RATE-AF Follow-Up CRF

UNIVERSITY OF BIRMINGHAM | BCTU Birmingham Clinical Trials Unit

IDENTIFYING DETAILS

Patient initials: ☐☐☐	**Trial Number:** ☐☐☐☐
Date of visit: DD/MM/YYYY	

TIMEPOINTS

Please indicate below, which visit this CRF relates to:

6 months ☐	12 months ☐

QUALITY OF LIFE QUESTIONNAIRES

Has the patient completed the following?	SF-36	No ☐	Yes ☐
	EQ5D-5L	No ☐	Yes ☐
	AF-EQT	No ☐	Yes ☐

BLOOD TESTS

Clinical samples (all bloods to be taken non-fasted)

Test		Not Applicable	Test		Not Applicable
Sodium:	☐☐☐ mmol/L		Albumin:	☐☐ g/L	☐
Potassium:	☐☐.☐ mmol/L		Calcium:	☐.☐☐ mmol/L	☐
Urea:	☐☐.☐ mmol/L		Phosphate:	☐.☐☐ mmol/L	☐
Creatinine:	☐☐☐ micromol/L		Magnesium	☐.☐☐ mmol/L	☐
eGFR	☐☐☐ mL/min/ 1.73m^2		Hb:	☐☐☐ g/L	☐
			HCT:	☐.☐☐ L/L	☐
INR:	☐☐.☐	☐			

CONCOMITANT MEDICATIONS

Please indicate whether the patient is on any of the following medication:

Anticoagulant medication: No ☐ Yes ☐

If known, please indicate which medication(s) the patient is on from the list below:

Warfarin ☐	Acenocoumarol ☐	Phenindione ☐	Dabigatran ☐	Edoxaban ☐	Rivaroxaban ☐	Apixaban ☐

Trial Number: ☐☐☐☐ Date of Visit: D D / M M M / Y Y Y Y

Antiplatelet medication: No ☐ Yes ☐				
If known, please indicate which medication(s) the patient is on from the list below (choose as many as required):				
Aspirin ☐	Dipyridamole ☐	Prasugrel ☐	Clopidogrel ☐	Ticagrelor ☐
Antihypertensive medication: No ☐ Yes ☐				
If known, please indicate which medication(s) the patient is on from the list below (choose as many as required):				
ACEi ☐	ARB ☐	Thiazide/loop diuretics ☐	CCBs ☐	Alpha-blockers ☐
Aldosterone antagonists ☐	Others ☐ *Please specify:*			
Inhalers for airway disease: No ☐ Yes ☐				

MEDICAL HISTORY

Please provide details about the patients recent medical history:

Atrial Fibrillation

Modified EHRA score: 1 ☐ 2a ☐ 2b ☐ 3 ☐ 4 ☐

Guidance on selecting modified EHRA score:

1: *None; AF does not cause any symptoms*

2a: *Mild; normal daily activity not affected; patient not troubled by symptoms*

2b: *Moderate; normal daily activity not affected; patient troubled by symptoms*

3: *Severe; normal daily activity affected by symptoms relating to AF*

4: *Disabling; normal daily activity discontinued*

Heart Failure

Has the patient been diagnosed with heart failure? No ☐ Yes ☐

Please complete the following:

NYHA Functional Classification: I ☐ II ☐ III ☐ IV ☐

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.*

Has the patient undergone any cardiovascular procedures since their last study visit? No ☐ Yes ☐

If yes, please retrieve a relevant summary of procedure and file in the investigator site file

Trial Number: ☐☐☐☐ Date of Visit: D D / M M M / Y Y Y Y

Pacemaker

Has the patient had a pacemaker fitted since their last trial visit? No ☐ Yes ☐

If yes, please complete the following section:

When was the pacemaker fitted? M M M / Y Y Y Y

Type of pacemaker: Single chamber ☐ Dual chamber ☐

Is the pacemaker? Pacing only ☐ ICD ☐ CRT-D ☐ CRT-P ☐

Is the patient pacemaker dependant? No ☐ Yes ☐

Reason for implantation: Bradycardia ☐ Atrial fibrillation (e.g. with tachy-brady syndrome) ☐ Heart failure ☐ Syncope ☐

Please provide details of any oral medications that the patient is currently taking to normalise their heart rate:

Oral medication				Current dose & frequency		
Type	Agent/ Brand	No	Yes	Dose	Units	Frequency
Digoxin		☐	☐			
β-blocker		☐	☐			
Diltiazem		☐	☐			
Verapamil		☐	☐			
Amiodarone		☐	☐			
Others (*please specify*)		☐	☐			
		☐	☐			

FOLLOW-UP PROCEDURES AND ASSESSMENTS

12-lead ECG:

Heart rate ☐☐☐ bpm	QRS duration ☐☐☐ ms	QT interval ☐☐☐ ms

Office blood pressure and heart rate. To be taken whilst patient is at rest, in a seated position:

BP 1: ☐☐☐ / ☐☐☐ mmHg	BP 2: ☐☐☐ / ☐☐☐ mmHg
Radial artery heart rate: ☐☐☐ bpm	Apical heart rate: ☐☐☐ bpm

Calculate heart rate from at least 30 second measurement

Trial Number: ☐☐☐☐ Date of Visit: D D / M M M / Y Y Y Y

Physical examination:

Does the patient have any signs of heart failure?	No ☐ Yes ☐
If yes, please indicate which ones below:	
Lung crepitations consistent with heart failure	No ☐ Yes ☐
Peripheral oedema	No ☐ Yes ☐
Raised jugular vein pressure	No ☐ Yes ☐
Abnormal heart sounds	No ☐ Yes ☐

Please specify: .....

