Guidelines for Data Entry



Introduction

This document is intended to explain how to use the STOP-ACEi Online System. It does not go into the detail of either the protocol or the randomisation procedure itself, but provides essential information that will help you to use the Online System for randomisation and data entry.

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Accessing and Using the System

Usernames and Passwords

- You need a username and password to use the system.
- The STOP-ACEi Trial Office at BCTU will provide your User Name and grant access to the STOP-ACEi Online System based on the delegation log. If you don't have a User Name please contact stopacei@trials.bham.ac.uk.
- You set your own password. Passwords are individual and should be known only to you.
- You will have one username and password for all BCTU-coordinated trials. If you use online systems for other BCTU trials, your username and password will also work for STOP-ACEi.
- To set or change your password:
 - Go to the BCTU User Account Management page: https://www.trials.bham.ac.uk/Password/.
 - Enter your e-mail address and click the link to set your password.
 - You must use the e-mail address held on our system. Please contact stopacei@trials.bham.ac.uk if your e-mail address is incorrect or changes.
- The user account management page will look like this:

BCTV User Account Management	Birmingham Clinical Trials
Edit your account Help Contact	0
nformation	
We use the email address you registered with to verify your identity. If you require further assistance with your BCTU user account please follow the links above f	or information and contact details.
We use the email address you registered with to verify your identity. If you require further assistance with your BCTU user account please follow the links above f Request Please enter your email address here and choose an option below:	or information and contact details.

- Follow the on-screen instructions to change/set your password.
- Password notes: Your password should be individual and known only to you. It should be composed of at least 8 characters including at least one number and mixed upper/lower case.
- After setting your password for the first time you will receive an email asking you to activate your password. Please follow the link as directed to activate your password.
- You may find that the activation email is directed into your 'Junk Email' folder. If this happens we suggest that you manually add bctu-webadmin@contacts.bham.ac.uk to your list of safe senders in your email clients.
- After activating your password you can Log-In using your Username and Password.

Accessing the STOP-ACEi system

- Direct your web browser to <u>https://www.trials.bham.ac.uk/STOPACEi</u>
- Log in using your username and password.

• The log-in page will look like this:

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	HOME	TR	IAL WEB	SITE											
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8		-	- 37	and a	als.	-18	Please	Log In					and a second	- 20	
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Greeting

• Once you have logged in, the greeting page will look like this:

e of last log-in	elcome, Marie Valente (MV975). Your name and username You are connected to: Development Change Logout Current connection
c of last log in	STOP_ACE
	HOME PATIENTS HELP TRIAL WEBSITE
	me and a second s
	Welcome to the STOP-ACEi Online Randomisation Service
	trial number is also allocated which we will use in our correspondence to you. Confirmation of the allocation is automatically sent to the responsible clinician via email.

• The welcome message on the top left should show your Name and your Username in brackets. If there is any problem with this, please choose the logout option, and then log back in again.

Live or Training Data Connection

 You can use a 'Live' or 'Training' data connection. You should be connected to 'Live' data by default. If you want to train on the STOP-ACEi system without affecting real trial data, click on 'Change' to change the data connection to 'Training'. The pages will all display a 'Training' watermark making it clear if the connection is not live (as in the example above).

Logging off

• To log off the system simply click the 'Logout' link at the top right hand side of the page. Remember to save any progress with form completion before you log out.

Randomisation

Randomisation is now closed for STOP-ACEi. It is not possible to access the randomisation function of the system

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Entering data

To view a patient's record:

1. From the Home page, select 'Patients' and then 'Find a Patient', as shown below:



2. This will show a list of patients, identified by their STOP-ACEi trial ID number and the date of birth in mmm/yyyy format. You will only be able to see patients from your centre. You can use the search bar to filter the list of patients, e.g. by trial ID number.

Welcom Last Log	ne, Marie V gin date: 24	-Sep-2014	V975). 4						You	are con	nected to	o: Develop	ment Cha	nge Logout	
ST	OP	-A(CEi											0	1
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atients :	Find patient														
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				1032		Jul-1967			View	Cinc	in their		oor a pr	actionere	č
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				1057		Sep-1950			View					19	
				1065		May-196	7		View						
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										1					

3. The next page you will see is the Patient Form. This contains basic information about the patient and their randomisation. It also shows a list of assessments and their status (e.g. 'Due Now', 'Received').



To add a form, enter data and submit a form

1. CRF data must be submitted electronically for STOP-ACEi. From the Patient Form, click 'Add' for the desired form. You will only be able to enter assessments that have the status 'Due Now' or 'Available'. Please contact the trial office if you need to enter an assessment that is not available.

Patient form: 1586		Assessm	ents		9
PATIENT DETAILS ELIGIBILITY EGFR DECLINE MINIMISATION RANDOMISATION INFO DEATH	NFO	Status: All	~		
NITHDRAWAL INELIGIBLITY RESEND EMAILS ADMIN - VIEW AUDIT ADMIN - VIEW CHANGES		Assessment	Status	sta .	1
s the potential participant aged 18 years or	^	SAE : New	Available	Add	
over (male or female)? Yes v or so		Baseline-Pt.1: Baseline	Due Now	Add	Click 'add' to add a form
Long vertice of the potential participant inter a large vertice of the second	ts	Baseline-Pt.2: Baseline	Due Now	Add	
Does the potential participant have progressive		Baseline-Pt.3: Baseline	Due Now	Add	1
the spreadsheet tool provided? (Progressive		Consent: Baseline	Received	View	
deterioration is defined as a fall in eGFR of		KDQOLSF: Baseline	Received	View	1
>2mL/min/year over the previous 24 months. A minimum of 3 eGFR measurements from the		Phone call-Pt.1: 4-6wk	Not Due Yet		

2. The next page you will see is the form you've added. Enter data using the drop-down lists and data fields. You can navigate to the different pages of the form using the tabs. Save the data entered for the whole form by clicking 'Save'. Clicking 'Undo' will remove all data entered since the last save.

