# 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: