

Serious Adverse Event Form

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Randomisation No.	R			/		
Participant Initials						

SAE details							
Start date End date d d			d d m m y y y y				
ÿ . —	RBL HAL	Date of procedure	d d m m y y y y				
Please choose and mark one of each below to rate the event:							
Seriousness Death* Life threatening Inpatient hospitalisation** Prolongs hospitalisation Persistent or significant disability/incapacity Congenital abnormality /birth defect	Frequency Solated Intermittent Continuous Unknown	Intensity Mild Moderate Severe	Outcome Recovered Improved Unchanged Deterioration Persisted Death*				
*Date of death							



Serious Adverse Event Form (cont.)

Randomisation No.	R			/		
Participant Initials						

**Hospital adm	mission					
Details						
Start date	Ongoing () or End date	m y y y y				
Please also complete the 'Concomitant Medications' form if it's felt that the information could help in the clinical judgement of this SAE.						
Date site staff be	ecame aware of the event	m y y y y				
Reporting persor / position Signature	Date of reporting	m y y y y				
To be completed	d by the PI / CI					
Expected SAE?	Yes No* Relationship to RBL/HAL Definite* Probable* Possible* Unlikely Unrelated Not assess	sable				
*In the event of a SUSAR please follow the expedited reporting procedure						
Name of PI /CI						
Signature	Date of signature	m y y y y				