

# Guidelines for Data Entry



## Introduction

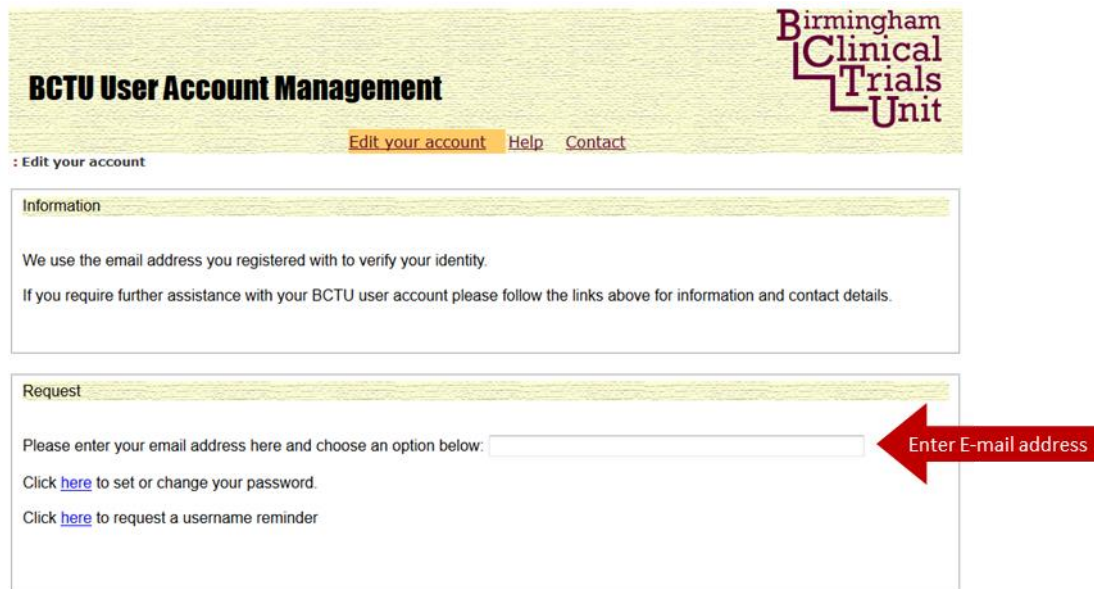
This document is intended to explain how to use the STOP-ACEi Online System. It does not go into the detail of either the protocol or the randomisation procedure itself, but provides essential information that will help you to use the Online System for randomisation and data entry.

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## Accessing and Using the System

### Username 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](mailto: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](mailto:stopacei@trials.bham.ac.uk) if your e-mail address is incorrect or changes.
- The user account management page will look like this:



**BCTU User Account Management**

[Edit your account](#) [Help](#) [Contact](#)

: Edit your account

**Information**

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 for information and contact details.

**Request**

Please enter your email address here and choose an option below:

Click [here](#) to set or change your password.

Click [here](#) to request a username reminder

- 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](mailto: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

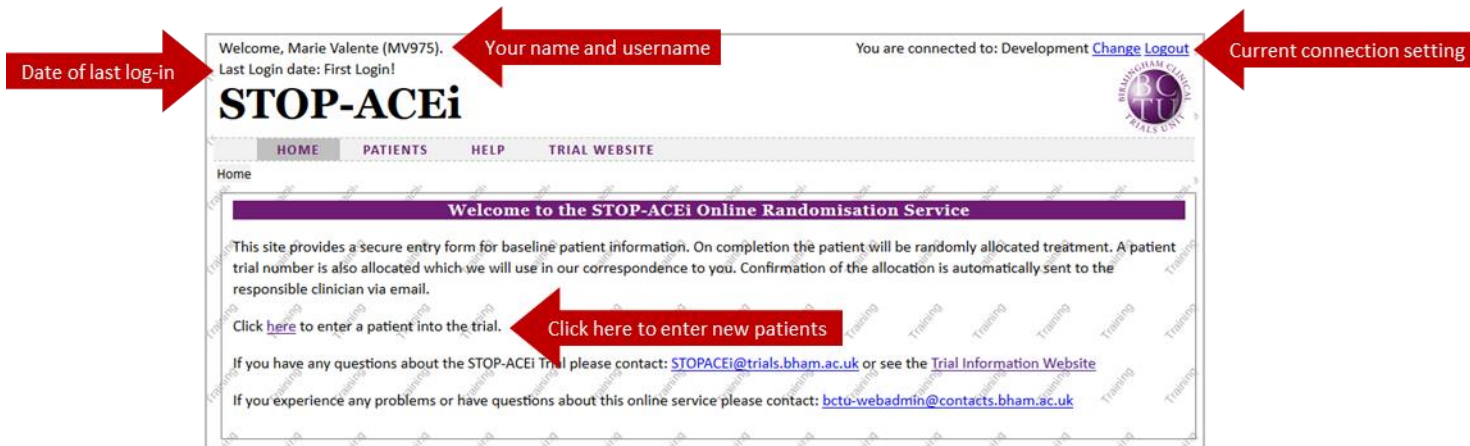
- Direct your web browser to <https://www.trials.bham.ac.uk/STOPACEi>
- Log in using your username and password.

