



RATE-AF Cardiovascular Event Form

UNIVERSITY OF
BIRMINGHAM



IDENTIFYING DETAILS	
Trial No.: <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	Participant initials: <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>
Date of birth: <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> / <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> / <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	
Which SAE does this Cardiovascular Event Form relate to: <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> / <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	

DETAILS OF EVENT	
Select as many options as required:	
Stroke or TIA <input type="checkbox"/>	Worsening of heart failure <input type="checkbox"/>
	Acute coronary syndrome <input type="checkbox"/>
	Other <input type="checkbox"/>
<i>If other, please select from list below:</i>	
Torsade de pointes tachycardia <input type="checkbox"/>	AV nodal block <input type="checkbox"/>
Drug-induced bradycardia <input type="checkbox"/>	Pulmonary vein stenosis <input type="checkbox"/>
Bleeding caused by catheter intervention or antithrombotic therapy <input type="checkbox"/>	Non-fatal cardiac arrest <input type="checkbox"/>
Drug toxicity of AF related therapy <input type="checkbox"/>	Percutaneous coronary (e.g. PCI), cerebrovascular or peripheral procedure <input type="checkbox"/>
Implantation of a pacemaker, ICD or any other device <input type="checkbox"/>	Pulmonary embolism or deep vein thrombosis <input type="checkbox"/>
Major bleeding <input type="checkbox"/>	Ventricular fibrillation <input type="checkbox"/>
Ventricular tachycardia <input type="checkbox"/>	Ablation or drug-induced atrial flutter or atrial <input type="checkbox"/>
Tachycardia <input type="checkbox"/>	Pericardial tamponade <input type="checkbox"/>
Cardiac transplantation <input type="checkbox"/>	Blood pressure related (hypotension, hypertension NOT syncope) <input type="checkbox"/>
Syncope <input type="checkbox"/>	Atrio-oesophageal fistula <input type="checkbox"/>
Hospitalisation for AF (e.g. cardioversion, initiation of antiarrhythmic therapy, AF ablation) <input type="checkbox"/>	Any type of cardiovascular surgery <input type="checkbox"/>
Cardiovascular infection <input type="checkbox"/>	
None of the above, please specify <input type="checkbox"/>	
.....	

Trial Number:

SAE Ref.: /

Stroke	Type of stroke/ TIA:	
	TIA <input type="checkbox"/>	Ischemic stroke (including transient events with matching lesion on cerebral imaging) <input type="checkbox"/> Haemorrhagic stroke <input type="checkbox"/> Stroke, unknown cause <input type="checkbox"/> Stroke, other cause <input type="checkbox"/>
	Rankin score of stroke severity: I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> V <input type="checkbox"/>	
	Guidance on selecting Rankin score of stroke severity:	
	Grade I	No significant disability (able to carry out all usual duties)
	Grade II	Slight disability (unable to carry out some of the previous activities but able to look after own affairs without assistance)
Grade III	Moderate disability (requiring some help but able to walk without assistance)	
Grade IV	Moderate severe disability (unable to walk without assistance and unable to attend to own bodily needs without assistance)	
Grade V	Severe disability (bedridden, incontinent and requiring constant nursing care and attention)	
Diagnostic procedures: CT <input type="checkbox"/> MRI <input type="checkbox"/> Other <input type="checkbox"/>		
Therapy given: Antiplatelet only <input type="checkbox"/> Lytic therapy <input type="checkbox"/> Local mechanical therapy <input type="checkbox"/> No therapy <input type="checkbox"/> Other <input type="checkbox"/>		
Heart Failure	Acute cardiac decompensation due to AF: No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown <input type="checkbox"/>	
	Lung oedema (documented in chest radiography): No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown <input type="checkbox"/>	
	Severe peripheral oedema: No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown <input type="checkbox"/>	
	BNP: Normal range <input type="checkbox"/> Pathological <input type="checkbox"/> Unknown <input type="checkbox"/>	
	BNP value: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> ng/L	NT-proBNP value: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> ng/L
	Acute therapy: IV diuretics <input type="checkbox"/> PO diuretics <input type="checkbox"/> Inotropic agents <input type="checkbox"/> No therapy <input type="checkbox"/> Other <input type="checkbox"/>	
	ICU/ CCU: No <input type="checkbox"/> Yes <input type="checkbox"/>	Duration of ICU/ CCU stay: <input type="text"/> <input type="text"/> <input type="text"/> days
	NYHA Functional Classification on admission: I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/>	
	Guidance on selecting NYHA Functional Classification:	
	I	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation or dyspnoea.
	II	Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation or dyspnoea.
III	Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation or dyspnoea.	
IV	Unable to carry out any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.	
Acute Coronary Syndrome	Type of acute coronary syndrome:	
	STEMI, anterior <input type="checkbox"/> STEMI, inferior <input type="checkbox"/> STEMI, other or not classifiable <input type="checkbox"/> NSTEMI <input type="checkbox"/> Unstable angina <input type="checkbox"/>	
Troponin: Normal range <input type="checkbox"/> Pathological <input type="checkbox"/> Unknown <input type="checkbox"/>		Maximal troponin value: <input type="text"/> <input type="text"/> <input type="text"/> ng/L

Cardiovascular Event Form completed by: You must have signed the trial signature and delegation log	Name:
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"/>	(please print)
	Signature: