

# Data Collection & Management

Investigator Meeting  
12<sup>th</sup> September 2017 - Sheffield



Jamie Godsall  
Data Manager, BCTU

UNIVERSITY OF  
BIRMINGHAM



Hull and East Yorkshire Hospitals  
NHS Trust





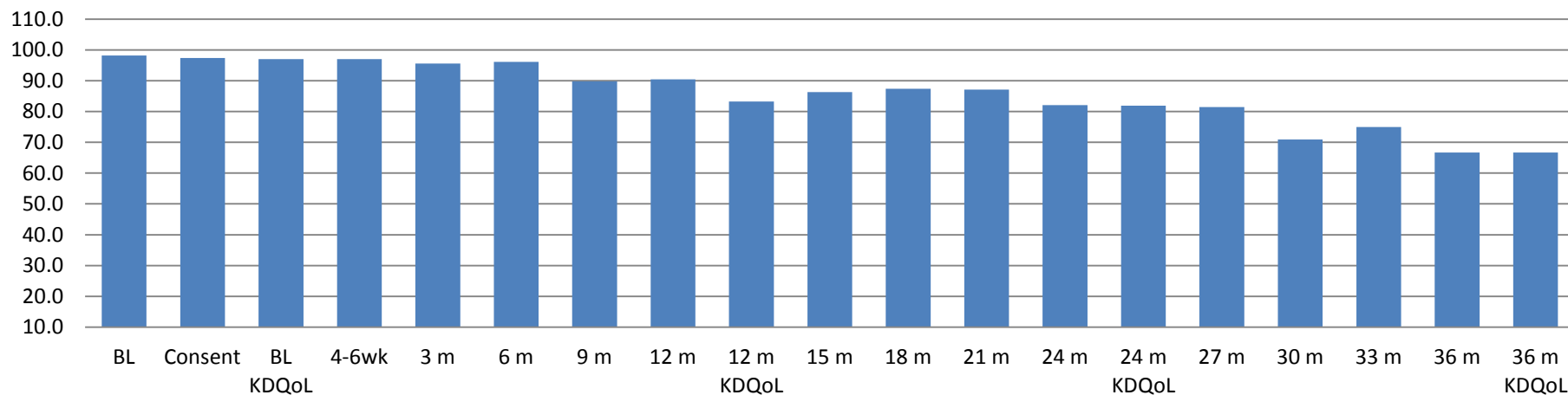
# CRF return rates

Form	Time point	Forms expected	Forms received	Percentage received
Baseline	BL	339	335	98.8
Consent	Consent	341	332	97.4
KDQOLSF	BL KDQoL	337	331	98.2
Phone call	4-6wk	329	325	98.8
Follow Up	3 m	311	304	97.7
Follow Up	6 m	279	276	98.9
Follow Up	9 m	247	230	93.1
Follow Up	12 m	216	200	92.6
KDQOLSF	12 m KDQoL	202	179	88.6
Follow Up	15 m	173	158	91.3
Follow Up	18 m	151	139	92.1
Follow Up	21 m	130	115	88.5
Follow Up	24 m	94	78	83.0
KDQOLSF	24 m KDQoL	91	77	84.6
Follow Up	27 m	52	44	84.6
Follow Up	30 m	31	22	71.0
Follow Up	33 m	8	6	75.0
Follow Up	36 m	3	2	66.7
KDQOLSF	36 m KDQoL	3	2	66.7
<b>Totals</b>		<b>3337</b>	<b>3155</b>	<b>94.5</b>

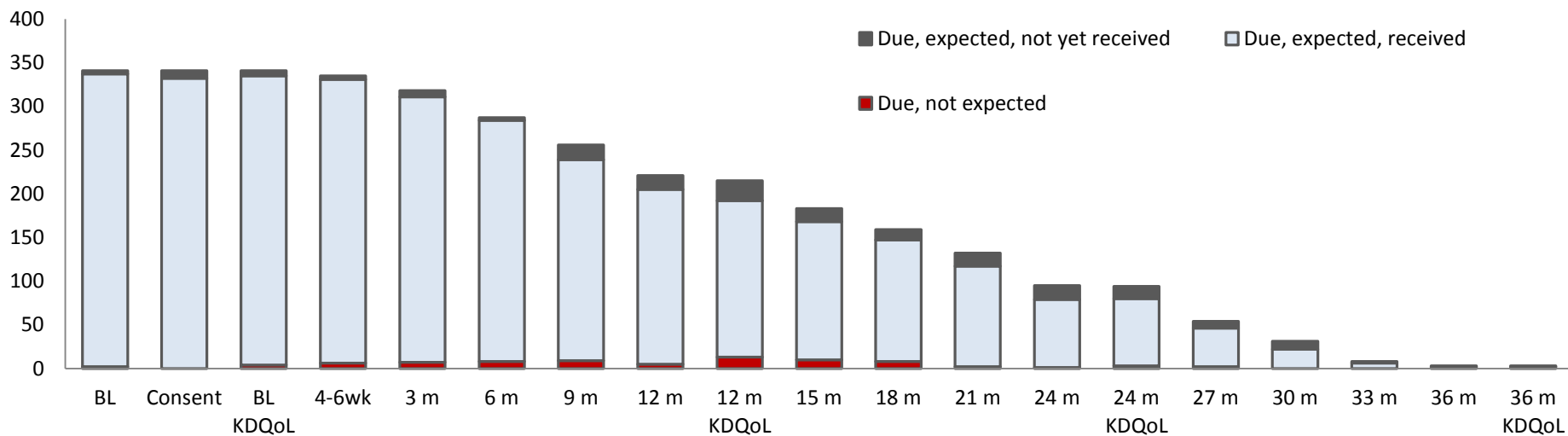


# CRF return rates

Percentage of Due Forms Received



Number of Due Forms Received





# ICFs

Participant consent forms should either be faxed or emailed to our NHS email address. Please send these as soon as possible after randomisation.



stop.ace@nhs.net

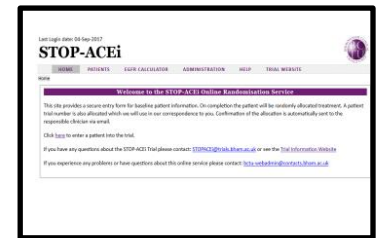
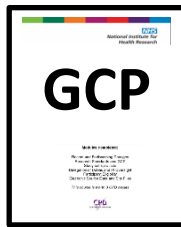
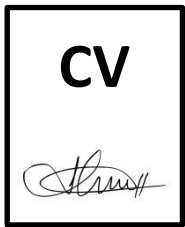


