



## RATE-AF SAE Form Part 2

UNIVERSITY OF  
BIRMINGHAM

  
Birmingham Clinical Trials Unit

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

### IDENTIFYING DETAILS

Trial No.:     Participant initials:

Date of birth:   /    /

### REPORT DETAILS

Is this report? Initial  Follow-up

If follow-up, give the SAE ref. number:   /

(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	Yes	Expected	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:   /    /

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="text"/> <input type="text"/> <input type="checkbox"/>	<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="text"/> <input type="checkbox"/>	<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="text"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>