- The log-in page will look like this:



### Greeting

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



- 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

## Entering data

To view a patient's record:

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

Welcome, Marie Valente (MV975).  
Last Login date: 23-Sep-2014

You are connected to: Development [Change Logout](#)

# STOP-ACEi

HOME PATIENTS ADMINISTRATION HELP TRIAL WEBSITE

Home Enter new patient Find patient

Welcome to the STOP-ACEi Online Randomisation Service

This site provides a secure entry form for baseline patient information. On completion the patient will be randomly allocated treatment. A patient 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.

Click [here](#) to enter a patient into the trial.

If you have any questions about the STOP-ACEi Trial please contact: [STOPACEI@trials.bham.ac.uk](mailto:STOPACEI@trials.bham.ac.uk) or see the [Trial Information Website](#)

If you experience any problems or have questions about this online service please contact: [bctu-webadmin@contacts.bham.ac.uk](mailto:bctu-webadmin@contacts.bham.ac.uk)

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.

Welcome, Marie Valente (MV975).  
Last Login date: 24-Sep-2014

You are connected to: Development [Change Logout](#)

# STOP-ACEi

HOME PATIENTS ADMINISTRATION HELP TRIAL WEBSITE

Patients: Find patient

Search for a patient

TNO	DOB	
1016	Mar-1982	<a href="#">View</a>
1024	Sep-1946	<a href="#">View</a>
1032	Jul-1967	<a href="#">View</a>
1040	Jul-1967	<a href="#">View</a>
1057	Sep-1950	<a href="#">View</a>
1065	May-1967	<a href="#">View</a>
1073	Aug-1954	<a href="#">View</a>

Search: 1024

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').

Welcome, Test E Template (xx005).  
Last Login date: 19-May-2015

You are connected to: Development [Change Logout](#)

# STOP-ACEi

HOME PATIENTS EGFR CALCULATOR ADMINISTRATION HELP TRIAL WEBSITE

Patients: Find patient: Patient Form

Patient form: 1180

PATIENT DETAILS ELIGIBILITY EGFR DECLINE MINIMISATION RANDOMISATION INFO  
DEATH INFO WITHDRAWAL INELIGIBILITY RESEND EMAILS ADMIN - VIEW AUDIT  
ADMIN - VIEW CHANGES

How many eGFR readings (taken over the last 24 months) do you wish to enter.

Creatinine 1:   $\mu\text{mol/L}$   Date:

Creatinine 2:   $\mu\text{mol/L}$   Date:

Creatinine 3:   $\mu\text{mol/L}$   Date:

Rate of eGFR change ( $\text{mL/min/1.73m}^2$  per year) at Randomisation

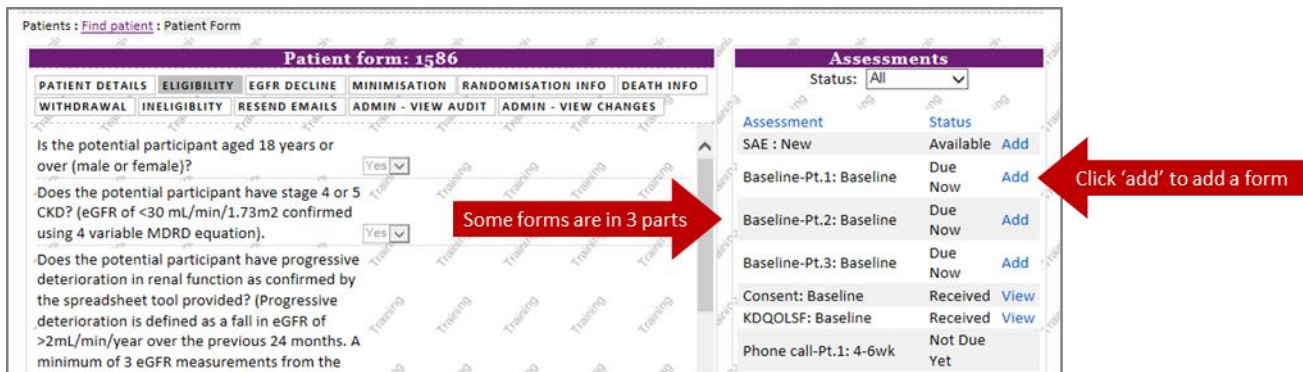
Assessments

Status: All

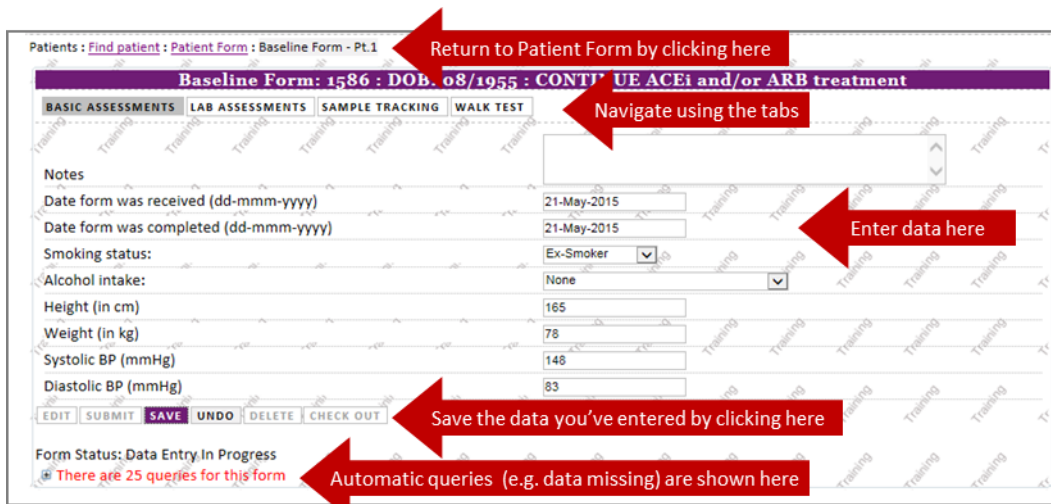
Assessment	Status	
SAE: New	Available	Add
Baseline-Pt.1: Baseline	Received	<a href="#">View</a>
Baseline-Pt.2: Baseline	Received	<a href="#">View</a>
Baseline-Pt.3: Baseline	Received	<a href="#">View</a>
Consent: Baseline	Received	<a href="#">View</a>
KDQOLSf: Baseline	Received	<a href="#">View</a>
Phone call-Pt.1: 4-6wk	Received	<a href="#">View</a>
Phone call-Pt.2: 4-6wk	Received	<a href="#">View</a>
Phone call-Pt.3: 4-6wk	Received	<a href="#">View</a>
Follow Up-Pt.1: 3 Month	Due Now	Add
Follow Up-Pt.2: 3 Month		Add
Follow Up-Pt.3: 3 Month		Add