BASIC ASSESSMENTS LAB ASSESSMENTS SAMPLE TRACKING WALK TEST	Navigate using t	ne tabs			- Training-
Notes		.co	100	V	50
Date form was received (dd-mmm-yyyy) Date form was completed (dd-mmm-yyyy)	21-May-2015		Ente	r data h	ere
Smoking status:	Ex-Smoker	50	32		30
Alcohol intake:	None	~	L.Collin	~ Color	1 Colle
Height (in cm)	165				
Veight (in kg)	78	airingo	airing	and the second	dine
Systolic BP (mmHg)	148	24	10	1	1 co
Diastolic BP (mmHg)	83	. e9	es.		
DIT SUBMIT SAVE UNDO DELETE CHECK OUT	ta you've entered by cliq	king her	e (alla	~roso	~ rollin

3. Once you've entered all the data and clicked 'save', the form will indicate that the save was successful. Some fields are required and you won't be able to save a form until the data is entered. You can review the data entered using the tabs. If you want to make changes, click 'Edit'. You can save and edit a form as much as you like before you click 'submit'. If you are happy with the data entered, click 'Submit'. Clicking 'Submit' tells the system that data entry has been completed and that the form is ready to be checked. It will also stop the system sending you automatic reminder e-mails.

Systolic BP (mmHg)	148		~	~	~ ~	
Diastolic BP (mmHg)	83		10	and a		
EDIT SUBMIT SAVE UNDO DELETE CHECK OUT	Click here to edit, subm	it or delete the for	m ²⁵⁰	×10"	Form saved	Indicates that form is saved
Form Status: Data Entry In Progress There are 0 queries for this form	tions are answered, there s	hould be no quer	ies _{xtaline}	(contraction	A Laboration of Laboration	

'Check out' a form, locked forms and editing forms after they have been submitted

Once you have submitted a form, you can still go back to amend data. You might want to do this if you notice a mistake, submitted the form too early by accident, or need to amend data following a query. Only 1 user can edit a form at a time, so you need to 'Check out' the form to edit it, similar to checking a book out of the library. Once a form is checked out to you, no-one else can make changes to it until you

submit it again (return it to the library!). You can save and edit a form as many times as you like before submitting it. Submitting a form makes it available for other users to edit, and indicates that it is complete and ready to be checked by BCTU. To check out and edit

- 1. Click 'Check out' on the form.
- 2. Provide a reason to explain why you are editing the form, e.g. 'enter missing creatinine lab result'
- 3. Click 'Edit'.

[EDIT	SUBMIT	SAVE	UNDO	DELETE	СНЕСК	оит					
[EDIT	SUBMIT	SAVE	UNDO	DELETE	Please g	ive reason	for checkou	t: Enter	r missing	lab result	CHECK OUT
						EDI	SUBMI	T SAVE U	NDO	DELETE	CHECK	OUT

- 4. Make the required changes to the form.
- 5. Click 'Save' to save the data.
- 6. Click 'Submit' to indicate the form is ready to be checked by BCTU, or to make it available for other users to edit.

Once all queries for a form have been resolved, the form is locked to editing by staff at BCTU, but you can make changes to a form up until this point. If you need to make changes to a form after it has been locked, please contact BCTU. If a form is locked, the 'Check out' button will not be available.

Form parts

The baseline and follow-up forms have been split into 3 parts on the online system. This is to improve the overall system performance.

1. Enter the date the form was completed in part 1 of the form. If all parts of a form are completed on the same date, you can click 'update form date' in parts 2 and 3 of the form to autofill the same date as entered in part 1.

