**SERIOUS ADVERSE EVENT (SAE) REPORTINGFORM**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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** | | | | | | | |  | | | | | | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **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)*