STOP-ACEi

CRF03 – TELEPHONE FOLLOW-UP

To be completed for the Telephone Follow-up that is performed 4-6 weeks after randomisation. If there are any concerns, please arrange for appropriate clinical care and monitoring as per routine practice.

The telephone follow-up should cover the following points:

- **Clinical visits** - Whether the participant has been seen by a doctor or other healthcare professional since the baseline visit, including at the GP, by a district nurse, in hospital or at A&E. Please detail any AEs that lead on from this question in the AE section;
- **Adverse events** - Whether the participant has been unwell or had any adverse events since the baseline visit. Please try to avoid leading questions or going through a list of symptoms. When completing the CRF, please categorise AEs based on the participant's description and detail any resulting changes to medications in the medications section;
- **Changes to medications & compliance** - Whether the participant has had any changes to medications, including stopping existing medications or starting new medications, and whether they have remained compliant to their trial treatment allocation.

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: Continued trial participation

Death	
Has the participant died since the baseline visit? If yes, please provide details.	No ☐ Yes ☐
Date of death:	D D / M M M / Y Y Y Y
Cause of death category: ☐	1 – Cancer, 2 – Cardiovascular, 3 – Cerebrovascular, 4 – Renal, 5 – Hepatic, 6 – Respiratory, 7 – Neurodegenerative, 8 – Accidental (death not caused by disease), 9 – Other
Details:	……
If the participant has died, please also complete CRF 10: SAE form and report this to the trial office within 24 hours of notification.	
Withdrawal	
Is the participant willing to continue in the study?	No ☐ Yes ☐
Has the participant withdrawn from the study? If yes, please provide details.	No ☐ Yes ☐
Reason: ☐ Participant lost to follow-up	
☐ Participant withdrew consent, reason if given: ……	
☐ Clinical decision. Details: ……	
☐ Other. Details: ……	
Type of withdrawal: (Select all that apply) Withdrawal from trial treatment	No ☐ Yes ☐
Withdrawal from trial follow-up schedule	No ☐ Yes ☐
Withdrawal of optional consent – trial samples	No ☐ Yes ☐

…Withdrawal cont'd		
Withdrawal of optional consent – access to HSCIC data	No ☐	Yes ☐
Withdrawal of consent to use patient records for trial follow-up	No ☐	Yes ☐
Withdrawal of consent to use existing anonymised samples	No ☐	Yes ☐
Other. Details: ……		

Part C: Clinical visits

Clinical visits		
Has the participant been seen by a doctor, nurse or other healthcare professional in primary care since the baseline visit?	No ☐	Yes ☐
Has the participant been seen in a hospital outpatients department since the baseline visit?	No ☐	Yes ☐
Has the participant been seen in a hospital A&E department since the baseline visit?	No ☐	Yes ☐
If yes, please record any related AEs or changes to medications in the AE and Medications sections of this form.		
Hospital admissions		
Has the participant been admitted to hospital since the baseline visit?	No ☐	Yes ☐
If yes, please provide the details below and record the details of any related AEs or changes to medications in the AE and Medications sections of this form. For additional hospital admissions, please use CRF05: Additional Hospital Admissions.		
Date admitted:	D D / M M M / Y Y Y Y	
Have they been discharged? No ☐ Yes ☐ - If yes, date:	D D / M M M / Y Y Y Y	
Was the visit related to the participant's CKD? No ☐ Yes ☐		
Main reason for admission: ……		
Treatment given: Prescription medicine** ☐	Advice to buy OTC medication** ☐	
Advice ☐	Referral to a specialist ☐	
Other ☐, specify: ……		

** Please note any new medications or changes to existing medications in the medications section of this form.

If any clinical visit relates to a serious adverse event, please also report it within 24 hours of notification using CRF10: SAE form.