	Baseline Form: 1586 : DOB: 08/1955	: CONTINUE ACI	Ei and/or ARB ti	reatment	í
	BASIC ASSESSMENTS LAB ASSESSMENTS SAMPLE TRACKING WALK TES	T		~ ~ ~	
				^ .<	and the second
	Notes			\sim	22
	Date form was received (dd-mmm-yyyy)	21-May-2015		and and	and a
	Date form was completed (dd-mmm-yyyy)	21-May-2015	Date com	pleted has been en	tered in r
	Smoking status:	Ex-Smoker	Butto comp		Coroca III I
	Patients : <u>Find patient : Patient Form</u> : Baseline Form - Pt.3 Baseline Form Pt 3: 1586 : DOB: 08/19	55 : CONTINUE A	CEi and/or ARB	treatment	2.
	Patients : Find patient : Patient Form : Baseline Form - Pt.3 Baseline Form Pt 3: 1586 : DOB: 08/19 MEDICATIONS ANTIHYP PRE-RAND ANTIHYP POST-RAND CONCOM ME	155 : CONTINUE A	CEi and/or ARB	treatment	
	Patients : Find patient : Patient Form : Baseline Form - Pt.3 Baseline Form Pt 3: 1586 : DOB: 08/19 MEDICATIONS ANTIHYP PRE-RAND ANTIHYP POST-RAND CONCOM ME	155 : CONTINUE A DS 12-LEAD ECG ECHO	CEi and/or ARB cardiogram	i treatment	
	Patients : Find patient : Patient Form : Baseline Form - Pt.3 Baseline Form Pt 3: 1586 : DOB: 08/19 MEDICATIONS ANTIHYP PRE-RAND ANTIHYP POST-RAND CONCOM ME Notes	155 : CONTINUE A DS 12-LEAD ECG ECHO	CEi and/or ARB	i treatment	
date form date' to autofill the	Patients : Find patient : Patient Form : Baseline Form - Pt.3 Baseline Form Pt 3: 1586 : DOB: 08/10 MEDICATIONS ANTIHYP PRE-RAND ANTIHYP POST-RAND CONCOM ME Notes Date form was completed (dd-mmm-yyyy)	155 : CONTINUE A DS 12-LEAD ECG ECHO 21-May-2015	CEi and/or ARB	i treatment	
date form date' to autofill the	Patients : Find patient : Patient Form : Baseline Form - Pt.3 Baseline Form Pt 3: 1586 : DOB: 08/10 MEDICATIONS ANTIHYP PRE-RAND ANTIHYP POST-RAND CONCOM ME Notes Date form was completed (dd-mmm-yyyy) UPDATE FORM DATE	155 : CONTINUE A DS 12-LEAD ECG ECHO 21-May-2015 Jate received and date co	CEi and/or ARB CARDIOGRAM ompleted as entered	• treatment	m
date form date' to autofill the te from part 1 in parts 2 and 3	Patients : Find patient : Patient Form : Baseline Form - Pt.3 Baseline Form Pt 3: 1586 : DOB: 08/19 MEDICATIONS ANTIHYP PRE-RAND ANTIHYP POST-RAND CONCOM ME Notes Date form was completed (dd-mmm-yyyy) UPDATE FORM DATE Is the participant currently on ESA treatment?	21-May-2015 date received and date c	CEi and/or ARB CARDIOGRAM ompleted as entered	on the Baseline Pt.1 For	m

2. Each part of the form needs to be added, completed and submitted individually. In the example below, parts 1 and 2 have been completed and submitted, while part 3 has been added, but not yet submitted.

	Patient form: 1586	Assessm	ents	
PATIENT DETAILS ELIGIBILIT WITHDRAWAL INELIGIBLITY	EGFR DECLINE MINIMISATION RANDOMISATION INFO DEATH INFO	Status: All	v Status	
Current Centre	Huli Royal Infirmary	Baseline-Pt.1: Baseline	Received View	
Current Consultant	Professor Sunil Bhandari	Baseline-Pt.2: Baseline	Received View	
Contact Centre (eg letters)	Hull Royal Infirmary	Baseline-Pt.3: Baseline	Due View	Add and submit each form part separat
Contact Person (eg letters)	Professor Sunil Bhandari	Consent: Baseline	Received View	
Recruiting Centre	King's College Hospital (Denmark Hill)	KDOOLSE: Baseline	Received View	

Using sub-forms

The baseline and follow-up forms contain sub-forms for medical history, antihypertensive medications, hospital admissions, cardiovascular events and adverse events. See the index of form parts at the end of this document for the location of the sub-forms.

- 1. Some sub-forms are only available if you answer 'yes' to a lead question.
- 2. You may need to save a form before you can enter data in a sub-form. Follow the instructions on screen.

BASIC ASSESSMENTS CKD AETIOLOGY CARDIOVASCULAR EVENTS	HEART FAILURE ME	DHISTORY						
Please indicate all conditions the patient has a known history or Heart failure, stroke and MI should be recorded in the previous s	current diagnosis o sections	of.					-raint.	r's all
Please indicate all conditions the patient has a known history or co	urrent diagnosis of.	0	and	in the second se	antin	in the second	in the second	- 1
Dichetes	NO V	No.	- Contraction	AS'		- Dieles		~
Malignangy	No v	res	nas be	en ente	ered to	r Diabe	tes	
Gastrointestinal	No V	All	-rillio	- raise	-rillion	1. Caller	- Light	- 14 ST
Musculoskeletal or connective tissue disorders	No V			0	0	0		
Infection	Yes	'Yes'	has be	en ent	ered fo	r Infect	ion	L. P
Pulmonary Disease	No 🗸							
Other	No 🗸	, diffe	in the second	in the second	isin ^O	in the second	in the second	in the second se
http://http://http://http://http://http://http://http://http://http://http://http://http://http://http://http:/	410 410	140	10	20	10	100	20	~
f 'Yes' has been answered to any of the questions above, please	add condition det	ails in the	grid belov	w	in	, in the	ano	3
First click on "Save" below then click "Add" in the table below Medical History - Conditions	~{ ¹ 0" ~ ¹ 0"	~100	1500	~201°	~10	~100	~10 ⁰	1.1
رهي هي هي دهر Category، Conditions	y Condition Date		The	sub-fo	orm and	pears h	ere	
		Add			and opp	ouro n	010	1

3. To add an entry to a sub-form, click 'Save' on the main form, then 'add' in the sub-form, as described on screen.

If 'Yes' has been answered to any of the questions abort First click on "Save" below then click "Add" in the table	ve, please add condition details in the e below	e grid bêlow.
Medical History - Conditions	Category Condition Date Add	Click 'add' to add an entry in the sub-form
End of Baseline Form Pt.2, please return to Patient Form	n to complete Baseline Form - Pt.3	Main form has saved

4. Once you click 'Add' on the sub-form you will be taken to the data entry page for the sub-form. The example below is for adding details of the patient's medical history.

