STOP-ACEi

CRF02 – BASELINE VISIT

To be completed for the Baseline Visit only. No trial assessments should be performed before informed consent is obtained.

Please also arrange for the participant to complete the KDQOL-SF™ questionnaire.

Name of person that completed CRF, please print: This person must be listed on the STOP-ACEi delegation log.	……
Date CRF completed:	D D / M M M / Y Y Y Y

Part A: Identifying Details

Trial No.: ☐☐☐☐	Centre: ……
DOB: M M M / Y Y Y Y	Assessment date: D D / M M M / Y Y Y Y

Part B: Basic assessments

Lifestyle					
Smoking status:	Never smoked ☐		Ex-smoker ☐		Current smoker ☐
Alcohol intake:	None ☐		≤20 units per week ☐		>20 units per week ☐
Anthropometric measures					
Height: ☐☐☐ cm, to nearest cm			Weight: ☐☐☐.☐ kg, to nearest 0.1 kg		
NB. The database will calculate BMI using height recorded at the baseline visit and weight reported here.					
Blood pressure					
Blood pressure: ☐☐☐ / ☐☐☐ mmHg					
NB. Blood pressure should be measured according to current BHS guidelines.					

Part C: Lab assessments

All assessments should be performed at site according to normal local practice.

eGFR			
eGFR will be calculated by the trial database system according to the 4V-MDRD equation. Only the creatinine level is required here, but please calculate eGFR for clinical monitoring.			
Serum creatinine: ☐☐☐☐ µmol/L			
Biochemical profile			
Sodium: ☐☐☐ mmol/L		Alkaline phosphatase: ☐☐☐ U/L	
Potassium: ☐☐.☐ mmol/L		Albumin: ☐☐ g/L	
Bicarbonate: ☐☐.☐ mmol/L		Total protein: ☐☐ g/L	
Calcium: ☐.☐☐ mmol/L		Alanine transferase: ☐☐ U/L	
Phosphate: ☐.☐☐ mmol/L			
Full blood count			
Haemoglobin: ☐☐☐ g/L		Platelets: ☐☐☐ x10^9/L	
Urinary protein:creatinine ratio (PCR) or albumin:creatinine ratio (ACR) by early morning spot urine			
Urinary PCR: ☐☐☐☐ mg/mmol		Urinary ACR: ☐☐☐☐.☐ mg/mmol	
C-reactive Protein (CRP)			
CRP: ☐☐☐.☐ mg/L			

Part D: Sample tracking

Tracking for centrally analysed samples. Approximately 1 mL is required for each aliquot.

Sample type	Was the sample taken?		Was sample taken on date of assessment?		Date sample taken If different to assessment date
	No	Yes	No	Yes	
Standard trial sample, serum All trial participants. 2 x aliquots required.	☐	☐	☐	☐	DD/MM/YYYY
Standard trial sample, EDTA plasma All trial participants. 2 x aliquots required.	☐	☐	☐	☐	DD/MM/YYYY
Biomarker sample, serum Only for participants that have provided optional consent. 3 x aliquots required.	☐	☐	☐	☐	DD/MM/YYYY
Biomarker sample, urine Only for participants that have provided optional consent. 3 x aliquots required.	☐	☐	☐	☐	DD/MM/YYYY

Problems with sample preparation

Please note any problems with sample preparation here. E.g. samples left out overnight, not enough serum collected etc.

Part E: Six-Minute Walk-Test

Six-minute walk test

Did the participant undergo the 6-minute walk test? No ☐ Yes ☐

If no, reason not performed: (Please select one option) Clinical reason ☐ Other reason ☐

Details: ……

Total distance covered in 6 minutes: ☐☐☐ m rounded to the nearest metre

Was the test stopped prematurely? No ☐ Yes ☐

If yes, stopped because of: (Please select one option)

Breathlessness ☐ Chest pain ☐

Fatigue ☐ Other pain (e.g. joint) ☐

Claudication ☐

Other ☐, specify: ……

Part F: Medical History

CKD aetiology

Is the cause of CKD known? If yes, please specify	No ☐	Yes ☐
Primary glomerulonephritis	No ☐	Yes ☐
Interstitial nephropathy, e.g. drug-induced	No ☐	Yes ☐
Obstructive or reflux nephropathy	No ☐	Yes ☐
Hereditary – Autosomal Dominant Polycystic Kidney Disease (ADPKD)	No ☐	Yes ☐