To add a form, enter data and submit a form

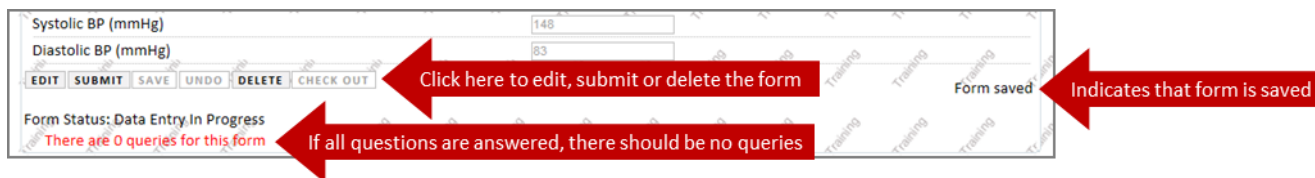
1. CRF data must be submitted electronically for STOP-ACEi. From the Patient Form, click 'Add' for the desired form. You will only be able to enter assessments that have the status 'Due Now' or 'Available'. Please contact the trial office if you need to enter an assessment that is not available.



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.



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.



'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'.



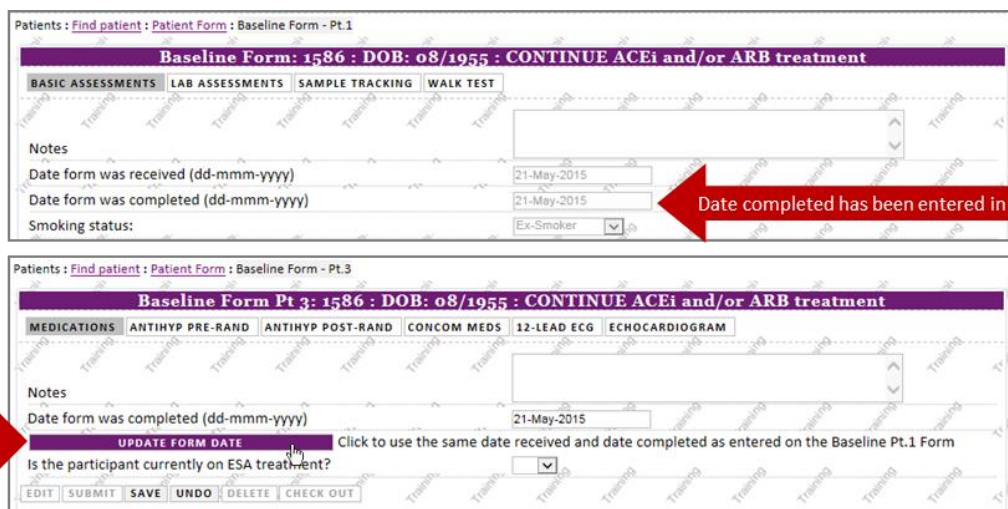
4. Make the required changes to the form.
5. Click 'Save' to save the data.
6. Click 'Submit' to indicate the form is ready to be checked by BCTU, or to make it available for other users to edit.

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.



- 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.

← Add and submit each form part separately

### 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.

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

← 'Yes' has been entered for Diabetes

← 'Yes' has been entered for Infection

← The sub-form appears here

← The main form needs to be saved before you can enter data in the sub-form

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

← Click 'add' to add an entry in the sub-form

← Main form has saved → Form 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.

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.

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 : [Find patient](#) : Patient Form : Baseline Form - Pt.2

**Baseline Form Pt 2: 1586 : DOB: 08/1955 : CONTINUE ACEi and/or ARB treatment**

BASIC ASSESSMENTS | CKD AETIOLOGY | CARDIOVASCULAR EVENTS | HEART FAILURE | **MED HISTORY**

Please indicate all conditions the patient has a known history or current diagnosis of.  
Heart failure, stroke and MI should be recorded in the previous sections  
Please indicate all conditions the patient has a known history or current diagnosis of.