0121 415 9135



# Online system

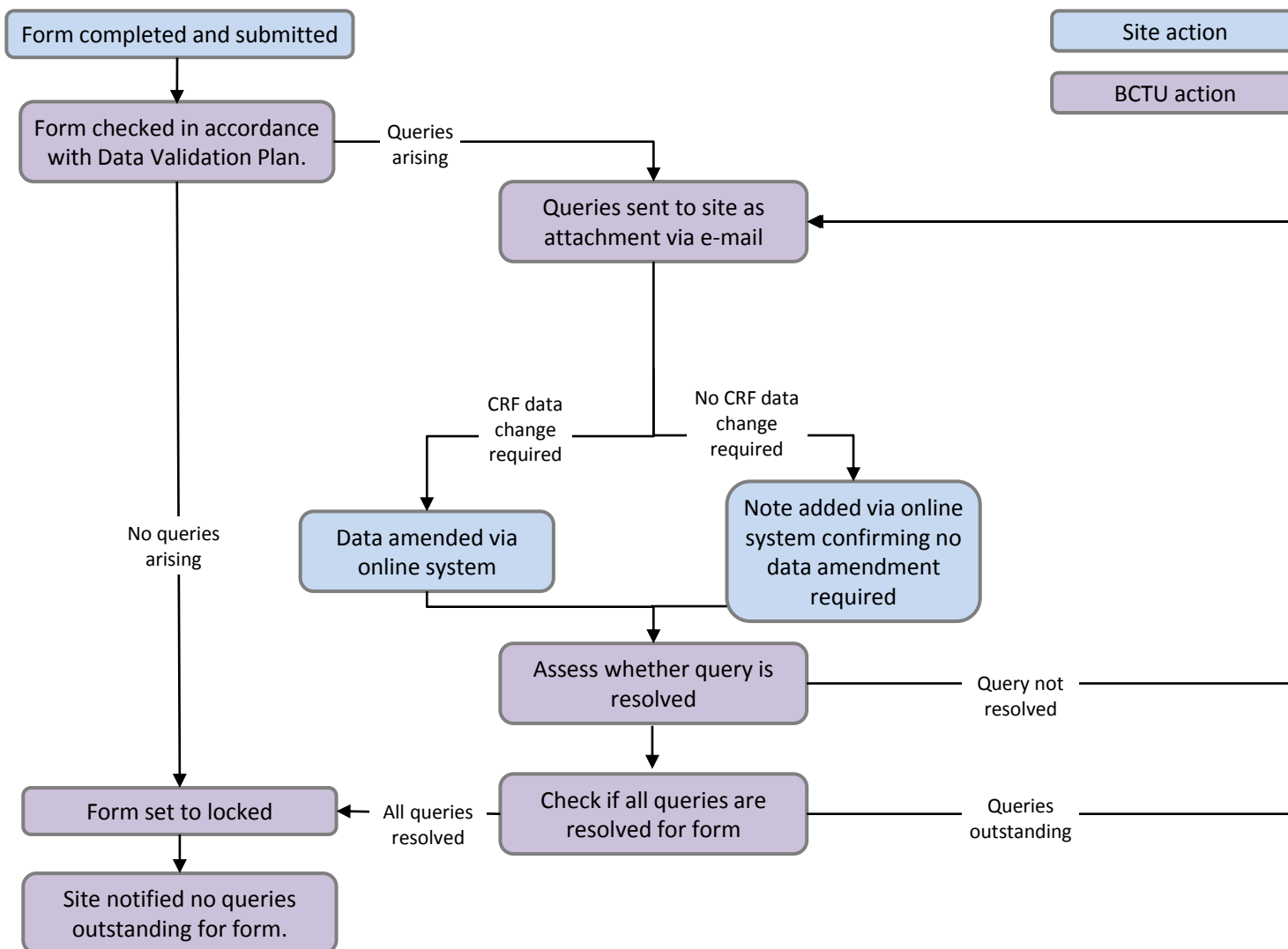
- To access the STOP-ACEi online system you must have a username and have set-up a password
- To add new staff to the trial we require:



- Data **must** be entered into online system from the source data
- You should have corresponding source data which must tally with everything submitted on the eCRF



# Query Process





# Query Process

Form completed and submitted

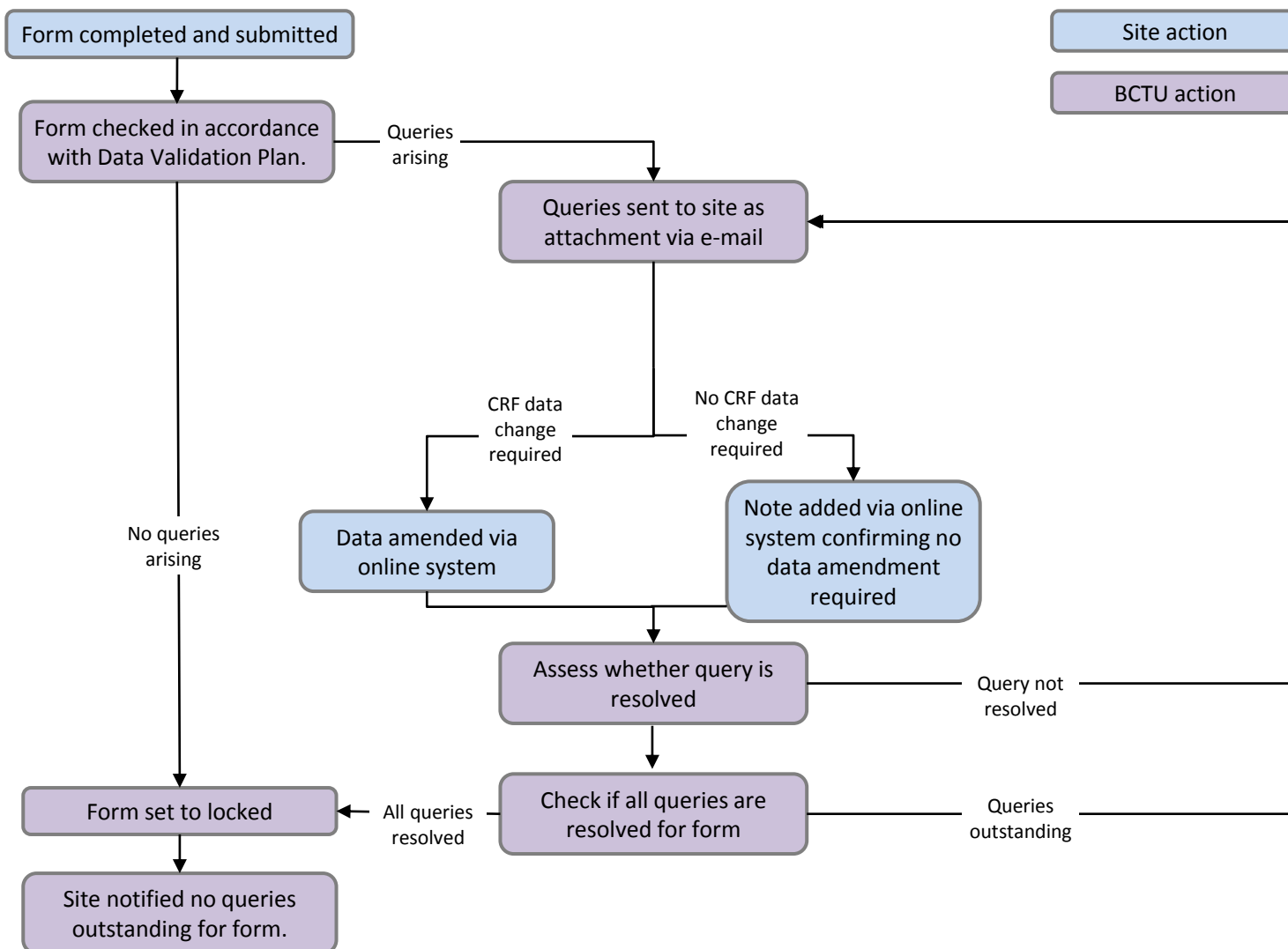
**Please remember to submit eCRFs once completed**

This lets me know that you have finished data entry and the form can be checked

Platelets x10 <sup>9</sup> /L	161
Urinary PCR or ACR by early morning spot urine	
PCR or ACR value given	PCR ▾
Urinary PCR mg/mmol	150
<div>EDIT <b>SUBMIT</b> SAVE UNDO DELETE CHECK OUT</div>	



# Query Process







# Query Process

Form checked in accordance  
with Data Validation Plan.