…CKD aetiology cont'd		
Hereditary – Alport's Syndrome	No ☐	Yes ☐
Hereditary – Any other	No ☐	Yes ☐
Renal vascular disease	No ☐	Yes ☐
Hypertensive nephropathy	No ☐	Yes ☐
Diabetic nephropathy	No ☐	Yes ☐
Secondary glomerulonephritis (please record SLE or vasculitis as secondary glomerulonephritis)	No ☐	Yes ☐
If secondary glomerulonephritis, is this SLE? (NK = not known)	No ☐	Yes ☐ NK ☐
If secondary glomerulonephritis, is this vasculitis?	No ☐	Yes ☐ NK ☐
If vasculitis, is the participant currently on treatment?	No ☐	Yes ☐ NK ☐
If vasculitis, which? Polyarteritis Nodosa / Kussmaul-Maier disease		☐
Wegener's granulomatosis / Granulomatosis with polyangiitis (GPA)		☐
Churg-Strauss syndrome / Eosinophilic granulomatosis with polyangiitis (EGPA)		☐
Not known		☐
Other ☐, specify: ……		
Other multisystem disease, specify: e.g. myeloma, amyloid, tumour, TB etc. ……	No ☐	Yes ☐
Other cause of CKD, specify: ……	No ☐	Yes ☐

Cardiovascular events			
Has the participant ever experienced any of the following major cardiovascular events?	**No**	**Yes**	**Date of most recent event**
Hospitalisation for heart failure	☐	☐	D D / M M M / Y Y Y Y
STEMI / MI	☐	☐	D D / M M M / Y Y Y Y
NSTEMI	☐	☐	D D / M M M / Y Y Y Y
Stroke / CVE	☐	☐	D D / M M M / Y Y Y Y

Heart Failure		
In the responsible clinician's opinion, does the participant have heart failure? If yes, please provide further information below.	No ☐	Yes ☐
Date of diagnosis: D D / M M M / Y Y Y Y		

Current NYHA Functional Classification (please select one):

- ☐ Class 1: Patients with no limitation of activities, they suffer no symptoms from ordinary activities.
- ☐ Class 2: Patients with slight, mild limitation of activity; they are comfortable with rest or with mild exertion.
- ☐ Class 3: Patients with marked limitation of activity; they are comfortable only at rest.
- ☐ Class 4: Patients who should be at complete rest, confined to bed or chair; any physical activity brings on discomfort and symptoms occur at rest.

…Heart Failure cont'd

Please indicate which major Framingham criteria are met:	NK = not known		
Paroxysmal nocturnal dyspnoea	No ☐	Yes ☐	NK ☐
Neck vein distention	No ☐	Yes ☐	NK ☐
Rales	No ☐	Yes ☐	NK ☐
Radiographic cardiomegaly	No ☐	Yes ☐	NK ☐
Acute pulmonary oedema	No ☐	Yes ☐	NK ☐
S3 gallop	No ☐	Yes ☐	NK ☐
Increased central venous pressure (>16 cm H_2O at right atrium)	No ☐	Yes ☐	NK ☐
Hepatojugular reflux	No ☐	Yes ☐	NK ☐
Weight loss >4.5 kg in 5 days in response to treatment	No ☐	Yes ☐	NK ☐

Please indicate which minor Framingham criteria are met:	NK = not known		
Bilateral ankle oedema	No ☐	Yes ☐	NK ☐
Nocturnal cough	No ☐	Yes ☐	NK ☐
Dyspnoea on ordinary exertion	No ☐	Yes ☐	NK ☐
Hepatomegaly	No ☐	Yes ☐	NK ☐
Pleural effusion	No ☐	Yes ☐	NK ☐
Decrease in vital capacity by one third from maximum recorded	No ☐	Yes ☐	NK ☐
Tachycardia (heart rate >120 beats/min.)	No ☐	Yes ☐	NK ☐

Was diuretic started or dose of diuretic increased for heart failure?	No ☐	Yes ☐	NK ☐
Has a BNP (brain natriuretic peptide) measure been taken?	No ☐	Yes ☐	NK ☐
Has an echo been performed? If yes, please also complete the echo section.	No ☐	Yes ☐	NK ☐
Is there another plausible cause of symptoms? E.g. fluid overload	No ☐	Yes ☐	NK ☐

Baseline medical history - Please indicate all conditions the patient has a known history or current diagnosis of.