Other Cardiovascular Disease  No  
Diabetes  Yes  
Malignancy  No  
Gastrointestinal  No  
Musculoskeletal or connective tissue disorders  No  
Infection  Yes  
Pulmonary Disease  No  
Other  No

If 'Yes' has been answered to any of the questions above, please add condition detail.  
First click on "Save" below then click "Add" in the table below

Medical History - Conditions

Category	Condition	Date	
Diabetes	Type 2 diabetes mellitus	01-Nov-2001	<a href="#">View</a>
Infection	Hepatitis C	01-May-1996	<a href="#">View</a>
Infection	Urinary tract infection	22-Jun-2014	<a href="#">View</a>

End of Baseline Form Pt.2, please return to Patient Form to complete Baseline Form - Pt.3

[EDIT](#) [SUBMIT](#) [SAVE](#) [UNDO](#) [DELETE](#) [CHECK OUT](#)

Form Status: Data Entry In Progress  
There are 0 queries for this form

**Responses in the main form correspond to the entries in the sub-form**

**Click 'view' to view/edit/delete an entry in the sub-form**

**Multiple entries can be made, e.g. 2 types of infection**

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 - Pt.2 : Medical History

**Baseline Form Pt.2 - Medical History: 1586 : DOB: 08/1955 : CONTINUE ACEi and/or ARB treatment**

PAGE 1

On the Baseline Pt.2 Form, you answered yes to the following categories; Diabetes, Infection,  
Please add details for each to the grid below.

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.

Category	Condition	Date	
Diabetes	Type 2 diabetes mellitus	01-Nov-2001	<a href="#">View</a>

Please add any conditions that you have answered as "Yes" on the form

Condition category: Diabetes  
Condition: Type 2 diabetes mellitus  
Date: 01-Nov-2001  
Exact date unknown - NK/Nov/2001

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](#)

Form Status: Data Entry In Progress  
There are 0 queries for this form

**Form saved**

**Make sure you are in the entry you want to delete before clicking delete. In this example, the entry for type 2 diabetes will be deleted.**

**Click 'Delete' when in a sub-form to remove that entry**

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](http://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

Haemoglobin g/L  \*

Platelets x10<sup>9</sup>/L

Urinary PCR or ACR by early morning spot urine

PCR or ACR value given

Urinary PCR mg/mmol

C-Reactive Protein (CRP)

CRP mg/L

Please correct the following errors:

- 'Haemoglobin g/L' cannot be more than '999'

Form Status: Data Entry In Progress

There are 3 queries for this form

- "Basic Assessments : Smoking status:" has not been answered
- "Serum Creatinine µmol/L:" is less than 45
- "Walk Test : Total distance covered in 6 minutes (in metres):" has not been answered

- 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 : DISCONTINUE ACEi and/or ARB treatment