## Lab Assessments

If a result is missing please leave the field blank

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

Field should be left blank:  
and note added explaining

## Compliance

If a patient has withdrawn from trial treatment please report non-compliance on every subsequent eCRF where they remain non-compliant.

## Annual visits (month 12, 24 and 36)

There have been a number of six-minute walk tests and questionnaires missed at the annual follow-ups. This data is important to the trial and should be obtained if possible.



# Query Process

Form checked in accordance  
with Data Validation Plan.

**Please complete all drop down boxes**

BASIC ASSESSMENTS	CKD AETIOLOGY	CARDIOVASCULAR EVENTS	HEART FAILURE	MED HISTORY	ADMIN - VIEW AUDIT	ADMIN - VIEW CHANGES
<b>Please indicate all conditions the patient has a known history or current diagnosis of.</b> <b>Heart failure, stroke and MI should be recorded in the previous sections</b>						
Please indicate all conditions the patient has a known history or current diagnosis of.						
Other Cardiovascular Disease				Yes		
Diabetes				Yes		
Malignancy						
Gastrointestinal						
Musculoskeletal or connective tissue disorders						
Infection						
Pulmonary Disease						
Other				Yes		

Form Status: Data Entry In Progress

There are 6 queries for this form

- "Med History : Malignancy" has not been answered
- "Med History : Gastrointestinal" has not been answered
- "Med History : Musculoskeletal or connective tissue disorders" has not been answered
- "Med History : Infection" has not been answered
- "Med History : Pulmonary Disease" has not been answered
- Baseline Medical History Form "Page 1 : Condition category" has not been answered

The system will query missing data



# Query Process

Form checked in accordance  
with Data Validation Plan.

A lot of queries are around medications with no corresponding medical condition. Please ensure that the patient's full medical history is included at baseline and new conditions are added after follow-up visits.

PAGE 1	MEDICATION	ANTIHYPERMEDIATIONS	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		
Cyclosporin				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



# Query Process

Form checked in accordance  
with Data Validation Plan.

## Differences between trial visits

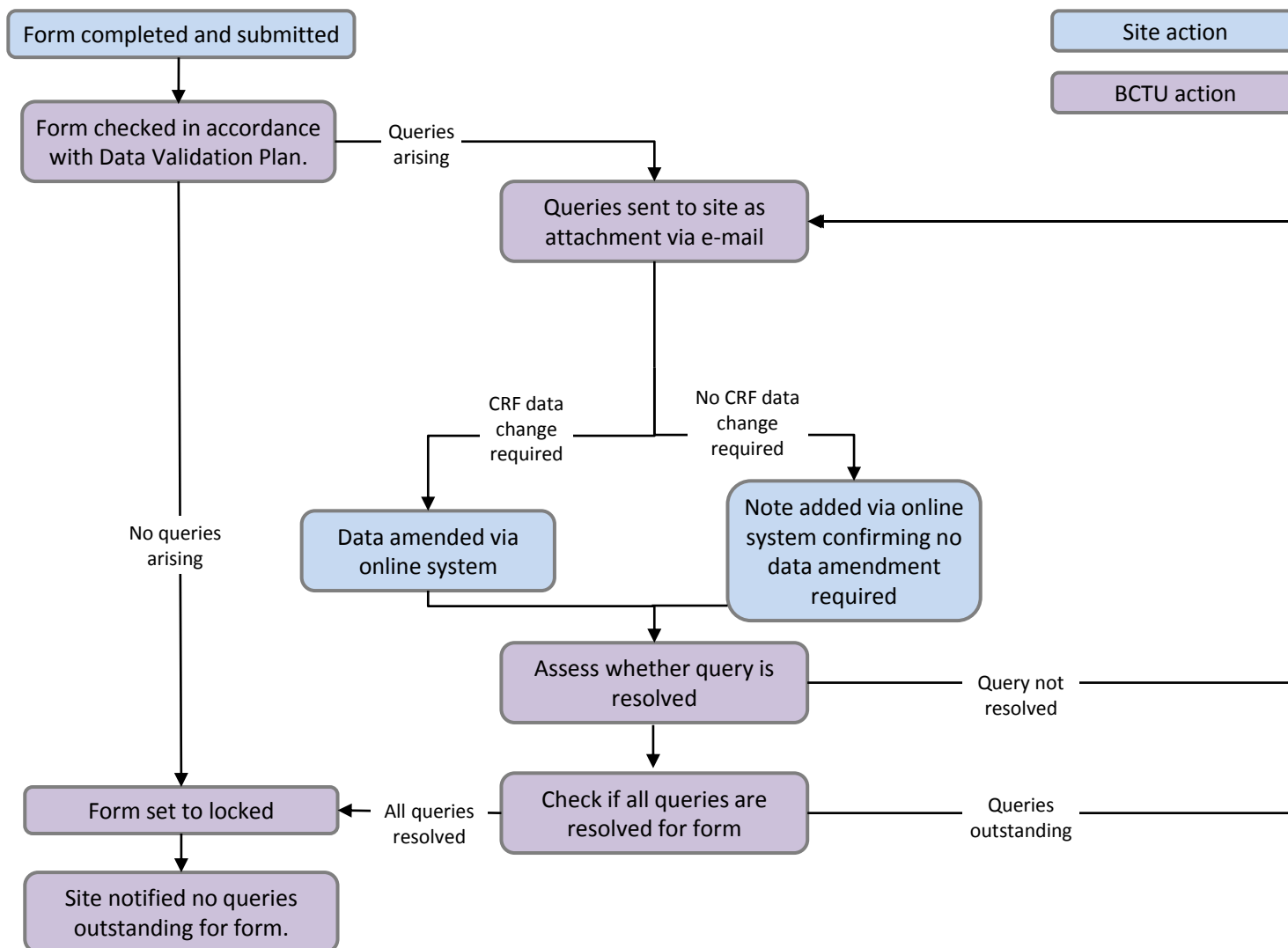
Queries are often raised about differences between trial visits with no explanation (e.g. no note added, no new medical condition, no SAE or adverse event).

