RATE-AF Baseline CRF

UNIVERSITY OF BIRMINGHAM | BCTU Birmingham Clinical Trials Unit

IDENTIFYING DETAILS

Patient initials: ☐☐☐	**Trial Number:** ☐☐☐☐
Gender: Male ☐ Female ☐	**Patient self-declared ethnicity code:** ☐☐ (Please refer to coded list, **Note 1** at the end of this document)
Date of visit: DD/MM/YYYY	

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		Test	
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:	☐☐.☐	NT-proBNP:	☐☐☐☐ ng/L

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 ☐

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 ☐

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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 past medical history:

Atrial Fibrillation

What year was the patient diagnosed with atrial fibrillation? Y Y Y Y

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.*

Vascular System

Has the patient had a myocardial infarction (MI)? No ☐ Yes ☐

Date of most recent MI: M M M / Y Y Y Y Date unknown: ☐

Has the patient had any of the following? Coronary angioplasty or stents ☐ Coronary artery bypass surgery ☐ Heart valve replacement ☐

Has the patient had a stroke? No ☐ Yes ☐

Date of most recent stroke: M M M / Y Y Y Y Date unknown: ☐

Has the patient had a transient ischaemic attack (TIA)? No ☐ Yes ☐

Date of most recent TIA: M M M / Y Y Y Y Date unknown: ☐

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Smoking Status	Never smoked ☐ Ex-smoker ☐ Current smoker ☐	
Alcohol	Does the patient have more than 8 drinks per week containing alcohol?	No ☐ Yes ☐
Respiratory System	Does the patient have asthma?	No ☐ Yes ☐
	Does the patient have COPD/ emphysema?	No ☐ Yes ☐
Gastrointestinal System	Does the patient have liver disease?	No ☐ Yes ☐
Endocrine System	Has the patient been diagnosed with: Type I diabetes ☐ Type II diabetes ☐ If yes to either, how is the patient's diabetes controlled? Insulin ☐ Oral medication ☐ Diet ☐	
	Has the patient had complications relating to their diabetes? No ☐ Yes ☐ *If yes, please specify below:* Retinopathy ☐ Nephropathy ☐ Neuropathy ☐ Vascular ☐	
	Has the patient received treatment for thyroid disease? No ☐ Yes ☐ *If yes, please specify below:* Hypothyroid (underactive thyroid) ☐ Hyperthyroid (overactive thyroid) ☐	
Bleeding	Has the patient had any major bleeds? No ☐ Yes ☐ *If yes, please specify where below:* Intracranial ☐ Gastrointestinal ☐ Other ☐ *please specify:*	
	Date of most recent bleed: ☐☐☐/☐☐☐☐	Date unknown: ☐

Please provide details of any unplanned hospital admissions and procedures relating to AF and/ or heart failure:

Has the patient had any unplanned admissions for AF or heart failure in the last 12 months? No ☐ Yes ☐

Has the patient taken previously anti arrhythmic drugs? No ☐ Yes ☐

Amiodarone ☐	Dronedarone ☐	Flecainide ☐	Profafenone ☐	Sotalol ☐

Others ☐ *please specify:* .....

Has the patient previously undergone any cardioversions? No ☐ Yes ☐

If yes, how many? ☐

Has the patient previously undergone AF ablation? No ☐ Yes ☐

If yes, how many? ☐

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Does the patient have a pacemaker? No ☐ Yes ☐

If yes, please complete the following section:

When was the pacemaker fitted? MMM/YYYY

Type of pacemaker: Single chamber ☐ Dual chamber ☐ ICD ☐

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

Please provide details of any medications that the patient has previously taken to normalise their heart rate:

Has the patient previously taken any of the following medication to normalise their heart rate? No ☐ Yes ☐

If yes, please specify which medications and the date that the last dose was taken below:

	No	Yes	When was the last dose taken? (MMM/YYYY) If date not known, please tick 'unknown'
Digoxin	☐	☐	MMM/YYYY Unknown ☐
Verapamil	☐	☐	MMM/YYYY Unknown ☐
Diltiazem	☐	☐	MMM/YYYY Unknown ☐
Beta blocker	☐	☐	MMM/YYYY Unknown ☐

BASELINE PROCEDURES AND ASSESSMENTS

12-lead ECG:

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

Echocardiogram:

Estimated ejection fraction: < 40% ☐ 40-49% ☐ ≥ 50% ☐

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	Apex beat heart rate: ☐☐☐ bpm

Calculate heart rate from at least 30 second measurement

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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:		
Height: *to nearest cm* ☐☐☐ cm	Weight: *to nearest kg* ☐☐☐ 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.*

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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

Baseline 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: ……

Note 1: Ethnicity codes based on 2011 Census	
31	White - English / Welsh / Scottish / Northern Irish / British
32	White - Irish
33	White - Gypsy or Irish Traveller
34	White - Any Other White background
35	Mixed / Multiple ethnic group - White and Black Caribbean
36	Mixed / Multiple ethnic group - White and Black African
37	Mixed / Multiple ethnic group - White and Asian
38	Mixed / Multiple ethnic group - Any Other Mixed / multiple ethnic background
39	Asian / Asian British – Indian
40	Asian / Asian British – Pakistani
41	Asian / Asian British – Bangladeshi
42	Asian / Asian British – Chinese
43	Asian / Asian British - Any other Asian background
44	Black / African / Caribbean / Black British – African
45	Black / African / Caribbean / Black British – Caribbean
46	Black / African / Caribbean / Black British – Any other Black / African / Caribbean background
47	Other ethnic group – Arab
48	Other ethnic group – Any other ethnic group
98	Any other
99	Not known/not provided