

REC Ref: 14/SC/1219

Patient ID:

PATIENT DETAILS

Patient initials Sex *Male* ☐ *Female* ☐ Date of Birth //
d d m m y y y y

EVENT DETAILS

Date of SAE //
d d m m y y y y Time of SAE :
(24 hr clock)

DESCRIPTION OF EVENT

Full description of event. If this is a follow-up, details of any additional actions taken/ further information since initial report should also be documented here.

RELATEDNESS

How related to the intervention was the event?

Possibly related ☐ *Probably related* ☐ *Definitely related* ☐

OUTCOME OF EVENT

Resolved, no sequelae ☐ *Resolved, with sequelae** ☐ *Ongoing* (please complete and return additional SAE report form within 5 days)* ☐ *Died* (give cause and PM details or Death Certificate)* ☐

*Give details. If event is ongoing, please follow up patient until event is resolved.

DETAILS OF PRINCIPLE INVESTIGATOR/ LOCAL COLLABORATOR

The completed SAE form must be signed off by the **PI or local collaborator** prior to upload.

I confirm that the contents of this form are accurate and complete

Name Signature Date //
d d m m y y y y

Name of person completing form* (capitals):

Signature of person completing form: Date completed (dd/mm/yyyy): //