Q 1-4 Q 5-11 Q 12-13 Q 14 PQ 15-16 Q 17-24

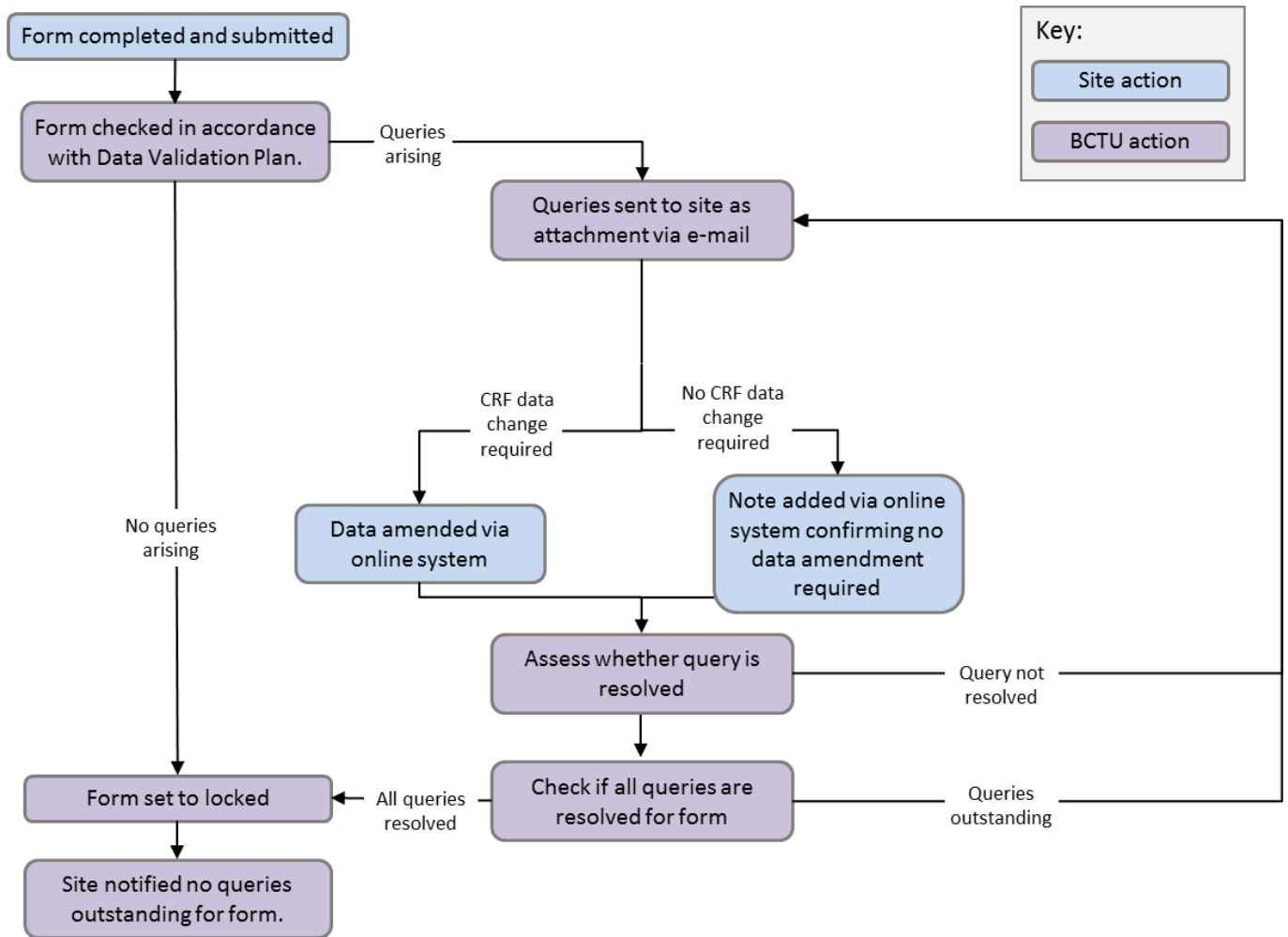
Notes

Could not measure height and blood pressure as visit was conducted by telephone.

Date form was completed (dd-mmm-yyyy)

## 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:

## 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	
Alkaline phosphatase U/L	130	Training
Albumin g/L	30	
Total protein g/L	0	
Alanine transferase U/L	15	Timing

- 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 <input type="checkbox"/> Yes	Aspirin <input type="checkbox"/> No
Bicarbonate <input type="checkbox"/> Yes	Bicarbonate <input type="checkbox"/> 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	CARDIOVASCULAR EVENTS	HEART FAILURE	MED HISTORY	ADMIN - VIEW AUDIT	ADMIN - VIEW CHANGES
<p>Please indicate all conditions the patient has a known history or current diagnosis of.  <b>Heart failure, stroke and MI should be recorded in the previous sections</b></p> <p>Please indicate all conditions the patient has a known history or current diagnosis of.</p>						
Other Cardiovascular Disease				Yes		
Diabetes				Yes		
Malignancy						
Gastrointestinal						
Musculoskeletal or connective tissue disorders						
Infection						
Pulmonary Disease						
Other				Yes		
<p>Form Status: Data Entry In Progress</p> <p>There are 6 queries for this form</p> <p>"Med History : Malignancy" has not been answered</p> <p>"Med History : Gastrointestinal" has not been answered</p> <p>"Med History : Musculoskeletal or connective tissue disorders" has not been answered</p> <p>"Med History : Infection" has not been answered</p> <p>"Med History : Pulmonary Disease" has not been answered</p> <p>Baseline Medical History Form "Page 1 : Condition category" has not been answered</p>						