MEDICATIONS	ANTIHYPER PRE-RAND	ANTIHYPER POST-RAND	CONCOM MEDS	12-LEAD ECG	ECH
ADMIN - VIEW CHANGES					
Other concomitant medications					
Is the participant currently taking any other medications?				Yes	▼
Statin				Yes	▼
Digoxin				No	▼
Nitrate				No	▼
Fibrate				No	▼
Ezetimibe				Yes	▼
Aspirin				Yes	▼
Bicarbonate				Yes	▼
Sulphonylurea, e.g. glicazide				No	▼
GLP-1 analogues/agonists, e.g. liraglutide, exenatide				No	▼
Clopidogrel				No	▼
Warfarin				No	▼
Phosphate Binders				No	▼
Calcium/Vitamin D				Yes	▼
Bisphosphonate				No	▼
Prednisolone				No	▼

MEDICATIONS	ANTIHYPER PRE-RAND	ANTIHYPER POST-RAND	CONCOM MEDS	12-LEAD ECG	ECH
ADMIN - VIEW CHANGES					
Other concomitant medications					
Is the participant currently taking any other medications?				Yes	▼
Statin				Yes	▼
Digoxin				No	▼
Nitrate				No	▼
Fibrate				No	▼
Ezetimibe				Yes	▼
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				Yes	▼
Bisphosphonate				No	▼
Prednisolone				No	▼



# Query Process





# Query Process

Queries sent to site as  
attachment via e-mail

Instead of a list of queries via email, queries will now be sent in a standard format as a pdf email attachment :



## Outstanding Data Queries by Site

Query number

7

Centre name

Hull Royal Infirmary

Participant number

1000

Query raised

06-Sep-17

Raised by

Jamie Godsall

Time point

Baseline

CRF

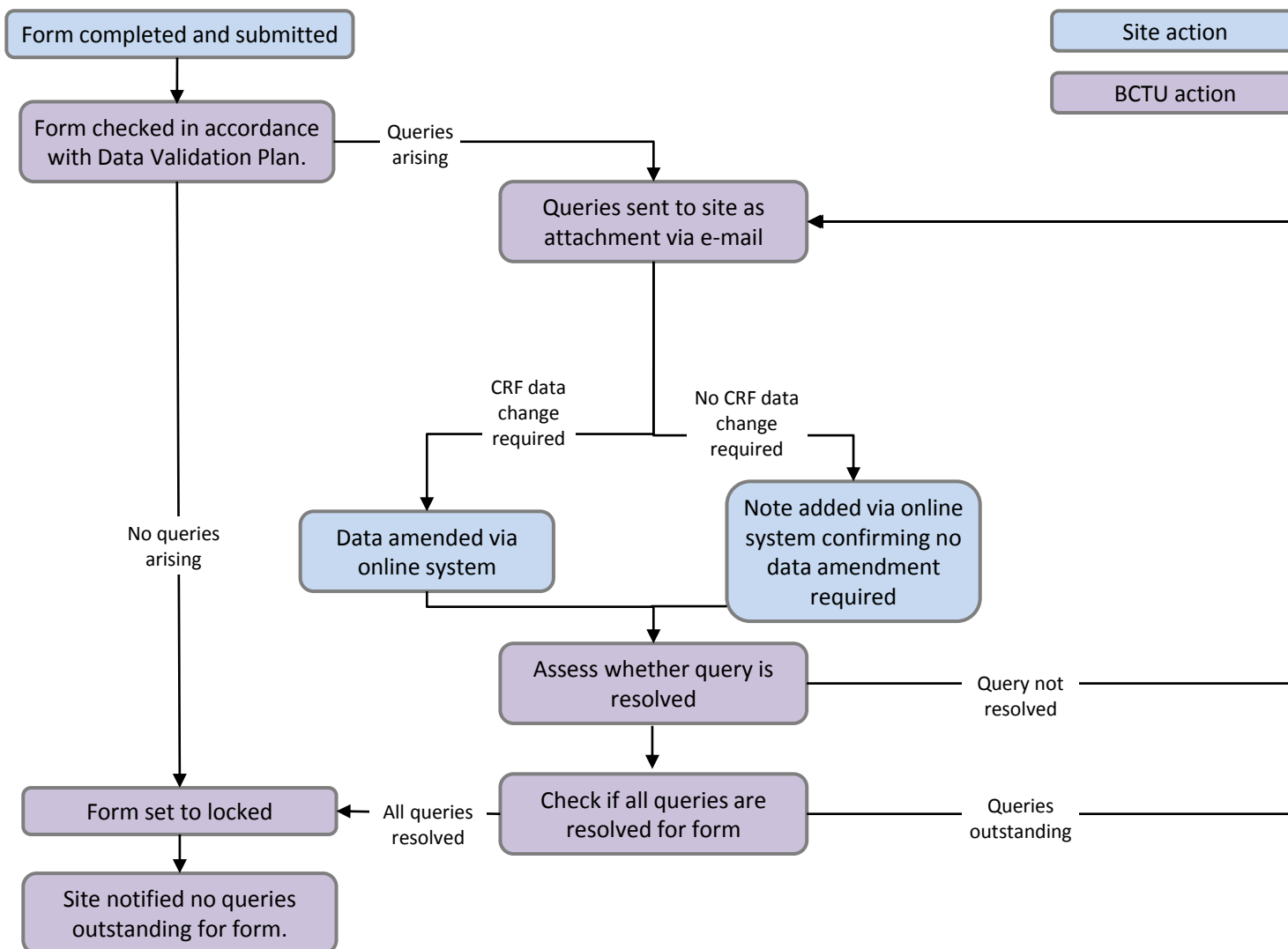
Medical History

Details of 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?



# Query Process





# Query Process

Data amended via  
online system

**If data needs amending sites must update the eCRF**

**BCTU staff are now locked out from making changes to the data**

You can check forms out to edit after they have been submitted (as long as I haven't locked them)

EDIT SUBMIT SAVE UNDO DELETE CHECK OUT

EDIT SUBMIT SAVE UNDO DELETE Please give reason for checkout: Enter missing lab result CHECK OUT

