SAE SUBCOMMITTEE RECOMMENDATION FORM

I. PROTOCOL INFORMATION

IEC Protocol Tracking No:		Drug/Intervention:	
Study Protocol No:		Studies included:	
Study Initiation Date:		Phase of Study:	
Title:		Date of Report:	
Name of Principal Investigator:		Date of Meeting:	

II. SAE REPORT

Event no.	Event	Offsite/Onsite	Onset/Stop of AE	Date drug started/stopped	Age	Sex	Country/ Race	Co-morbid	CAI	CAS	Action	Reviewer's Causality Assessment

III. STUDY SAE STATISTICS

Total number of SAE	
No. of certain	
No. of probable	
No. of possible	
No. of unlikely	
No. of conditional	
No. of unclassifiable	
No. of deaths	
Item(s) in need of follow-up	

REVIEWERS:

[name/signature]

IV. SAE SUBCOMMITTEE RECOMMENDATION(S)

AE SUBCOMMITTEE RECOMMENDS THE FOLLOWING ACTION(S):	REMARKS / COMMENTS / SPECIFICATIONS
☐ More information needed	
☐ No modification required, study to continue	
☐ Modification(s) needed in the following areas:	
○ Inclusion/exclusion criteria for study participants	
○ Informed consent to include a description of newly found risk	
○ Other:	
☐ Implementation of additional procedure(s):	
○ Screening procedure prior to start of new participant(s)	
○ Monitoring procedure during the study period	
○ Monitoring procedure after the study period	
○ Other:	
☐ Suspension of:	
○ enrolment of new participants	
○ research procedure among current participants	
○ entire study	