Anthropometric measurements:

Weight: ☐☐☐ kg, to nearest kg	Waist circumference: *taken above the hip bones in expiration, to nearest cm* ☐☐☐ cm

Please provide details of the patients recent (within the last 7 days) physical activity:

During the last 7 days, how much time did the patient spend sitting on a week day?	☐☐☐☐ minutes per weekday
During the last 7 days, on how many days did the patient walk for at least 10 minutes at a time?	☐ days per week
What is the total amount of time the patient spent walking over the last 7 days?	☐☐☐☐ minutes per week
During the last 7 days, on many days did the patient undertake moderate physical activities?	☐ days per week
How much time in total has the patient spent over the last 7 days doing moderate physical activities?	☐☐☐☐ minutes per week
During the last 7 days, on how many days did the patient undertake vigorous physical activities?	☐ days per week
How much time in total has the patient spent over the last 7 days doing vigorous physical activities?	☐☐☐☐ minutes per week

Guidance on completing physical activity fields:

Sitting	*Ask the patient to think about the time they spent sitting on week days during the last 7 days. Include time spent at work, at home, while doing course work, and during leisure time. This may include time spent sitting at a desk, visiting friends, reading or sitting or lying down to watch television.*
Walking	*Ask the patient to think about the time they spent walking in the last 7 days. This includes at work and at home, walking to travel from place to place, and any other walking that they might have done solely for recreation, sport, exercise, or leisure.*
Moderate physical activities	*Ask the patient to think about the time they spent undertaking activities which take moderate physical effort over the last 7 days. Moderate physical activities are those that made them breathe somewhat harder than normal and may have included carrying light loads, bicycling at a regular pace, or doubles tennis. Do not include walking. Again, ask that the patient thinks about only those physical activities that they did for at least 10 minutes at a time.*
Vigorous physical activities	*Ask the patient to think about all the vigorous activities which take hard physical effort that they did in the last 7 days. Vigorous activities are those that made them breathe much harder than normal and may include heavy lifting, digging, aerobics, or fast bicycling. Ask that the patient thinks about only those physical activities that they did for at least 10 minutes at a time.*

Trial Number: ☐☐☐☐ Date of Visit: D D / M M M / Y Y Y Y

Six-minute walk test:	
Did the patient undergo the six-minute walk test? No ☐ Yes ☐	
Total time spent undertaking the test: ☐☐ : ☐☐ min/s	Total distance covered: ☐☐☐ m, to nearest m
Was the test stopped prematurely? No ☐ Yes ☐	
If yes, please specify the reason the procedure was stopped (choose one option):	Breathlessness ☐ Fatigue ☐ Claudication ☐ Chest pain ☐ Other pain e.g. joint ☐ Other (please specify) ☐ .....
Peak heart rate: ☐☐☐ bpm	

Mini mental state examination (please refer to RATE-AF Worksheet). Record only the total test score on this CRF:

MMSE total test score: ☐☐ /30

TREATMENT COMPLIANCE

Has the patient been compliant with drugs used to control heart their rate? All ☐ Some ☐ None ☐
Assessed by asking the participant how much of their medication they've taken

If some, how compliant has the patient been? > 75 % ☐ > 50 – 75 % ☐ > 25 – 50 % ☐ ≤ 25 % ☐
Assessed by asking the participant

ADVERSE EVENTS

Please record patient reported adverse events:

Since the last visit, has the participant been unwell or experienced any side-effects or other adverse events? No ☐ Yes ☐

If 'yes', please complete below:
If a previously recorded AE has resolved or changed since the last visit, please update the AE records.

Did the event include any of the following?

	No	Yes		No	Yes
Gastrointestinal upset	☐	☐	Dizziness	☐	☐
Blurred vision	☐	☐	Headache	☐	☐
Rash	☐	☐	Lethargy	☐	☐
Peripheral oedema	☐	☐	Upper respiratory tract symptoms	☐	☐
Symptomatic bradycardia	☐	☐	Symptomatic hypotension	☐	☐

Trial Number: ☐☐☐☐ Date of Visit: D D / M M M / Y Y Y Y

Other (*please specify*) .....

.....

.....

.....

Has the patient stopped taking trial medication because of **adverse event(s)?** No ☐ Yes ☐

If yes, has the medication been stopped? Temporarily ☐ Permanently ☐

If medication has been stopped **permanently**, what date was the last dose of medication taken? D D / M M M / Y Y Y Y

If medication has been stopped temporarily, please provide dates:
Date stopped: D D / M M M / Y Y Y Y
Date restarted: D D / M M M / Y Y Y Y

If the patient has stopped taking medication for **any reason other than adverse events,** please provide details below, including the date medication was stopped:

.....

Date stopped: D D / M M M / Y Y Y Y

Serious adverse events

SAE: Any adverse event, reaction or unexpected adverse reaction, respectively that: Results in death; is life threatening; requires hospitalisation or prolongation of existing hospitalisation; results in persistent or significant disability or incapacity; consists of a congenital anomaly.

Since the last visit, has the participant experienced any serious adverse events? No ☐ Yes ☐

If 'yes', please complete an SAE form

Follow-Up CRF completed by:
You **must** have signed the trial signature and delegation log

Name: .....
(please print)

Date: D D / M M M / Y Y Y Y

Signature: .....