EDIT SUBMIT SAVE UNDO DELETE CHECK OUT





# Query Process

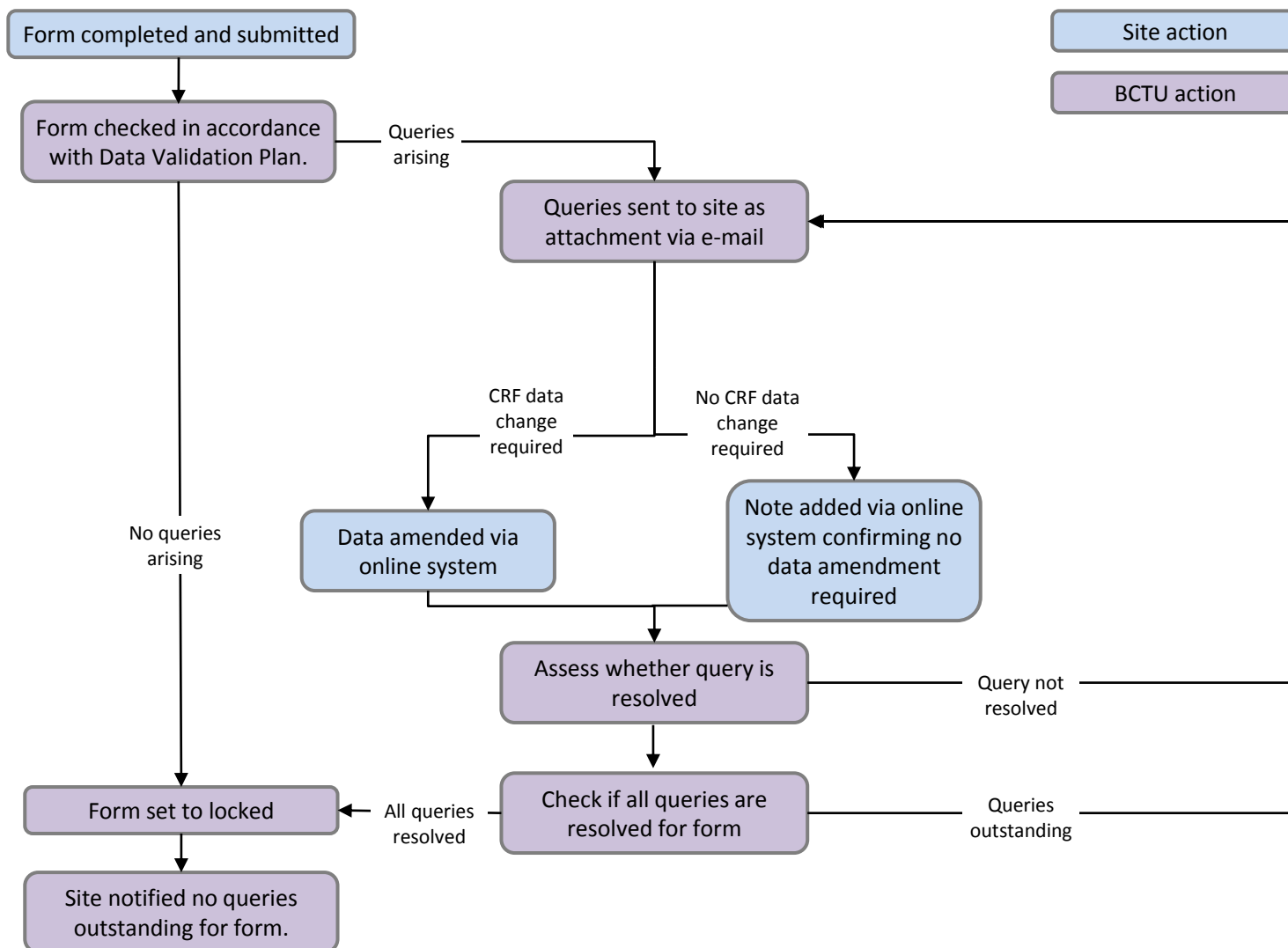
Data amended via  
online system

Site updates eCRF, then saves **and submits** the form again

PAGE 1	LAB ASSESSMENTS	ADMIN - VIEW AUDIT	ADMIN - VIEW CHANGES
Serum Creatinine $\mu\text{mol/L}$ :		260	
Biochemical profile			
Sodium mmol/L		140	
Potassium mmol/L		3.9	
Bicarbonate mmol/L		20.5	
Calcium mmol/L		2.40	
Phosphate mmol/L		1.01	
Alkaline phosphatase U/L		75	
Albumin g/L		47	
Total protein g/L		71	
Alanine transferase U/L		15	
Full blood count			
Haemoglobin g/L		119	
Platelets $\times 10^9/\text{L}$		229	
Urinary PCR or ACR by early morning spot urine			
PCR or ACR value given		ACR	
Urinary ACR mg/mmol		11.6	
EDIT	SUBMIT	SAVE	UNDO
DELETE	CHECK OUT		



# Query Process





# Query Process

Note added via online system confirming no data amendment required

Note boxes can be found on each part of the eCRF:

<b>Notes</b>	
<div></div>	
Has this form been checked by BCTU Trial Team	<input type="checkbox"/>
Admin lock this form? (this will prevent non-admin users from being able to edit the form)	<input type="checkbox"/>
Date form was completed (dd-mmm-yyyy)	31-Jul-2015
Smoking status:	Ex-Smoker
Alcohol intake:	Less than or equal to 20 units per week
Height (in cm)	179
Weight (in kg)	85.70
Systolic BP (mmHg)	130
Diastolic BP (mmHg)	76
<div>EDIT SUBMIT SAVE UNDO DELETE CHECK OUT</div>	



# Query Process

Note added via online system confirming no data amendment required

Notes

Query 7: No bicarbonate or protein result available from this visit

Notes

Query 15: Confirm Doxazosin dose has increased to 8mg daily and patient has stopped taking Atenolol

Notes

Query 24: Confirm patient has stopped taking Aspirin and Tramadol (as of 06Sep17) and started Allopurinol (gout - already added to Adverse Events)

Notes

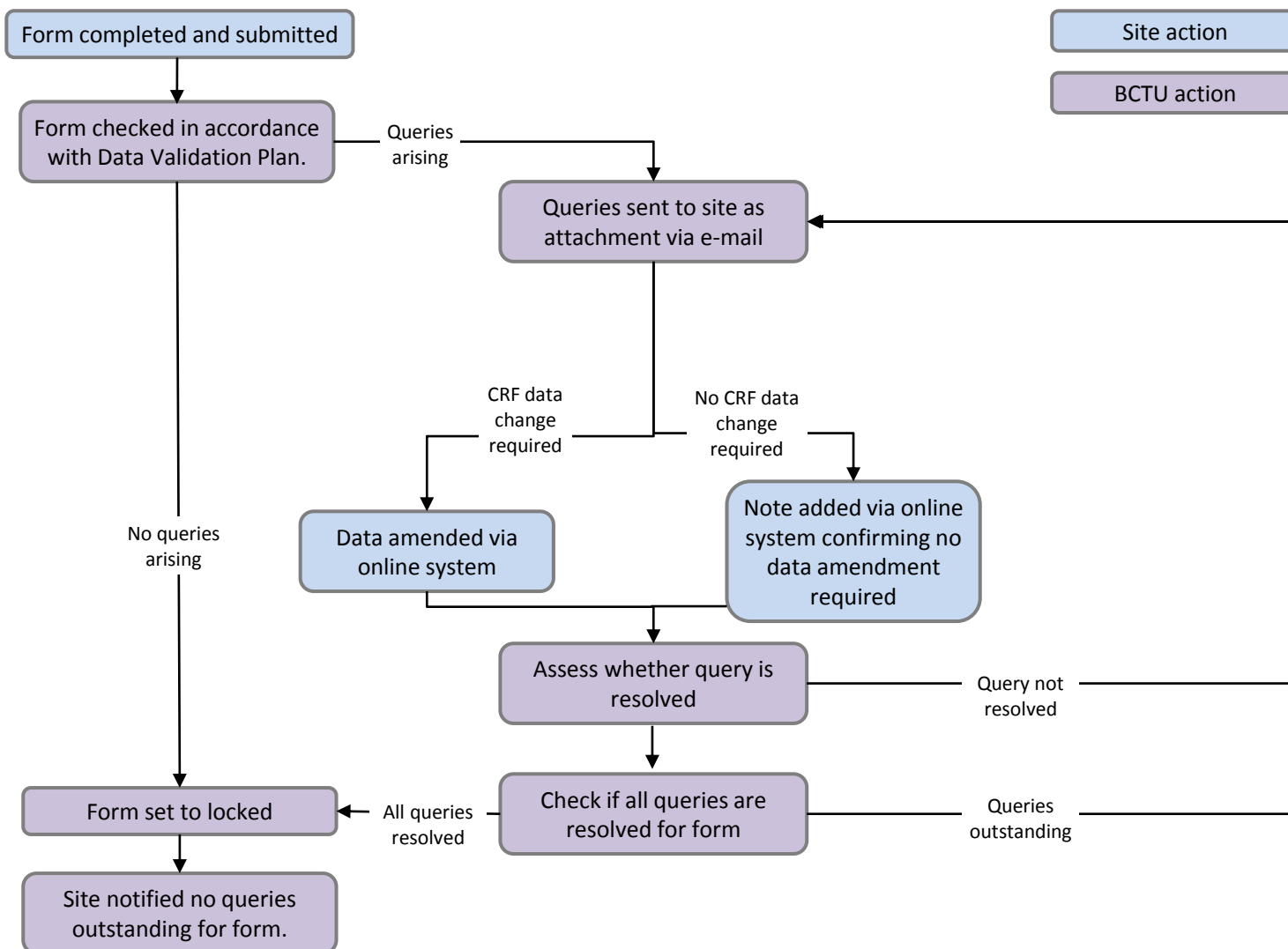
Query 33: Patient had stopped taking Amoxicillin by this trial visit