- 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	ANTHYP MEDS	CONCOM MEDS	COMPLIANCE	ECHOCARDIOGRAM	AD
Other concomitant medications						
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		
GLP-1 analogues/agonists, e.g. liraglutide, exenatide				No		
Clopidogrel				No		
Warfarin				No		
Phosphate Binders				No		
Calcium/Vitamin D				No		
Biphosphonate				No		
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		
NSAIDS				No		
Thiazolidinedione/glitazone				Yes		
DPP-4 inhibitor (incretins) e.g. sitagliptin, vildagliptin				No		
Other Concomitant Med 1:				Yes		
Other Concomitant Med 1: Specify				Allopurinol		

Hypercholesterolemia

Polymyalgia rheumatica

Diabetes Type 2

Gout

## Important General Notes

### Dates

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

Date	Long Date	How to enter the date in the STOP-ACEi system
1/10/30	1 <sup>st</sup> October 1930	01-Oct-1930
12/11/98	12 <sup>th</sup> November 1998	12-Nov-1998
1/4/02	1 <sup>st</sup> 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](mailto: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	<ul style="list-style-type: none"> <li>Part A: Identifying details</li> <li>Part B: Basic assessments</li> <li>Part C: Lab assessments</li> <li>Part D: Sample tracking</li> <li>Part E: Six-minute walk test</li> </ul>	-
	Baseline Pt.2	<ul style="list-style-type: none"> <li>Part F: Medical history</li> </ul>	<ul style="list-style-type: none"> <li>Medical History</li> </ul>
	Baseline Pt.3	<ul style="list-style-type: none"> <li>Part G: Medications</li> <li>Part H: 12-Lead ECG</li> <li>Part I: Echocardiogram</li> <li>Part J: Visit checklist</li> </ul>	<ul style="list-style-type: none"> <li>Antihypertensive medication pre-randomisation</li> <li>Antihypertensive medication post-randomisation</li> </ul>
KDQoL-SF™	KDQOLSF	All sections	-
CRF03 Telephone Follow-Up	Phone call-Pt.1	<ul style="list-style-type: none"> <li>Part A: Identifying details</li> <li>Part B: Continued trial participation</li> <li>Part C: Clinical visits</li> </ul>	<ul style="list-style-type: none"> <li>Hospital admissions</li> </ul>
	Phone call-Pt.2	<ul style="list-style-type: none"> <li>Part D: Adverse events</li> </ul>	<ul style="list-style-type: none"> <li>Cardiovascular events</li> <li>Adverse events/diagnoses (since last visit)</li> </ul>
	Phone call-Pt.3	<ul style="list-style-type: none"> <li>Part E: Medications</li> <li>Part F: Compliance</li> </ul>	<ul style="list-style-type: none"> <li>Antihypertensive medications</li> </ul>
CRF04 3-Monthly Visits	Follow Up-Pt.1	<ul style="list-style-type: none"> <li>Part A: Identifying details</li> <li>Part B: Assessment point (completed automatically)</li> <li>Part C: Continued trial participation</li> <li>Part D: Basic assessments</li> <li>Part E: Lab assessments</li> <li>Part F: Sample tracking<sup>†</sup></li> <li>Part G: Six-minute walk test<sup>†</sup></li> </ul>	-
	Follow Up-Pt.2	<ul style="list-style-type: none"> <li>Part H: Clinical visits</li> <li>Part I: Adverse events</li> </ul>	<ul style="list-style-type: none"> <li>Hospital admissions</li> <li>Cardiovascular events</li> <li>Adverse events/diagnoses (since last visit)</li> </ul>
	Follow Up-Pt.3	<ul style="list-style-type: none"> <li>Part J: Medications</li> <li>Part K: Compliance</li> <li>Part L: 12-Lead ECG<sup>†</sup></li> <li>Part M: Echocardiogram</li> <li>Part N: Visit checklist</li> </ul>	<ul style="list-style-type: none"> <li>Antihypertensive medications</li> </ul>
CRF10 SAE Form	SAE*	All sections	-

\* Consent forms and SAE forms cannot be submitted online. Please fax them to BCTU or email them to [stop.ace@nhs.net](mailto:stop.ace@nhs.net). 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.