If there have been multiple events, please record the date of the most recent event. For ongoing or chronic conditions (e.g. hypertension), please record the date of diagnosis or first occurrence. Please use the 'details' section to give further information (e.g. if there have been multiple events). If only the month is known, please input as the 1st of that month.

Other Cardiovascular Disease	No ☐ Yes ☐ – if yes, please provide details			
	No	**Yes**	**Date** (dd/mmm/yyyy)	**Details**
Angina	☐	☐	……/……/……	……
Coronary Intervention (PCI)	☐	☐	……/……/……	……
Coronary Intervention (CABG)	☐	☐	……/……/……	……
Carotid intervention	☐	☐	……/……/……	……
Hypertension	☐	☐	……/……/……	……
Atrial fibrillation / flutter	☐	☐	……/……/……	……
Venous thromboembolism	☐	☐	……/……/……	……

…Baseline medical history cont'd - Please indicate all conditions the patient has a known history or current diagnosis of.

…Other CV disease cont'd	**No**	**Yes**	**Date** (dd/mmm/yyyy)	**Details**
Peripheral vascular disease	☐	☐	……/……/……	……
If yes, please indicate which:	Claudication			No ☐ Yes ☐
	Radiological/surgical intervention			No ☐ Yes ☐
	Amputation			No ☐ Yes ☐
	Other, specify: ……			No ☐ Yes ☐
Other cardiovascular condition	☐	☐	……/……/……	……

Diabetes	No ☐ Yes ☐ – if yes, please provide details:			
	No	**Yes**	**Date** (dd/mmm/yyyy)	**Details**
Type 1 diabetes mellitus	☐	☐	……/……/……	……
Type 2 diabetes mellitus	☐	☐	……/……/……	……

Malignancy	No ☐ Yes ☐ – if yes, please provide details:			
	No	**Yes**	**Date** (dd/mmm/yyyy)	**Details**
Any malignancy	☐	☐	……/……/……	……
If yes, please indicate which:	Solid organ			No ☐ Yes ☐
	Skin – non-melanoma			No ☐ Yes ☐
	Haematological			No ☐ Yes ☐
	Other, specify: ……			No ☐ Yes ☐

Gastrointestinal	No ☐ Yes ☐ – if yes, please provide details:			
Please only record GI symptoms that the responsible clinician considers significant				
	No	**Yes**	**Date** (dd/mmm/yyyy)	**Details**
Bloating, abdominal distention or abdominal pain	☐	☐	……/……/……	……
Constipation	☐	☐	……/……/……	……
Dyspepsia	☐	☐	……/……/……	……
Gastritis	☐	☐	……/……/……	……
Loose stools / diarrhoea	☐	☐	……/……/……	……
Nausea / vomiting	☐	☐	……/……/……	……
Ulceration	☐	☐	……/……/……	……
Other GI condition	☐	☐	……/……/……	……

Musculoskeletal or connective tissue disorders	No ☐ Yes ☐ – if yes, please provide details:			
	No	**Yes**	**Date** (dd/mmm/yyyy)	**Details**
Avascular osteonecrosis	☐	☐	……/……/……	……
Fractures	☐	☐	……/……/……	……
Osteoporosis	☐	☐	……/……/……	……

…Baseline medical history cont'd - Please indicate all conditions the patient has a known history or current diagnosis of.

… Musculoskeletal cont'd	**No**	**Yes**	**Date** (dd/mmm/yyyy)	**Details**
Osteopenia	☐	☐	……/……/……	……
Other musculoskeletal or connective tissue disorder	☐	☐	……/……/……	……

Infection	No ☐ Yes ☐ – if yes, please provide details:			
	No	**Yes**	**Date** (dd/mmm/yyyy)	**Details**
Urinary tract infection	☐	☐	……/……/……	……
Cytomegalovirus	☐	☐	……/……/……	……
Herpes Simplex Virus	☐	☐	……/……/……	……
Varicella Zoster Virus	☐	☐	……/……/……	……
Human Immunodeficiency Virus	☐	☐	……/……/……	……
Hepatitis B	☐	☐	……/……/……	……
Hepatitis C	☐	☐	……/……/……	……
Other infection	☐	☐	……/……/……	……

Pulmonary disease	No ☐ Yes ☐ – if yes, please provide details:			
	No	**Yes**	**Date** (dd/mmm/yyyy)	**Details**
COPD	☐	☐	……/……/……	……
Interstitial lung disease	☐	☐	……/……/……	……
Other pulmonary disease	☐	☐	……/……/……	……

