

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

Off Bertil Harding Highway, Kotu East, Kanifing Municipality, P.O. Box 3162, Serekunda, The Gambia
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Protocol Number		MCA CT No	
PACTR No		Other numbers	
Principal Investigator			
Clinical Trial Site			

PARTICIPANT INFORMATION (at time of SAE onset)

Participant ID		Date of Birth Day/Month/Year	Age	Sex
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SERIOUS ADVERSE EVENT

Event onset Day/Month/Year	Outcome of Event		
		<input type="checkbox"/> Ongoing	<input type="checkbox"/> Recovered	<input type="checkbox"/> Unknown

Tick all appropriate to adverse event

<input type="checkbox"/> Participant died	<input type="checkbox"/> Involved or prolonged hospitalisation
<input type="checkbox"/> Life threatening	<input type="checkbox"/> Involved in persistent or significant disability or incapacity

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

INVESTIGATIONAL MEDICINAL PRODUCT INFORMATION				Blinded: <input type="checkbox"/> Yes <input type="checkbox"/> 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:					
<input type="checkbox"/> Definite	<input type="checkbox"/> Probable	<input type="checkbox"/> Possible	<input type="checkbox"/> Unlikely	<input type="checkbox"/> Unrelated	
Did event abate after stopping IMP	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	Did event reappear after IMP reintroduction	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA		

TYPE OF REPORT			
Date of this report Day/Month/Year	Date site aware of SAE Day/Month/Year
<input type="checkbox"/> Initial Report		<input type="checkbox"/> Follow-up report # _____	

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Principal Investigator Signature

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Date

OFFICIAL USE

Date received:	MCA SAE number:
Comments:	