Part D: Adverse events

CKD progression				
Since the baseline visit, has the participant…?	**No**	**Yes**	**Date** (dd/mmm/yyyy)	**Details**
Started renal replacement therapy	☐	☐	……/……/……	……
Had a diagnosis of ESRD	☐	☐	……/……/……	……

Cardiovascular events			
Has the participant had any of the following major cardiovascular events since the baseline visit?			
Event code	**Event**	**No**	**Yes**
1	Hospitalisation for heart failure	☐	☐
2	STEMI / MI	☐	☐
3	NSTEMI	☐	☐
4	Stroke / CVE	☐	☐

…Cardiovascular events cont'd

If the participant had any of the above major cardiovascular events. Please enter the dates for all events since the baseline visit below. E.g. if the participant was admitted for heart failure twice since the baseline visit, give dates for both events. If you need more space, please use another CRF03.

Event code	Date	Event Code	Date
	DD/MM/YYYY		DD/MM/YYYY
	DD/MM/YYYY		DD/MM/YYYY
	DD/MM/YYYY		DD/MM/YYYY
	DD/MM/YYYY		DD/MM/YYYY

Adverse Events – Please indicate all new events or diagnoses the participant has had since the baseline trial visit

If there have been multiple events, please record the date of the first event since the baseline visit. Please use the 'details' section to give further information (e.g. if there are 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	☐	☐	……/……/……	……
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	☐	☐	……/……/……	……

Adverse Events – Please indicate all new events or diagnoses the participant has had since the baseline visit			
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	☐	☐	……/……/……	……
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	☐	☐	……/……/……	……

Adverse Events – Please indicate all new events or diagnoses the participant has had since the baseline visit				
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	☐	☐	...../...../.....	.....

SAE check		
Since the baseline visit, has the participant experienced any adverse events that:		
Resulted in death	No ☐	Yes ☐
Were life threatening	No ☐	Yes ☐
Required in-patient hospitalisation or prolongation of existing hospitalisation	No ☐	Yes ☐
Resulted in persistent or significant disability or incapacity	No ☐	Yes ☐
Resulted in a congenital anomaly or a birth defect	No ☐	Yes ☐

If you have answered 'yes' to any of the SAE check questions above, please complete an SAE form and alert the STOP-ACEi Trial Office within 24 hours of being notified of the event.

Part E: Medications

Medication changes

Has the participant had any changes to their medications since the baseline visit? No ☐ Yes ☐
If no, please move on to the next section (Compliance). If yes, please complete all questions in this section.

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 is currently taking.

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 is currently taking:

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 F: Compliance

Compliance with trial treatment allocation					
Has the participant remained compliant to their trial treatment allocation since the baseline visit? i.e. if on the experimental (discontinue ACEi/ARB) arm, hasn't taken any ACEis or ARBs OR, if on the control (continue ACEi/ARB) arm, has continued to take their ACEis or ARBs.			No ☐	Yes ☐	
If there has been non-compliance, please indicate the reasons (select all that apply):					
Worsening renal function	No ☐	Yes ☐	Acute kidney injury	No ☐	Yes ☐
Hypertension	No ☐	Yes ☐	Hypotension	No ☐	Yes ☐
Hyperkalaemia	No ☐	Yes ☐	Hypokalaemia	No ☐	Yes ☐
Headache	No ☐	Yes ☐	Nausea/GI symptoms	No ☐	Yes ☐
Facial swelling / lip swelling	No ☐	Yes ☐	Dry cough	No ☐	Yes ☐
Dizziness	No ☐	Yes ☐	Angioedema	No ☐	Yes ☐
Rash	No ☐	Yes ☐	Taste disturbance	No ☐	Yes ☐
Other clinical reason	No ☐	Yes ☐ – if yes, details:	……..…….…		
Other reason	No ☐	Yes ☐ – if yes, details:	……..…….…		
If non-compliance relates to an AE, please also record this in the AEs section of this form.					

Part N: Visit checklist

In addition to the data above, the following forms may also be required for the telephone follow-up:

- CRF10: SAE form (where applicable).
- CRF05: Additional Hospital Admissions (where required).

Thank you for completing the STOP-ACEi CRF03: Telephone Follow-up

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