Other	No ☐ Yes ☐ – if yes, please provide details:			
	No	**Yes**	**Date** (dd/mmm/yyyy)	**Details**
Current pregnancy	☐	☐	……/……/……	……
Psychosis	☐	☐	……/……/……	……
Gout	☐	☐	……/……/……	……
Breathlessness	☐	☐	……/……/……	……
Peripheral Oedema	☐	☐	……/……/……	……
Anaemia	☐	☐	……/……/……	……
Leukopenia	☐	☐	……/……/……	……
Thrombocytopenia	☐	☐	……/……/……	……
Endocrine or metabolic disorder	☐	☐	……/……/……	……
Cataracts	☐	☐	……/……/……	……
Other, please specify	☐	☐	……/……/……	……
Other, please specify	☐	☐	……/……/……	……
Other, please specify	☐	☐	……/……/……	……
Other, please specify	☐	☐	……/……/……	……

Part G: Medications

ESA dose

Is the participant currently on ESA treatment? No ☐ Yes ☐

If yes, please provide details here:

Type	No	Yes	Please see list of possible options at end of this document.			
			Current dose	**Unit**	**Current freq.**	**Route**
Epoetin alfa (e.g. eprex)	☐	☐				
Epoetin beta (NeoRecormon®)	☐	☐				
Darbepoetin alfa (Aranesp®)	☐	☐				
Mircera	☐	☐				
Other, specify:	☐	☐				

Antihypertensive medications

Please indicate what antihypertensive medications the participant was taking at the point of randomisation, i.e. before any trial-related changes.

Category	No	Yes	Type/brand name	Please see list of possible options at end of this document.			
				Current dose	**Unit**	**Current freq.**	**Route**
ACE inhibitor	☐	☐					
ARB	☐	☐					
CCB	☐	☐					
Loop diuretic	☐	☐					
Thiazide diuretic	☐	☐					
Thiazide-like diuretic	☐	☐					
K^+-sparing diuretic	☐	☐					
Mineralocorticoid Receptor Antagonist e.g. spironolactone	☐	☐					
Alpha blocker	☐	☐					
Beta blocker	☐	☐					
Methyldopa	☐	☐					
Moxonidine	☐	☐					
Hydralazine	☐	☐					
Other antihypertensive	☐	☐					

Changes to prescription of antihypertensive medications

Have there been any changes made to the antihypertensive medications prescribed to the trial participant following randomisation? No ☐ Yes ☐

If yes, please indicate what antihypertensive medications the participant was prescribed at the baseline visit. E.g. If the participant was randomised to the experimental arm (discontinue ACEi/ARBs), please indicate which other antihypertensives were started following randomisation.

…Changes to prescription of antihypertensive medications cont'd

Category	No	Yes	Type/brand name	Please see list of possible options at end of this document.			
				Current dose	**Unit**	**Current freq.**	**Route**
ACE inhibitor	☐	☐					
ARB	☐	☐					
CCB	☐	☐					
Loop diuretic	☐	☐					
Thiazide diuretic	☐	☐					
Thiazide-like diuretic	☐	☐					
K^+-sparing diuretic	☐	☐					
Mineralocorticoid Receptor Antagonist e.g. spironolactone	☐	☐					
Alpha blocker	☐	☐					
Beta blocker	☐	☐					
Methyldopa	☐	☐					
Moxonidine	☐	☐					
Hydralazine	☐	☐					
Other antihypertensive	☐	☐					

Other concomitant medications

Is the participant currently taking any other medications? No ☐ Yes ☐
If yes, indicate what other medications the participant was on at the point of randomisation:

Category	No	Yes	Category	No	Yes	Category	No	Yes
Statin	☐	☐	Clopidogrel	☐	☐	Mycophenolate mofetil (MMF)	☐	☐
Digoxin	☐	☐	Warfarin	☐	☐	Ciclosporin	☐	☐
Nitrate	☐	☐	Phosphate binders	☐	☐	Cyclophosphamide	☐	☐
Fibrate	☐	☐	Calcium/Vitamin D	☐	☐	Azathioprine	☐	☐
Ezetimibe	☐	☐	Bisphosphonate	☐	☐	Tacrolimus	☐	☐
Aspirin	☐	☐	Prednisolone	☐	☐	Methotrexate	☐	☐
Bicarbonate	☐	☐	Metformin	☐	☐	NSAIDS	☐	☐
Sulphonylurea, e.g. glicazide	☐	☐	Sirolimus	☐	☐	Thiazolidinedione/glitazone	☐	☐
GLP-1 analogues/agonists, e.g. liraglutide, exenatide	☐	☐	SGLT2 inhibitor, e.g. dapagliflozin	☐	☐	DPP-4 inhibitor (incretins), e.g. sitagliptin, vildagliptin	☐	☐

Please detail any other medications the participant is currently taking. Only name/type is required.

