RATE-AF
SAE Form Part 1

UNIVERSITY OF BIRMINGHAM | BCTU Birmingham Clinical Trials Unit

! Please fax the completed form (and any relevant reports) to the RATE-AF Trial Office on 0121 415 9135 or 0121 415 9136 within 24 hours of being made aware of the SAE. !

IDENTIFYING DETAILS

Trial No.: ☐☐☐☐	Participant initials: ☐☐☐
Date of birth: DD / MM / YYYY	

REPORT DETAILS

Is this report?	Initial ☐	Follow-up ☐
If this is a follow-up report, has the relatedness changed as a result of new information?	No ☐	Yes ☐
If follow-up, give the SAE ref. number: (ref. no. will be provided by BCTU)	☐☐/☐☐☐☐	

TRIAL INTERVENTION CAUSALITY ASSESSMENT

The assessment of causality **must** be confirmed by a physician so delegated and recorded on the Delegation Log:

Causality Assessment *(tick only one)*

1) Unrelated to trial intervention	☐	Unrelated
2) Unlikely to be related to trial intervention	☐	
3) Possibly related to trial intervention	☐	Related
4) Probably related to trial intervention	☐	
5) Definitely related to trial intervention	☐	

If boxes 3-5 in the 'Causality Assessment' have been ticked, please give reasons why you consider the event to be related to the intervention:

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REASON FOR REPORTING SAE

Please refer to Section 10 in the current protocol.

Seriousness of event (please provide a response to each question)	**No**	**Yes**	**Details**
Death	☐	☐	If Yes, date of death: DD / MMM / YYYY
Life threatening event	☐	☐	
In-patient hospitalisation or prolongation of existing hospitalisation	☐	☐	If Yes, **Initial** ☐ **Prolonged** ☐ If **Yes**, number of days spent in hospital as result of the SAE (or number of days estimated prolongation): ☐☐☐
Persistent or significant disability/incapacity; or consists of a congenital anomaly or birth defect	☐	☐	
Other pertinent medical reason for reporting?	☐	☐	If **Yes**, please specify: …… …….. ……..

DETAILS OF EVENT

Date of onset:	DD / MMM / YYYY
Date it became serious	DD / MMM / YYYY
Date resolved:	DD / MMM / YYYY

Brief description of event/ diagnosis e.g. relevant investigations, treatment:

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In the investigators opinion, is this a cardiovascular-related event? *As judged by a medically qualified doctor* *If yes, please complete a* ***Cardiovascular Event Form***	No ☐ Yes ☐ Not assessable ☐
CTCAE category Please refer to coded list at the end of this form	☐☐

Trial Number: ☐☐☐☐ SAE Ref.: ☐☐ / ☐☐☐☐

RANDOMISED TREATMENT ALLOCATION

Please indicate which trial treatment the patient was randomised to:

Investigational Medicinal Products	**Tick if yes**	**Start date** (dd/mmm/yyyy)	**Stop date** (dd/mmm/yyyy)	**Tick if continuing**	**Dose**	**Unit**	**Freq.**
Digoxin	☐	DD/MMM/YYYY	DD/MMM/YYYY	☐			
Bisoprolol	☐	DD/MMM/YYYY	DD/MMM/YYYY	☐			

Has the patient taken any other drugs which may interact with the intervention or influence the SAE? No ☐ Yes ☐

CONCOMITANT MEDICATION

Please provide details of other medication the patient was taking/ given immediately prior to the event:

- A list of concomitant medications taken within the 7 days prior to the event will be requested at a later date and should be documented on the Concomitant Medication Continuation Sheet

Drug Name (generic name)	**Indication**	**Start date** (dd/mmm/yyyy)	**Stop date** (dd/mmm/yyyy)	**Tick if continuing**	**Dose**	**Unit**	**Freq.**	**Route***
		DD/MMM/YYYY	DD/MMM/YYYY	☐				
		DD/MMM/YYYY	DD/MMM/YYYY	☐				
		DD/MMM/YYYY	DD/MMM/YYYY	☐				
		DD/MMM/YYYY	DD/MMM/YYYY	☐				
		DD/MMM/YYYY	DD/MMM/YYYY	☐				
		DD/MMM/YYYY	DD/MMM/YYYY	☐				
		DD/MMM/YYYY	DD/MMM/YYYY	☐				
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		DD/MMM/YYYY	DD/MMM/YYYY	☐				
		DD/MMM/YYYY	DD/MMM/YYYY	☐				
		DD/MMM/YYYY	DD/MMM/YYYY	☐				

**Select from the following for medication route: Buccal (buc), Inhaled (INH), Intramuscular (IM), Intravenous (IV), Nasal (NAS), Oral (PO), Rectal (PR), By ear (AU), Topical (top), Subcutaneous (SQ), Sublingual (SL), Transdermal (TD), Unknown (UKN)*

RELEVANT MEDICAL HISTORY

Please list any underlying comorbidities or lab tests or investigations that are relevant. Where investigations or lab tests are appended please ensure patient identifiable details are replaced with the trial number. If none, please indicate 'nil relevant':

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DETAILS OF PERSON REPORTING

Signature of Person Reporting: **(you must have signed the site delegation log)** ……	Name of Person Reporting: …… Position: ……
Tel: ……	Email: ……
Fax: ……	Date: D D / M M M / Y Y Y Y
Signature of Principal Investigator: (if not reported by PI) ……	

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Coded Reference Lists

Common Terminology Criteria for Adverse Events (CTCAE Coded List)

Code	Category	Code	Category
1	Allergy/Immunology	15	Infection
2	Auditory/Ear	16	Lymphatics
3	Blood/Bone Marrow	17	Metabolic/Laboratory
4	Cardiac Arrhythmia	18	Musculoskeletal/Soft Tissue
5	Cardiac General	19	Neurology
6	Coagulation	20	Ocular/Visual
7	Constitutional Symptoms	21	Pain
8	Death	22	Pulmonary/Upper Respiratory
9	Dermatology/Skin	23	Renal/Genitourinary
10	Endocrine	24	Secondary Malignancy
11	Gastrointestinal	25	Sexual/Reproductive Function
12	Growth and Development	26	Surgery/Intra-Operative Injury
13	Haemorrhage/Bleeding	27	Syndromes
14	Hepatobiliary/Pancreas	28	Vascular