Notes

Query 42: Unsure if patient was seen in primary care so box left blank

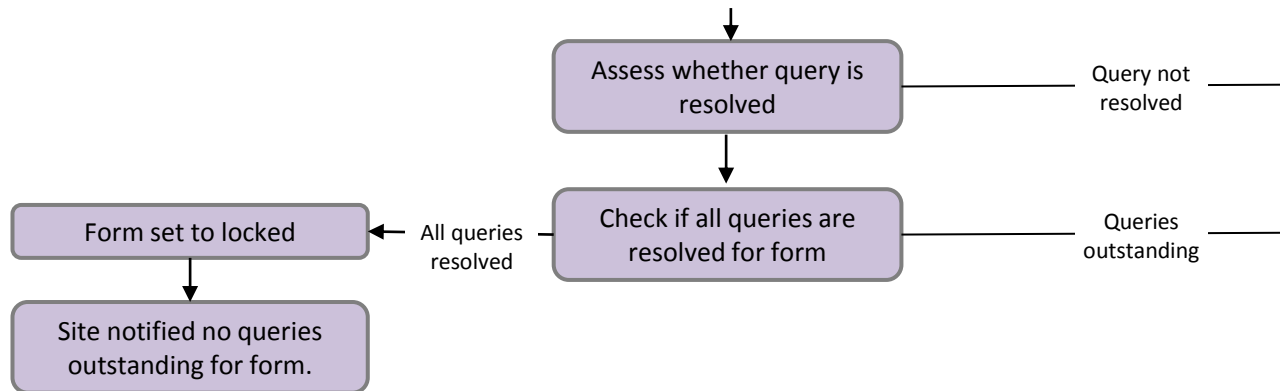


# Query Process





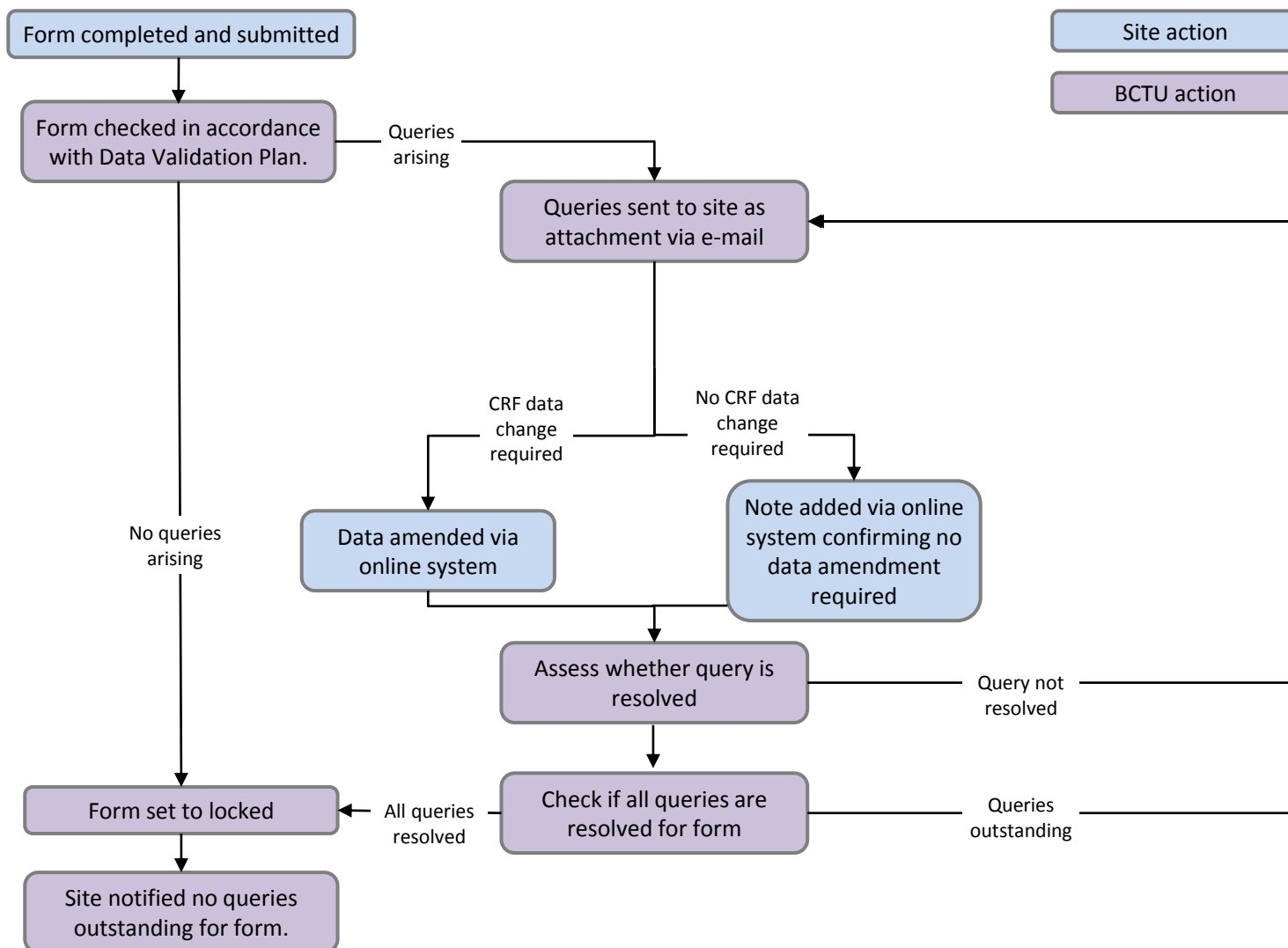
# Query Process



- BCTU will check the form once it has been updated
- If queries are outstanding or a query is not resolved completely a new query will be raised
- Once all queries have been completed the eCRF will be locked. However, if you need to make changes the form will be unlocked again.
- BCTU will send an email notifying sites once queries have been resolved

