# Safety Reporting

**Full title of study:**

**Study Reference number:**

**Date of this report** (dd/mm/yyyy):

**NIMS Record** **Number** (if applicable)**:**

**Please select reason for completing this report:**

[ ]  Serious Adverse Reaction (i.e. Event at least possibly related to the study drug/ intervention/procedures

[ ]  Suspected Unexpected Serious Adverse Reactions (SUSARs)

[ ]  Unforeseen event(s) that may have affected the risk/benefits profile of the study (i.e. new and emerging evidence that relates to the safety profile of the study such as a recent publication or safety signal etc.)

**Is this the**

[ ]  Initial Report [ ]  Follow-up to the report dated:

**Why is this event Serious? Please tick the appropriate option:**

Death [ ]

Life Threatening [ ]

Hospitalisation or prolongation of existing hospitalisation [ ]

Persistent or significant disability or incapacity [ ]

Congenital anomaly or birth defect [ ] Medically significant (requires interventions to prevent permanent impairment or damage [ ]

**Description of the Event:**

**Information about the Event:**

Start Date (and if known time):

[ ]  Ongoing [ ]  Stop date (and if known time):

**In the opinion of the Principal Investigator the relationship to study:**

[ ]  Possible [ ]  Probable [ ]  Definite

**Reporter Information Principal Investigator**

Name: Name:

Title: Title:

Email: Email:

Date (dd/mm/yyyy): Date (dd/mm/yyyy):

 Signature: