



RATE-AF SAE Form Part 2

UNIVERSITY OF
BIRMINGHAM



! To be completed by the Chief Investigator or named delegate.
Not to be sent to the Principal Investigator. **!**

IDENTIFYING DETAILS	
Trial No.: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Participant initials: <input type="text"/> <input type="text"/> <input type="text"/>
Date of birth: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	

REPORT DETAILS	
Is this report? Initial <input type="checkbox"/>	Follow-up <input type="checkbox"/>
If follow-up, give the SAE ref. number: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (ref. no. will be provided by BCTU)	

RANDOMISED TREATMENT ALLOCATION				
Please indicate which trial treatment the patient was randomised to:				
Intervention	Review of causality assessment		Assessment of expectedness	
	Related		Expected	
	Yes	No	Yes	No
Digoxin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bisoprolol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

CAUSALITY ASSESSMENT
The causality assessment must be made with reference to the relevant safety information:
If the evaluator's review disagrees with the PI's assessment, please state why:

DETAILS OF PERSON EVALUATING CAUSALITY AND ASSESSING EXPECTEDNESS	
Signature: (you must have signed the site delegation log) 	Name of Person Reporting: Position: (CI or delegate)
Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	

Trial Number:

SAE Ref.: /

BCTU USE ONLY

		Yes	No
Does this event require expedited reporting to:	A competent authority	<input type="checkbox"/>	<input type="checkbox"/>
	An ethics committee	<input type="checkbox"/>	<input type="checkbox"/>
	The Sponsor	<input type="checkbox"/>	<input type="checkbox"/>

		Reporting timeframe met?		
		Yes	No	
If yes, state date sent to:	A competent authority	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
	An ethics committee	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The Sponsor	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>