

Serious Adverse Event Reporting Form

Section 1 - Site Details

Site Name: _____	Name of PI: _____
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Section 2 - Patient Details

Trial Number: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Patient Gender: <i>Please tick one</i> <input type="radio"/> Male <input type="radio"/> Female
Patient Initials: <i>First, Middle, Last</i> <input type="text"/> <input type="text"/> <input type="text"/>	

Section 3 - Report Type

Report type: <input type="radio"/> Initial Report <input type="radio"/> Follow-up Report	SAE number: <i>Enter once provided by BCTU and ensure this is recorded on any follow up forms</i> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
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If "Follow-up" has the new information changed the causality assessment by the PI: ☐ No ☐ Yes

Is this the final report? ☐ No ☐ Yes

Section 4 - Event Information

Signs and symptoms:

Section 5 - Event Diagnosis

Diagnosis:

Event Severity: ☐ Mild ☐ Moderate ☐ Severe ☐ Life Threatening ☐ Fatal

Section 6 - Seriousness of Event (Each Yes/No question requires a response)

Death: *If yes please complete an Trial Exit/Change of Status Form* ☐ No ☐ Yes

Date of death: D D - M M - Y Y Y Y Cause of death: _____

Life Threatening Event ☐ No ☐ Yes

In-patient Hospitalisation or Prolongation of Existing Hospitalisation: ☐ No ☐ Yes

If 'Yes', Initial or Prolonged? ☐ Initial ☐ Prolonged If 'Yes', Date of Discharge: *e.g. 31-Jan-2017*
 D D - M M - Y Y Y Y

Persistent or Significant Disability/Incapacity: ☐ No ☐ Yes

Congenital Anomaly or Birth Defect: ☐ No ☐ Yes

Other Medical Reason For Reporting: ☐ No ☐ Yes

If 'Yes', Please Specify:

Please continue to next page

Trial Number: Initials: First, Middle, Last

Section 7 - Details of Event

Date of Onset: *E.g. 31-Jan-2017*Date Became Serious: *E.g. 31-Jan-2017*D D - M M M - Y Y Y YD D - M M M - Y Y Y YDate Became Aware: D D - M M M - Y Y Y YEvent is Ongoing: *Tick one*☐ No ☐ YesIf 'No', Date Resolved: *E.g. 31-Jan-2017*D D - M M M - Y Y Y Y

Section 8 - Concomitant Medications

Has the patient taken any other drugs which may interact with the intervention or influence the SAE? *If yes record in below table*☐ No ☐ Yes

Concomitant Medication Table

Drug Name	Dose (including units)	Start Date (dd/mm/yyyy)	Ongoing No (tick if applicable)	Ongoing Yes (tick if applicable)	Stop Date (dd/mm/yyyy)

Section 9 - Causality Assessment *to be completed by the PI or delegated clinician only*

Is the event related to the trial intervention?

☐ No ☐ Yes

If the event is unrelated, please provide details of an alternative explanation for the event:

List any underlying comorbidities or investigations etc. that may be relevant: *Where investigations or lab tests are appended, please ensure patient identifiers are replaced with trial number only*

Section 10 - Details of Person Reporting

Name of Person Reporting:

Job Title of Person Reporting: _____

Signature of Person Reporting: *Must appear on delegation log*Date of Signature: *E.g. 31-Jan-2017*D D - M M M - Y Y Y YDate Reported: *E.g. 31-Jan-2017* D D - M M M - Y Y Y Y

Signature of Principal Investigator or Medically Qualified Delegate: _____

Date of PI/Delegate Signature: *E.g. 31-Jan-2017* D D - M M M - Y Y Y YReturn this form to the TOPIC 2 Trial Office by faxing to 0121 415 9135 or scan and email to topic2@trials.bham.ac.uk

Trial Number: Initials: First, Middle, Last

Section 11 - To Be Completed By Chief Investigator or Named Delegate

Review of relatedness to the intervention by Chief Investigator or delegate: ☐ Related ☐ UnrelatedAssessment of expectedness with reference to the Protocol by Chief Investigator or delegate: ☐ Expected ☐ UnexpectedIs the event related and unexpected? *Serious related and unexpected events require reporting to the REC and sponsor* ☐ No ☐ Yes

Section 12 - Signatures

In signing this form the Investigator or delegate confirms the Causality and Expectedness of the event

Name of CI or Delegate:

Signature of CI or Delegate:

Date of CI or Delegate Signature: *e.g. 31-JAN-2017* - -

Section 13 - Office Use Only

SAE Reference Number: Date Reported to REC: *e.g. 31-JAN-2017*N/A ☐ - - Date Reported to Sponsor: *e.g. 31-JAN-2017*N/A ☐ - -