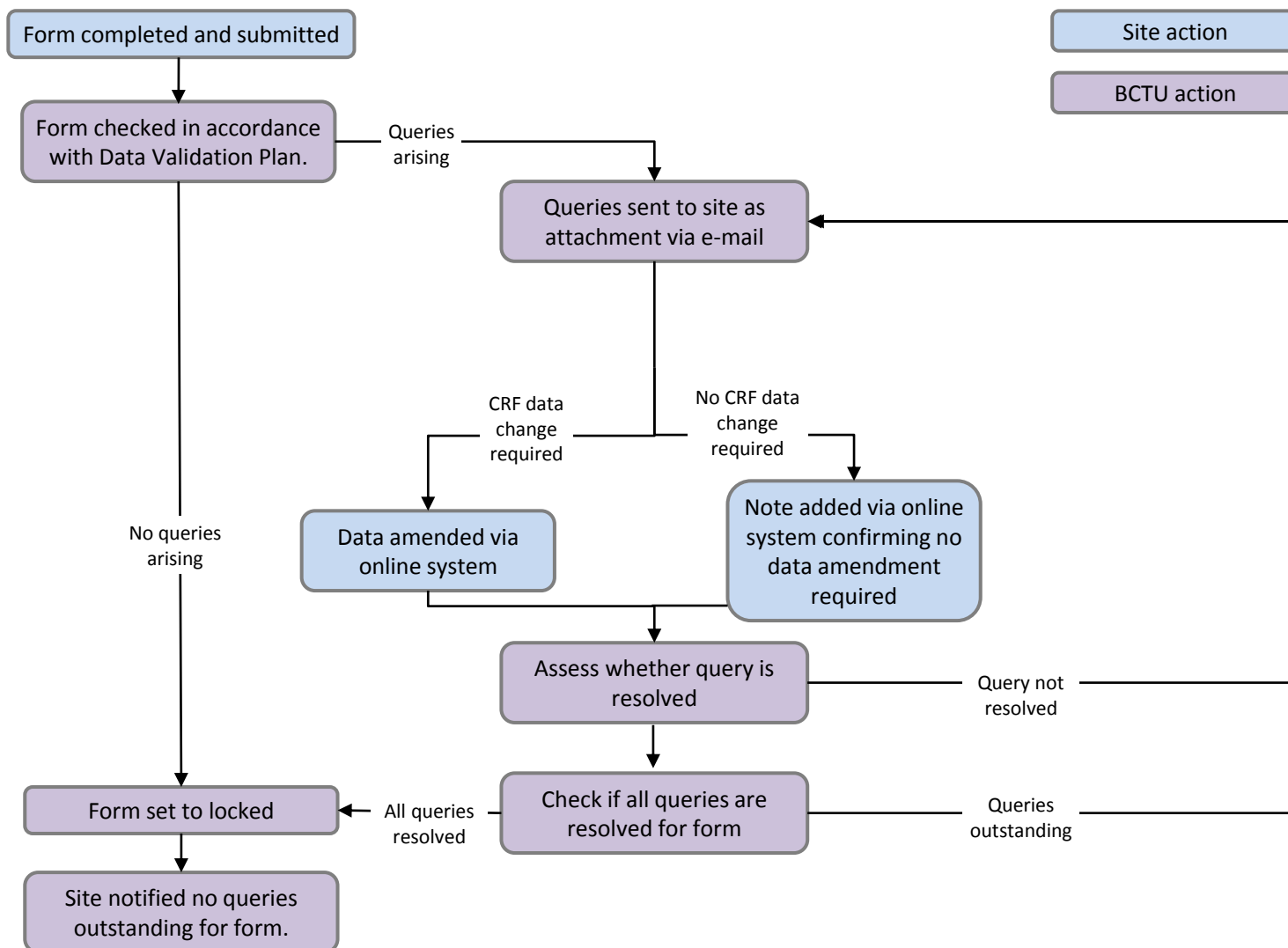


# Query Process





# Query Process







# Query Process

## Add notes to minimise queries and to let us know additional information

- Medication changes
  - Medication stopped or started
  - Dose or frequency changed
  - Why a patient has started a medication if no adverse event listed
- Missing lab results
- Incomplete data
- Visit done outside window
- Lab results are from different dates

Allopurinol has been stopped since the last trial visit. Ramipril dose increased to 10mg OD

No BP available from this visit

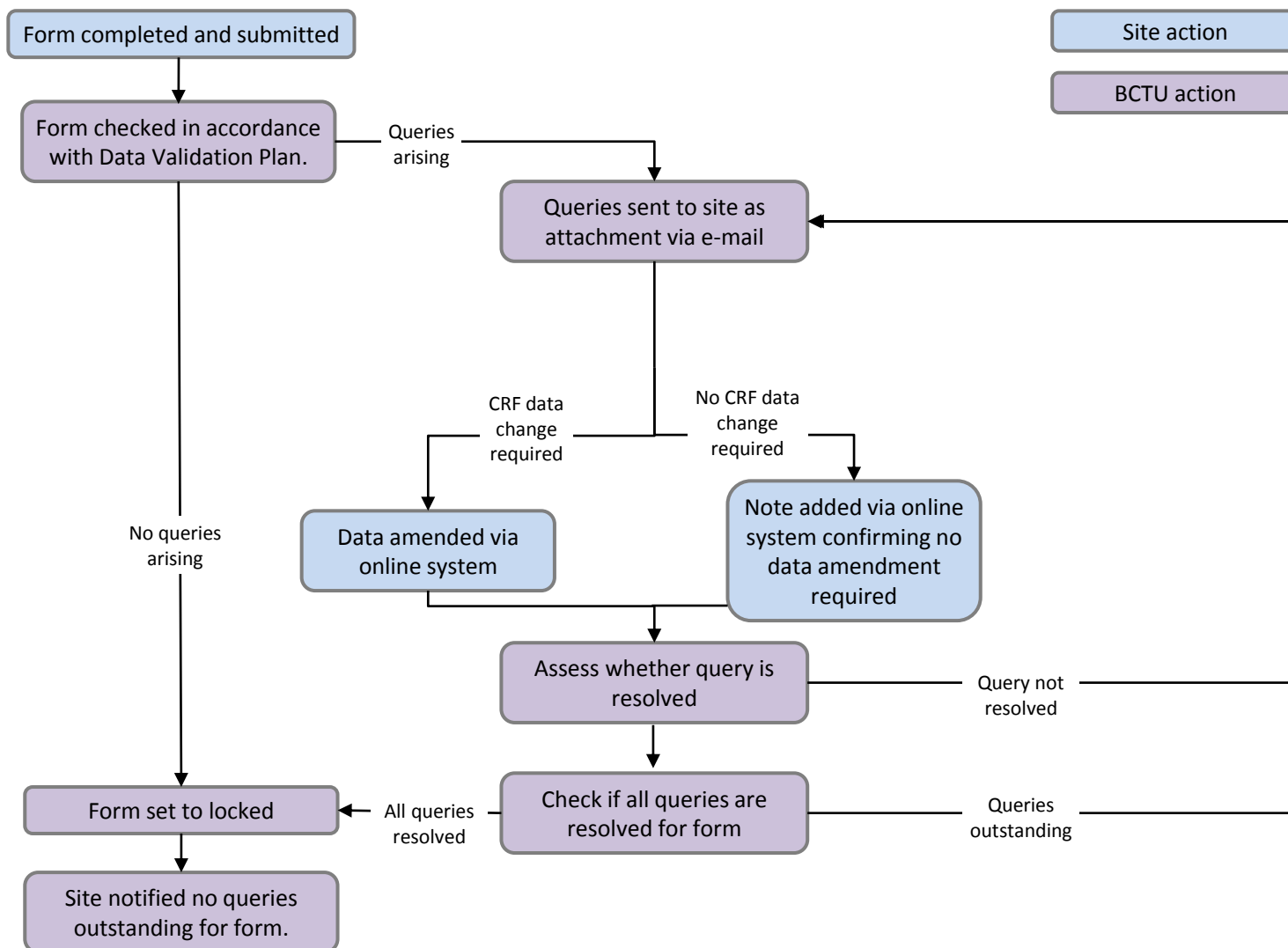
Urinary ACR result is from 22-Jul-2017. All other results from the day of the follow-up.

