

ERC Form 4J: Serious Adverse Event Summary Report



SAE SUMMARY REPORT

STUDY PROTOCOL INFORMATION			
RIHS ERC Code:			
Study Protocol Title:			
Principal Investigator:			
No. of Events:			
No. of Onsite Events:			
Report No.	Event No.	Event	
«Report_No» «Date_of_Report»	«Event_No»	Nature	«NATURE_OF_AE»
		Date of AE	«Date_of_AE»
		Date of Randomization	«Date_of_Randomization»
		Age	«Age»
		Sex	«Sex»
		Country	«Country»
		Co-morbidities	«Comorbidity_1» «Comorbidity_2»
		Causality Assessment of Investigator	«Causality_Investigator»
		Causality Assessment of Sponsor	«Causality_Sponsor»
		Action	«Action»
	Outcome	«Status»	