	SERIOUS ADVERSE EVENT (SAE) REPORT FORM	MCA-F-501/09

MEDICINES CONTROL AGENCY

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Protocol Number		**MCA CT Number**	
PACTR No		**Other numbers**	
Principal Investigator			
Clinical Trial Site			

SUBJECT INFORMATION (at time of SAE onset)					
Subject ID		**Date of Birth**	_____/_____/_____ **Day / Month / Year**	**Age**	**Sex**

SERIOUS ADVERSE EVENT		
Event onset	_____/_____/_____ **Day / Month / Year**	**Outcome of Event** ☐ **Ongoing** ☐ **Recovered** ☐ **Unknown**

Tick all appropriate to adverse event

☐ **Subject died** ☐ **Involved or prolonged hospitalisation**

☐ **Life thretening** ☐ **Involved persistence or significant disability or incapacity**

Describe event(s) in detail (including relevant tests/lab data)

INVESTIGATIONAL MEDICINAL PRODUCT INFORMATION			**Blinded:** ☐ Yes ☐ No	
IMP Name/Identifier	**Route**	**Daily Dose/Unit**	**Start date Day/Month/Year**	**Stop date Day/Month/Year**

CONCOMITANT MEDICATION OR AUXILIARY MEDICINE (exclude those used to treat event)					
Generic name	**Indication**	**Daily Dose**	**Route**	**Start date Day/Month/Year**	**Stop date Day/Month/Year**

ASSESSMENT OF CAUSALITY WITH IMP			
SAE is related to IMP:	Definite ☐	Probable ☐ Possible ☐	Unlikely ☐ Unrelated ☐
Did event abate after stopping IMP	☐ Yes ☐ No ☐ NA	**Did event reappear after IMP reintroduction**	☐ Yes ☐ No ☐ NA

TYPE OF REPORT			
Date of this report	____ / _____ / _____ **Day / Month / Year**	**Date site aware of SAE**	___ / _____ / _____ **Day / Month / Year**
☐ **Initial Report**	☐ **Follow-up report # _____**		

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Principal Investigator Signature **Date**

OFFICIAL USE

Date received:	**MCA SAE number**:.....
Comments:	