Patient did not fully complete the questionnaire. Q7-8 not done.

Patient stopped taking Losartan for 3 days during SAE but has now restarted. This is why compliance section has been completed as non-compliant despite Losartan being listed.



# Questions on the query process?





# www.birmingham.ac.uk/STOPACEi

**UNIVERSITY OF BIRMINGHAM** Alumni Working here Events Visit Dubai

[Study](#) [Research](#) [International](#) [Business](#) [News](#) [About us](#)

[Home](#) > [Research](#) > [Research activity](#) > [Research in the College of Medical and Dental Sciences](#) > [Birmingham Clinical Trials Unit](#) > [Current Trials](#) > [STOPACEi](#) > [For Investigators](#) > [Recruitment](#)

## Recruitment

Last updated 21 Aug 2017

STOP-ACEi is open to recruitment. We aim to recruit 410 patients from centres across the UK.

### Overview

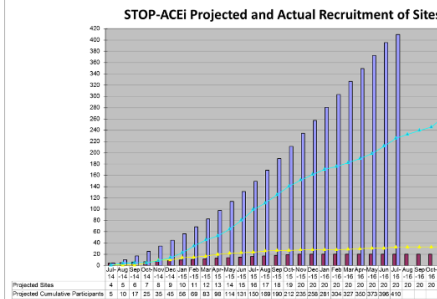
Date first participant randomised

Total recruitment to date

Total number of centres with full approval

## STOP-ACEi Patient Recruitment

[Click here for a larger image of the recruitment graph.](#)



**UNIVERSITY OF BIRMINGHAM** Alumni Working here Events Visit

[Study](#) [Research](#) [International](#) [Business](#) [News](#) [About us](#)

[Home](#) > [Research](#) > [Research activity](#) > [Research in the College of Medical and Dental Sciences](#) > [Birmingham Clinical Trials Unit](#) > [Current Trials](#) > [STOPACEi](#) > [For investigators](#) > [Trial Documentation](#)

## Trial Documentation

These documents are for use by collaborators involved in the STOP-ACEi trial. They are the property of the University of Birmingham and Hull and East Yorkshire Hospitals NHS Trust and do not constitute any form of advice to participants.

Please see links below to download STOP-ACEi documentation.

[Open all sections](#)

**In 'For Investigators'**

- > [For Investigators](#)
- > [Trial Documentation](#)
- > [Recruitment](#)

## STOP-ACEi Protocol and REC-approved study documents

### STOP-ACEi Protocol

[STOP-ACEi Protocol, V3.0, 14th May 2014](#)

[MRC START in STOP-ACEi Protocol, V1.0, 10th December 2014](#)

### STOP-ACEi PIS, GP Letters & Consent Form

[STOP-ACEi Participant Information Sheet, V3.0 Standard, 10th December 2014](#)

[STOP-ACEi Participant Consent Form, V3.1, 24th March 2015](#)

[STOP-ACEi GP Letter - Treatment Continuation, V2.0, 6th January 2014](#)

[STOP-ACEi GP Letter - Treatment Discontinuation, V2.0, 6th January 2014](#)

### STOP-ACEi Other REC-approved documentation

[STOP-ACEi Letter to accompany PIS, V2.0 Standard, 10th December 2014](#)

[STOP-ACEi Participant Advice Letter - Treatment Continuation, V1.0, 1st November 2013](#)

[STOP-ACEi Participant Advice Letter - Treatment Discontinuation, V1.0, 1st November 2013](#)

[STOP-ACEi Participant Diary, V1.0, 1st November 2013](#)

[STOP-ACEi Clinic Poster, V2.0, 6th January 2014](#)

[STOP-ACEi Advertising Text, V1.0, 1st November 2013](#)

### Version history

[List of current documents and amendment log, last updated 14th August 2017](#)

[STOP-ACEi CRFs and KDQOL-SF™ questionnaire](#)

**UNIVERSITY OF BIRMINGHAM** Alumni Working here Events Visit

[Study](#) [Research](#) [International](#) [Business](#) [News](#) [About us](#)

[Home](#) > [Research](#) > [Research activity](#) > [Research in the College of Medical and Dental Sciences](#) > [Birmingham Clinical Trials Unit](#) > [Current Trials](#) > [STOPACEi](#)

# STOP-ACEi

STOP-ACEi is a national multi-centre randomised controlled trial of Angiotensin Converting Enzyme inhibitor (ACEi) / Angiotensin Receptor Blocker (ARB) withdrawal in advanced renal disease.

**In 'STOPACEi'**

- > [Birmingham Clinical Trials Unit \(CTU\)](#)
- > [STOPACEi](#)
  - > [For Investigators](#)
  - > [For Trial Participants](#)
  - > [News and events](#)
  - > [Publications](#)
  - > [Contact us](#)

## Trial details

**Full Title:** Multi-centre Randomised Controlled Trial of Angiotensin Converting Enzyme inhibitor (ACEi) / Angiotensin Receptor Blocker (ARB) withdrawal in advanced renal disease

**Short Title:** The STOP-ACEi Trial

**Aim of the study:** To test the hypothesis that stopping treatment with ACEi, ARB or a combination of both, compared with continuing on these treatments, improves or stabilises renal function in patients with progressive stage 4 or 5 Chronic Kidney Disease (CKD).

**Trial design:** Open-label randomised controlled trial (RCT).

**Sample size:** 410 patients will be recruited into the study (205 in each arm) over a 2 year period.



# STOP-ACEi Twitter



Join over 200 other Twitter users and  
Follow us @STOPACEi\_trial





# Contact details

---

Trial website: [www.birmingham.ac.uk/STOPACEi](http://www.birmingham.ac.uk/STOPACEi)

Online randomisation & data entry: [www.trials.bham.ac.uk/STOPACEi](http://www.trials.bham.ac.uk/STOPACEi)

E-mail: [STOPACEi@bham.ac.uk](mailto:STOPACEi@bham.ac.uk)  
[STOP.ACE@nhs.net](mailto:STOP.ACE@nhs.net)

Telephone: 0121 415 9133

Fax: 0121 415 9135

Post: Birmingham Clinical Trials Unit  
Public Health Building  
University of Birmingham  
Edgbaston  
B15 2TT

STOP-ACEi staff: Elizabeth Brettell, Renal Team Leader  
Marie Valente, Trial Coordinator  
Jamie Godsall, Data Manager



# Before you leave

---

- Slides will be made available online
- Certificates / CPD credits
- Feedback forms
- Expenses forms