On the Baseline PL2 Form, you answered yes to the following categories; Diabetes, Intection, Selected 'yes' for on the main form If there have been multiple events, please record the date of the most recent event. For ongoing or chr. 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. Category Condition Date Please add any conditions that you have answered as "Yes" on the form Condition category Diabetes mellitus Date 01-Nov-2001 Enter condition details here Please add the condition details above, then click "Save" to add them to the table above. Click 'add' above to add another condition, or click "Return to Baseline Pt.2 Form" to return to the main form. RETURN TO BASELINE PT.2 FORM Notes	1. 19		. ¹⁴ 9	The form shows whic	h categories vou
If there have been multiple events, please record the date of the most recent event. For ongoing or chire is 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. Category Condition Date Please add any conditions that you have answered as "Yes" on the form Condition category Diabetes Please add any conditions that you have answered as "Yes" on the form Condition Type 2 diabetes mellitus Date Details Please add the condition details above, then click "Save" to add them to the table above. Click 'add' above to add another condition, or click "Return to Baseline Pt.2 Form" to return to the main form. RETURN TO BASELINE PT.2 FORM Notes Differ Super INDO DELETE CHECK OUT Click 'save' to add this entry to the sub-form	On the Baseline Pt.2 Form, you answered y Please add details for each to the grid belo	yes to the following catego ow.	ories; Diabetes, Infection,	selected 'yes' for on	the main form
Category Condition Date Add Please add any conditions that you have answered as "Yes" on the form. Condition category Diabetes Condition Type 2 diabetes mellitus Date Date Date Date Date Date Details Please add the condition details above, then click "Save" to add them to the table above. Click 'add' above to add another condition, or click "Return to Baseline Pt.2 Form" to return to the main form. RETURN TO BASELINE PT.2 FORM Notes Colick 'save' to add this entry to the sub-form	If there have been multiple events, please r hypertension), please record the date of dia (e.g. if there have been multiple events). If	ecord the date of the most agnosis or first occurrence. only the month is known, p	t recent event. For ongoing or chi Please use the 'details' section to please input as the 1st of that mo	c conditions (e.g. o give further information nth.	Training to a
Please add any conditions that you have answered as "Yes" on the form Condition category Condition Type 2 diabetes Condition Date Details Please add the condition details above, then click "Save" to add them to the table above. Click 'add' above to add another condition, or click "Return to Baseline Pt.2 Form" to return to the main form. RETURN TO BASELINE PT.2 FORM Notes Click 'save' to add this entry to the sub-form Click 'save' to add this entry to the sub-form	and the teach the teach the	Category Co	Add 50 Ad	Calific Calific Calif	A Transfer as
Condition category Condition Type 2 diabetes Condition Type 2 diabetes Condition Type 2 diabetes Condition Date Condition Cond	Please add any conditions that you have an	swered as "Yes" on the for	m, _o o o		o
Condition Type 2 diabetes mellitus Type 2 diabetes mellitus Date Details Details Please add the condition details above, then click "Save" to add them to the table above. Click 'add' above to add another condition, or click "Return to Baseline Pt.2 Form" to return to the main form. RETURN TO BASELINE PT.2 FORM Notes Click 'save' to add this entry to the sub-form Click 'save' to add this entry to the sub-form	Condition category	~	Diabetes	 Aligned Aligned 	A COST AND A
Date Details Exact date unknown - NK/Now/2001 Enter condition details her Uncompared another condition, or click "Save" to add them to the table above. Click 'add' above to add another condition, or click "Return to Baseline Pt.2 Form" to return to the main form. RETURN TO BASELINE PT.2 FORM Notes Click 'save' to add this entry to the sub-form Click 'save' to add this entry to the sub-form	Condition		Type 2 diabetes mellitus 🗸		
Details Please add the condition details above, then click "Save" to add them to the table above. Click 'add' above to add another condition, or click "Return to Baseline Pt.2 Form" to return to the main form. RETURN TO BASELINE PT.2 FORM Notes Click 'save' to add this entry to the sub-form	Date		01-Nov-2001	in and	Enter condition details her
Please add the condition details above, then click "Save" to add them to the table above. Click 'add' above to add another condition, or click "Return to Baseline Pt.2 Form" to return to the main form. RETURN TO BASELINE PT.2 FORM Notes EDIT SUBMIT SAVE UNDO DELETE CHECK OUT Click 'save' to add this entry to the sub-form	Details	the the the	Exact date unknown - NK/Nov/2001.		
Notes	Please add the condition details above, the Click 'add' above to add another condition	en click "Save" to add ther , or click "Return to Baseli	n to the table above. ne Pt.2 Form" to return to the m	ain form.	- California - C. A
Notes	RETURN TO BASELINE PT.2 FORM		<u>ه</u>	A A	
EDIT SUBMIT SAVE UNDO DELETE CHECK OUT Click 'save' to add this entry to the sub-form	Notes	California California Cal			< rolling reg
	EDIT SUBMIT SAVE UNDO DELETE CHEC	Click 'save'	to add this entry to the s	ub-form	A TRANSA TO
	arm Status: Data Entry In Programs				

5. Once you have saved the sub-form you can either add another entry or return to the main form. The saved entry will now show in the sub-form grid.