Part H: 12-Lead ECG

12-lead ECG						
Was a 12-lead ECG performed?	No ☐	Yes ☐				
If no, reason not done:						
Ventricular rate: ☐☐☐ b.p.m.			QTc duration: ☐☐☐ ms			
The ECG is: (Please select one option)	Normal ☐	Abnormal, not clinically significant ☐	Abnormal + clinically significant ☐			
If abnormal and clinically significant, please provide details below (NK = not known).						
Is there evidence of myocardial infarction?	No ☐	Yes ☐	NK ☐			
Cardiac rhythm: Sinus rhythm?	No ☐	Yes ☐	NK ☐			
Is there evidence of atrial fibrillation?	No ☐	Yes ☐	NK ☐			
Is there evidence of other supraventricular tachycardia? (e.g. flutter)	No ☐	Yes ☐	NK ☐			
Paced rhythm?	No ☐	Yes ☐	NK ☐			
Other rhythm abnormality, specify:						
Is there evidence of a conduction defect?	No ☐	Yes ☐	NK ☐			
Is this left bundle branch block?	No ☐	Yes ☐	NK ☐			
Other conduction defect, specify:						
Is there evidence of left ventricular hypertrophy?	No ☐	Yes ☐	NK ☐			

Part I: Echocardiogram

Echocardiogram						
Has the participant had a cardiac echocardiogram in the last 12 months? If yes, please provide the available details for the most recent echo. Please record values that have not been indexed to body size. This is the most common measure available. NK = not known.	No ☐	Yes ☐				
Date of echo: D D / M M M / Y Y Y Y						
Is LV (left ventricular) ejection fraction known?	No ☐	Yes ☐	– If yes, please provide: ☐☐ %			
If a value for LVEF is not known, please indicate LV systolic function (please select one option):						
Normal ☐	Mildly impaired ☐	Moderately impaired ☐	Mod.-severely impaired ☐	Severely impaired ☐		
Is estimated pulmonary artery systolic pressure known?	No ☐	Yes ☐	– If yes, please provide: ☐☐☐ mmHg			
Is left atrial volume known?	No ☐	Yes ☐	– If yes, please provide: ☐☐ mL^3			
Is there evidence of LV hypertrophy?	No ☐	Yes ☐	NK ☐			
If yes, severity (please select one option):	Mild ☐	Moderate ☐	Severe ☐	NK ☐		

Part J: Visit checklist

In addition to the data above, the following forms are also required for the baseline visit:

- A copy of the completed KDQOL-SF™ form (for baseline (visit 1) and months 12, 24 and 36 only).

Additional forms		
Has the KDQOL-SF ™ form been completed?	No ☐	Yes ☐

Thank you for completing the STOP-ACEi CRF02: Baseline Visit

Please enter data online at: https://www.trials.bham.ac.uk/STOPACEi

STOP-ACEi Study Office, Birmingham Clinical Trials Unit, College of Medical & Dental Sciences, University of Birmingham, Edgbaston, Birmingham, B15 2TT.
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STOP-ACEi website: www.birmingham.ac.uk/STOPACEi

Answer Options for Concomitant Medications

Unit		**Route**	**Frequency**
mg	Milligram	Intraarterial	Twice a day
mcg	Microgram	Intraperitoneal	Three times a day
g	Gram	Intravenous	Four times a day
Puffs		Oral	Hourly
U	Units	Respiratory (inhalation)	4 hourly
mL	Millilitre	Subcutaneous	Daily
mg/mL	Milligrams per millilitre	Topical	Alternate days
mg/kg	Milligrams per kilogram	Suppository	As desired
mcg/mL	Micrograms per millilitre	Intraocular	If necessary
AUC	Area Under Curve	Intramuscular	Slow release
Other, **specify**		Other, **specify**	Other, **specify**
Not known		Not known	Not known