCR Number:** |  |
| **Sponsor:** | Chief Investigator Name: |  |
| Email: |  |
| **Clinical Investigation Plan title & version number** |
| **Site Number***(For multicenter studies only)* | **Site Name:** |  |
| **Principal Investigator**  | **Name:** |  |
| **PI Institution Address:** |  |
| **Email:** |  |
| **Contact Number:** |  |
| **Date of site becoming aware of the event**  | *(dd/mm/yyyy):* |
| **Report type** | Initial report | Follow up report | Final report  |
| **Participant Information:** |
| **Participant Date of Birth (DOB)** | **Participant Initials:** | **Participant Gender:** |
| dd | mm | yyyy |  | Male |  | Female |  |
| **Participant Randomisation No:** |
| **Evaluation of Event:** |
| **Event/Reaction:** *(keywords: e.g. body site, symptoms, severity, treatment)* |
| **Date of onset:** | *(dd/mm/yyyy)* | **Date person completing form became aware of event** | *(dd/mm/yyyy)* |
| **Criteria for definition as SAE:** | Congenital abnormality / birth defect |  |
| Resulted in death |  |
| Life threatening |  |
| In patient hospitalization / prolongation of hospitalization |  |
| Persistent or significant disability |  |
| Other e.g. is otherwise considered medically significant by the investigator |  |
| ***\**** *If there is more than one criterion, choose the more / most significant one.* |
| **Describe the event:** *(A summary of signs and symptoms, diagnosis, treatment of event, concurrent treatment, other relevant medical history, including re-challenge details if applicable. Please include the point in the study at which the event occurred.)* |
|  |
| **In the investigators opinion was the event related to a research procedure?** | Definitely |  |
| Likely |  |
| Possibly |  |
| Unlikely |  |
| Not related |  |
| **Please specify which procedure if applicable** |  |

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| **Outcome of event** |
| **What is the outcome of the SAE?** |  |
| **Date of event resolved:** | *(dd/mm/yyyy)* |
| **Date of patient died:** | *(dd/mm/yyyy)* |
| **Recovered** |  |  |
| **Recovered with Sequalae** |  |  |
| **Continuing** |  |  |
| **Resulted in death** |  |  |
| **Unknown** |  |  |
| **Cause of death obtained from:** | Coroner’s inquest |  |
| Death certificate |  |
| Working diagnosis |  |
| ***Contact and signatures*** |
| **Please supply contact details where further information may be obtained:** | *Person to contact* |  |
| *Contact number* |  |
| *Email Address* |  |

***Signature*** *(Person completing report)* Date: *(dd/mm/yyyy)*

***PI Signature*** *(if multicenter trial)* Date: *(dd/mm/yyyy)*

***CI Signature*** *(If not completing report)* Date: *(dd/mm/yyyy)*