PAGE 1		-						-		
On the Baseline Pt.2 Form, you answered ye Please add details for each to the grid below If there have been multiple events, please re hypertension), please record the date of diag	es to the fol v. cord the da gnosis or firs	lowing cat te of the n	tegories; D most recen nce. Please	Diabetes, Info t event. For e use the 'de'	Click 'a to add new en	dd' la try furth	tions (e.g.	ation	- search	
(e.g. if there have been multiple events). If o	nly the mon	th is know	vn, please i	input as the	Da.				~	
a a a a	Category	Condition		Date	Add		J.Co	Sec.	Sec.	
a ha ha ha ha	Diabetes	Type 2 dia	betes mell	litus 01-Nov	-2001 View	Sav	/ed entr	v shows	in the	gric
Please add any conditions that you have any	wered as "Y	es" on the	<> form	Allen A	and the second		- Academic	all the	- California	
Condition category										
a			Dia	increa		0	⊻]			
Condition Date	.11	.15	Typ 01-	pe 2 diabetes m 30 Nov-2001		- California	×1	-control	C. California	
Condition Date Details		.ar	Dia Typ 01- Exa	betes 2 diabetes m Nov-2001 ct date unknown	nellitus 💽 🥠 🦚	- Inderes	×1	-transition	Trans	
Condition Date Details Please add the condition details above, ther	n click/"Save	" to add t	Dia Typ 01- Exact them to the	e table abov	nellitus V con krosson n - NK/Nov/2001. /e.	rianth rianth	1.00000	-tostos	rano Lano	
Condition Date Details Please add the condition details above, ther Click 'add' above to add another condition, RETURN TO BASELINE PT.2 FORM	n click "Save or current Click h	" to add t wro to Pa ere to ro	them to the	beres De 2 diabetes m Nov-2001 ct date unknown e table abov Form" to co the main	reliius v Augusta NK/Nov/2001. Ye. form	nain form,	1.000000	Tradina C	Trainin Trainin Trainin	
Condition Date Details Please add the condition details above, ther Click 'add' above to add another condition, RETURN TO BASELINE PT.2 FORM	n click "Save or c"Pol Click h	" to add t ere to r	them to the	e table abov	re.	nain form,	T Contraction	Trans	and a second	
Condition Date Details Please add the condition details above, ther Click 'add' above to add another condition, RETURN TO BASELINE PT.2 FORM Notes	n click "Save Click h	" to add t wro to Po ere to r	Dis Typ 01-1 Enset them to the regime Di 2 eturn to	e table abov Form" to re- the main	reliitus v door NK/Nov/2001. /e. form	nain form.	× . 	ton of the second secon	And a second sec	ave

6. Back on the main form you can see the entries added via the sub-form. You can add as many entries as required using the sub-form. In the example below, two different types of infection have been added. You can view, edit or delete existing entries by clicking 'View' and going back into the sub-form.

7. For the medical history sub-form, there should be at least one entry in the sub-form for each type of condition in the lead question, i.e. if 'Infection' is answered 'yes', there should be at least one infection listed in the sub-form grid.

Patients : <u>Find patient</u> : <u>Patient Form</u> : Baseline Form - Pt.2	and a continue ace; and/or a	P.P. treatment	
BASIC ASSESSMENTS CKD AETIOLOGY CARDIOVASCULAR EVENTS H	ART FAILURE MED HISTORY	KB treatment	
Please indicate all conditions the patient has a known history or or Heart failure, stroke and MI should be recorded in the previous se Please indicate all conditions the patient has a known history or cu	urrent diagnosis of. ctions rrent diagnosis of.		12.00
Other Cardiovascular Disease	No V Stand Stand	A Strate	2
Diabetes	Yes		
Malignancy	No V		8
Gastrointestinal	Responses in the	main form correspond	25
Musculoskeletal or connective tissue disorders	No We a	es in the sub-form	
Infection	Yes V	and all all all	as per
Pulmonary Disease	No 💌		
Other	Click 'view' to view/edit/	- Alle Alle Alle	11 000
If 'Yes' has been answered to any of the questions above, please a First click on "Save" below then click "Add" in the table below Medical History - Conditions	add condition details entry in the sub-form	com com com	
and the second category Condition	Date Add	and and and	as left
Diabetes Type 2 dial	etes mellitus 01-Nov-2001 View		· · · · ·
Infection Hepatitis C	01-May-1996 View	Itiple entries can be ma	ade e.g. 2 types of infectio
ें 🦉 🦿 🦿 Infection Urinary tra	ct infection 22-Jun-2014 View	inple entries can be ma	ide, e.g. z types of infectio
End of Baseline Form Pt.2, please return to Patient Form to comple	te Baseline Form - Pt.3		
EDIT SUBMIT SAVE UNDO DELETE CHECK OUT	S. S. S. S. S. S.	Land Charles Land	1. M.
There are 0 queries for this form	می می می می می	می هی هی	

8. Click 'Delete' in a sub-form to delete that entry. Ensure that you are in the sub-form entry you want to delete before clicking the delete button. A message will warn you that you are about to delete a record before the entry is deleted.

Patients : Find patient : Patient Form : Baseline Form Baseline Form Pt 2 - Medical	Pt2: Medical History	OB: 08/1955 :	CONTINUE	ACEi and	or ARB tre	eatment	,		
PAGE 1			contractor						
On the Baseline Pt.2 Form, you answered yo Please add details for each to the grid below	es to the following cate	egories; Diabetes, Ir	nfection,		ee.	A CONTRACT	~ ~		
If there have been multiple events, please re hypertension), please record the date of diag	cord the date of the m mosis or first occurren	ost recent event. Fo ce. Please use the 'd	r ongoing or chro letails' section to	nic condition give further i	s (e.g. nformation	C. Martin	as for		
(e.g. if there have been multiple events). If o	nly the month is known	n, please input as th	e 1st of that mon	th.					
1 1 1 1	Diabetes Type 2 diab	otes mellitus 01-N	Add	- suma	caller caller	A robins	4		
Please add any conditions that you have ans	wered as "Yes" on the	<> form	and and	and the second	1	- and			
Condition category		Diabetes							I I I A I I F
Condition Date	.HH.	Type 2 diabetes	mellitus V	Tree	clicking de	lete. In t	e in the enti his example	, the entry for	type 2 diabetes
Details		Exect date unknow	wn - NK/Nov/2001.			ana.	will be d	eleted.	
Please add the condition details above, the Click 'add' above to add another condition, RETURN TO BASELINE PT 2 FORM	n click "Save" to add th or click "Return to Bas	nem to the table ab eline Pt.2 Form" to	ove. return to the ma	in form.	an an	- The second	~		
	LCD LCD	1 ⁰⁰ - 10	1	11	<i>"</i> "	- Action	14 D		
Notes	Caller Staff		stall stall		staffer Scotter	- Contraction	L. B		
EDIT SUBMIT SAVE UNDO DELETE C	Click 'Delete	when in a sub	-form to remo	ove that er	ntrv	Form sa	aved		
Form Status: Data Entry In Progress		AND CAR	AND AND		1 . J	Control of	, A		

Notes on entering data and using the online forms

- All CRF data is submitted online for STOP-ACEi, however, there are paper CRFs which show what data will be collected for each assessment. To review what data will be required at a visit, you can check the paper CRF for that visit. All the CRFs can be downloaded directly from the trial website: www.birmingham.ac.uk/stopacei/docs.
- SAEs must be completed on paper and faxed or e-mailed to BCTU. Staff at BCTU will enter the data onto the Online System and you will be able to view the SAE data after it's entered. See the STOP-ACEi SAE guide for further details.
- Assessments are grouped into their assessment time-point and are shown in the order that they're expected in. You will only be able to add forms that have the status 'Due Now'. Contact the STOP-ACEi trial office if you need to add a form that isn't currently available to you.
- Once you add a form, it is 'Checked out' to you. Only the person that has the form checked out to them can edit it. If you want to transfer a form to a colleague you can submit the form and then they will be able to check it out themselves.
- Remember to use the tabs to navigate between the different pages of a form. Most forms have multiple pages. You do not need to save a form between each tab. Clicking 'save' will save the data on the whole form, i.e. in all tabs.
- Some fields are programmed to have acceptable limits and query ranges. This is to detect unexpected or implausible data, e.g. a date of birth that would give a patient an age of 150 years. An error message will show if you enter data that is outside the permitted range.
- Some fields are required and you will see an error message if you try to save the form without entering the required data. All data at randomisation is required.
- If you have any queries (shown at the bottom of the page) please resolve the issues, e.g. by adding any missing data, before you submit the form. Staff at BCTU will query any missing or invalid data if the form is received before these issues are addressed.

Full blood count											
Haemog	lobin g/L			1005		×		he * sho	ows whe	re the i	nvalid data is
Platelets	x10 ⁹ /L	100		311	.0		410	1.E	150	K.C.	14
Urinary PCR or A	ACR by early morning spot urin	e "o	, es	e la companya de la compa		e,	es.	es.	,es	es.	4
PCR or A	CR value given	2	~	PCR	 State 	L.COSTON	~ Californ	~ com	Liditat	~ raint	les 1
Urinary I	PCR mg/mmol			250							
C-Reactive Prote	ein (CRP) 🖉	and and	, in the	.drs		, in the		in the second		.350	in the second
CRP mg/	L			3.3		~~	~10	~500	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	~101	14
Please correct the	e following errors: bin g/L' cannot be more than '	999' Invalio	J data w	ill show (errors	-robins	- raining	Training	-reliefe	- raining	2 Million
EDIT SUBMIT	AVE UNDO DELETE CHECK (Transfer Trainfe	Training	- roising	Lugar Contract	Training	Training	Training	~roising	Training	1. Contraction of the second s
There are 3 qu "Basic Asse "Serum Creation"	ieries for this form ssments : Smoking status:" ha atinine μmol/L:" is less than 4	s not been answere 5	d rights	Training	- and	Missin ₍	ی g or Inva	ی alid data	ی will rai	ی se queri	es
"Walk Test	: Total distance covered in 6 m	ninutes (in metres):	" has not	been answ	ered		. Se	. Star	. All	S.	1

If you cannot complete a field or have any issues with data entry, you can describe any problems in the 'Notes' section of the form. Staff at BCTU will be able to see any notes you add to a form and this may help with data queries. All forms have a 'Notes' section at the beginning of the form.

KDQOLSF: 1073 : DOB: 08/1954 : DIS	CONTINUE ACEi and/or ARB treatment	
Q 1-4 Q 5-11 Q 12-13 Q 14 PQ 15-16 Q 17-24		
	telephone. Use 'Notes	' to describe any issues with data entry
Notes	.:;	
Date form was completed (dd-mmm-yyyy)	[24-Sep-2014	

Data Queries

- The Online System automatically flags some issues, mostly missing or out of range data. These are listed as queries in red on the electronic form (see Entering data section above). Try to resolve these issues before you submit a form.
- If the data is not available, e.g. because a test was not performed, you can minimise queries by providing an explanation in the 'notes' field of the form. This will not remove the automatic query, but will prevent BCTU raising a query about it.
- In addition to the automatic queries, BCTU check all incoming data. Any inconsistencies are queried according to the process below.



How queries are raised

Queries are generated by BCTU staff using a database. All queries have a unique reference number. They are sent to site as a PDF file. An example is below:

P. C. P. A. C. P.	Outstanding Data Queries by Site							
Query numb	Query number 7 Centre name Hull Royal Infirmary Participant number 1000							
Query raised	06-Sep-17	Raised by	Jamie Godsall					
Time point	Baseline	CRF	Medical History					
Details of que	Details of query No medical history has been entered. Please can you confirm via the notes that this is accurate or if not, please can you complete the patient's medical history?							

How to resolve queries

Queries will be sent as a PDF via e-mail, but are resolved on the Online System. Some queries will require a change to the form data, while others will simply require an explanation.

To resolve a query where the form data needs to be updated, simply amend the form data via the Online System. You might need to do this if the data initially submitted was inaccurate, or to complete some data which was initially missed in error.

To resolve a query where the form data is correct, record an explanation in the 'notes' field of the form. You might need to do this if a field was left blank because a test was not performed, or if there have been genuine changes to the patient's medications which flagged a query because of inconsistencies across the follow-up forms.

The process is the same for both types of query:

- 1. Check out the form
- 2. When prompted for a reason, enter "DCF" (which stands for Data Clarification Form) and then the query number, e.g. DCF 7.
- 3. Click 'Edit'
- 4. Amend the form to address the query, either by amending the form data or by providing an explanation in the 'notes' field.
- 5. Click 'Save'
- 6. Click 'Submit' to indicate that the form is ready to be checked.

Common queries

• "0" entered for a missing lab result. If a test was not performed, the field should be left blank. "0" should only be entered if this is the result returned from the lab. Avoid a query by providing an explanation for the missing data in the 'notes' field, e.g. "test not done".

	Phosphate mmol/L	1.71	
0	Alkaline phosphatase U/L	130	
	Albumin g/L	30	
	Total protein g/L	0	
8	Alanine transferase U/L	15	

- Non-compliance with the randomised treatment allocation should be reported on each form. This is
 because non-compliance can be temporary or long term. Non-compliance is where a patient that was
 randomised to 'STOP' takes an ACEi/ARB, or where a patient randomised to 'CONTINUE' does not
 take their ACEi/ARB, regardless of the reasons.
- If there are inconsistencies across follow-up forms, we will raise a query to check the data is complete. Avoid a query by explaining medication changes in the 'notes' field, e.g. "aspirin and bicarb stopped between the 3 and 6 month visits".

3 month form		6 month form	
Aspirin	Yes 💌 🙏	Aspirin	No 💌
Bicarbonate	Yes 💌	Bicarbonate	No 🖵

• Missing data with no explanation will result in a query. Avoid a query by completing all data, or providing an explanation for missing data in the 'notes' field, "e.g. patient declined to answer QoL question 16". Remember to complete all the drop down boxes:

BASIC ASSESSMENTS	CKD AETIOLOGY	CARDIOVASCU	LAR EVENTS	HEART	FAILURE	MED HISTORY	ADMIN	- VIEW	AUDIT	DMIN - VIEV	V CHANGES
Please indicate all c Heart failure, stroke	onditions the pa e and MI should	tient has a kno be recorded ir	own histor n the previo	y or cur ous sect	rent diag	nosis of.					LIGITICS
Please indicate all @	onditions [®] the pati	ent has a know	vn history or	r current	diagnosi	s of. 🦽	S.C.	and the second s	10°	in the second se	and the second s
Other Cardiovascula	r Disease	ç			Yes 👻	LEON A	LOII	LEON	LO	LE	LEAN
Diabetes					Yes 👻						
Malignancy	~		~				L ^{illino}	L. Silling		Lilling .	L. Willing
Gastrointestinal					-						
Musculoskeletal or c Infection Pulmonary Disease	onnective tissue	disorders	byi				Lolling	Linne.	A COLORING	and the second sec	
	LIDE LO	2°	1.010	Light.	Yes V	Traning V	Lopin th	Lidino	10000		1-colling
Form Status: Data	Entry In Progres eries for this for	m < ^{toline}	koline K	Lollino Collins	Lighting	Libilito	1 tolding	1 coline	» 20	.10,	
"Med Histor "Med Histor "Med Histor "Med Histor "Med Histor Baseline Me	y : Malignancy" y : Gastrointest y : Musculoskel y : Infection" ha y : Pulmonary D dical History Fo	has not been inal" has not etal or conne s not been ar isease" has n orm "Page 1 :	answered been answ ctive tissu nswered not been an Condition	i vered e disoro nswere catego	ders" has d ry" has n	s not been an	işwered	Libilit	a rice	70.	

 We usually expect medications to have a corresponding condition in the baseline medical history, or new medications to have been started due to a new adverse event. Avoid queries by reporting all medical history, or providing an explanation in the 'notes' field if medications are used, but with no corresponding condition, e.g. "aspirin started prophylactically – no new condition" or "bicarb prescribed for CKD – no further conditions".

PAGE 1 MEDICATION ANTIHYP MEDS CONCOM MEDS COMP	LIANCE ECHOCARDIOGRAM AD	
Other concomitant medications	1. 10 L. 10 L.	
Is the participant currently taking any other medications?	Yes 💌	
Statin	No 💌	
Digoxin	No 💌	
Nitrate	No 💌 👝	
Fibrate	Yes 💌 🛖	
Ezetimibe	No 💌	
Aspirin	No 💌 🖉	
Bicarbonate	No 💌 📈	
Sulphonylurea, e.g. glicazide	No 💌	Numercholesterolemia
GLP-1 analogues/agonists, e.g. liraglutide, exenatide	No 💌	
Clopidogrel	No 💌	
Warfarin	No 💌 👝 👝	
Phosphate Binders	No 💌	
Calcium/Vitamin D	No 💌	- Polymyalgia rheumatica
Bisphoshonate	No 💌 🖉	- I Orynnyaigia meumatica
Prednisolone	Yes 💌	
Metformin	No 💌	
Sirolimus	No 💌	
SGLT2 inhibitor, e.g. dapagliflozin	No 💌	
Mycophenolate mofetil (MMF)	No 💌 🚕 🦽	
Ciclosporin	No 💌	
Cyclophosphamide	No 💌	
Azathioprine	No 💌 🖉	
Tacrolimus	No 💌	
Methotrexate	No 💌	— Diahetes Type 2
NSAIDS	No 💌	Diabetes type 2
Thiazolidinedione/glitazone	Yes 💌	
DPP-4 inhibitor (incretins) e.g. sitagliptin, vildagliptin	No 💌 🔊	Gout
Other Concomitant Med 1:	Yes 💌	
Other Concomitant Med 1: Specify	Allopurinol	

Important General Notes

<u>Dates</u>

All dates entered into the system are in the "dd-mmm-yyyy" format. This means that the first 2 digits indicate the <u>days</u> of the month, then a hyphen ("-"), then the next 3 letters indicate the <u>month</u>, another hyphen, and then the four digits indicating the <u>year</u>. For example:

Date	Long Date	How to enter the date in the STOP-ACEi system
1/10/30	1 st October 1930	01-Oct-1930
12/11/98	12 th November 1998	12-Nov-1998
1/4/02	1 st April 2002	01-Apr-2002

This ensures that there is no possibility of mixing up days and months, and years such as 1912 and 2012.

Dates can be entered either by typing the date into the box in the following format: dd-mmm-yyyy (e.g. 05-sep-2012), or accessing the drop down calendar by clicking into the box.

The Next and Previous Buttons

It is advised that whilst using the system, the use of the browser back and forward browser buttons are *avoided*. Please use the navigation control buttons on the web forms: 'Next' and 'Previous'. (Moving away from a page using the browser back & forward buttons would mean any data entered is not saved).

Security

When using the STOP-ACEi Online Randomisation, all data that is sent over the Internet is encrypted. There should be no danger of anyone being able to intercept the information and use it. However, if anyone has your user name and password then they can use the system as you do. Please do not reveal your user name and password to anyone. Each person using the STOP-ACEi Online Randomisation and Data Entry System will have their own User Name and Password.

Web Browsers

The system is usable by the most common browsers including Chrome, Firefox, Microsoft Edge and Internet Explorer. Please let us know about any compatibility issues you may have.

Questions or Problems

If you have any problems please contact the Renal Trials Team on 0121 415 9133 or e-mail us at stopacei@trials.bham.ac.uk.

Index of Form Parts

Paper Form	Online Form	Sections	Sub-forms on online system
Consent Form	Consent*	All sections	-
CRF02 Baseline Visit	Baseline Pt.1	 Part A: Identifying details Part B: Basic assessments Part C: Lab assessments Part D: Sample tracking Part E: Six-minute walk test 	-
	Baseline Pt.2	Part F: Medical history	Medical History
	Baseline Pt.3	 Part G: Medications Part H: 12-Lead ECG Part I: Echocardiogram Part J: Visit checklist 	 Antihypertensive medication pre- randomisation Antihypertensive medication post- randomisation
KDQoL-SF™	KDQOLSF	All sections	-
CRF03 Telephone Follow-Up	Phone call-Pt.1	 Part A: Identifying details Part B: Continued trial participation Part C: Clinical visits 	Hospital admissions
	Phone call-Pt.2	Part D: Adverse events	 Cardiovascular events Adverse events/diagnoses (since last visit)
	Phone call-Pt.3	Part E: MedicationsPart F: Compliance	Antihypertensive medications
CRF04 3-Monthly Visits	Follow Up-Pt.1	 Part A: Identifying details Part B: Assessment point (completed automatically) Part C: Continued trial participation Part D: Basic assessments Part E: Lab assessments Part F: Sample tracking[†] Part G: Six-minute walk test[†] 	-
	Follow Up-Pt.2	 Part H: Clinical visits Part I: Adverse events 	 Hospital admissions Cardiovascular events Adverse events/diagnoses (since last visit)
	Follow Up-Pt.3	 Part J: Medications Part K: Compliance Part L: 12-Lead ECG[†] Part M: Echocardiogram Part N: Visit checklist 	Antihypertensive medications
CRF10 SAE Form	SAE*	All sections	-

* Consent forms and SAE forms cannot be submitted online. Please fax them to BCTU or email them to <u>stop.ace@nhs.net</u>. The data will be entered onto the online system by staff at BCTU.

⁺ Assessments needed at annual time points only (e.g. 6-minute walk test) will only be visible for the annual forms on the online system, i.e. baseline form and forms for month 12, 24 and 36.