Data Collection & Management

Investigator Meetings

1st and 2nd September 2016 - London and Leeds

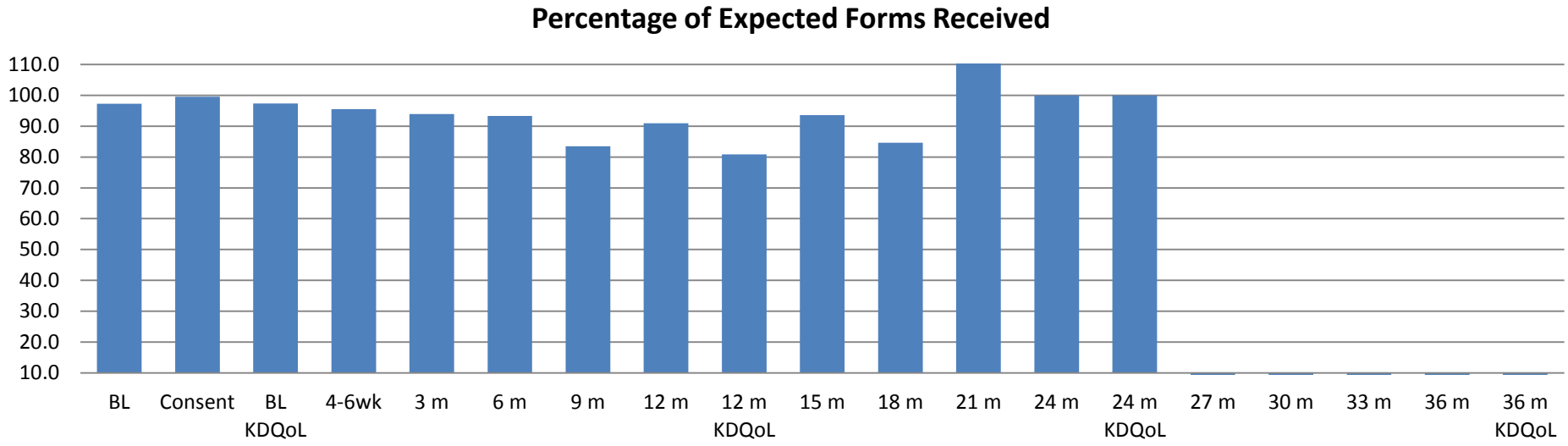
Jamie Godsall
Data Manager, BCTU

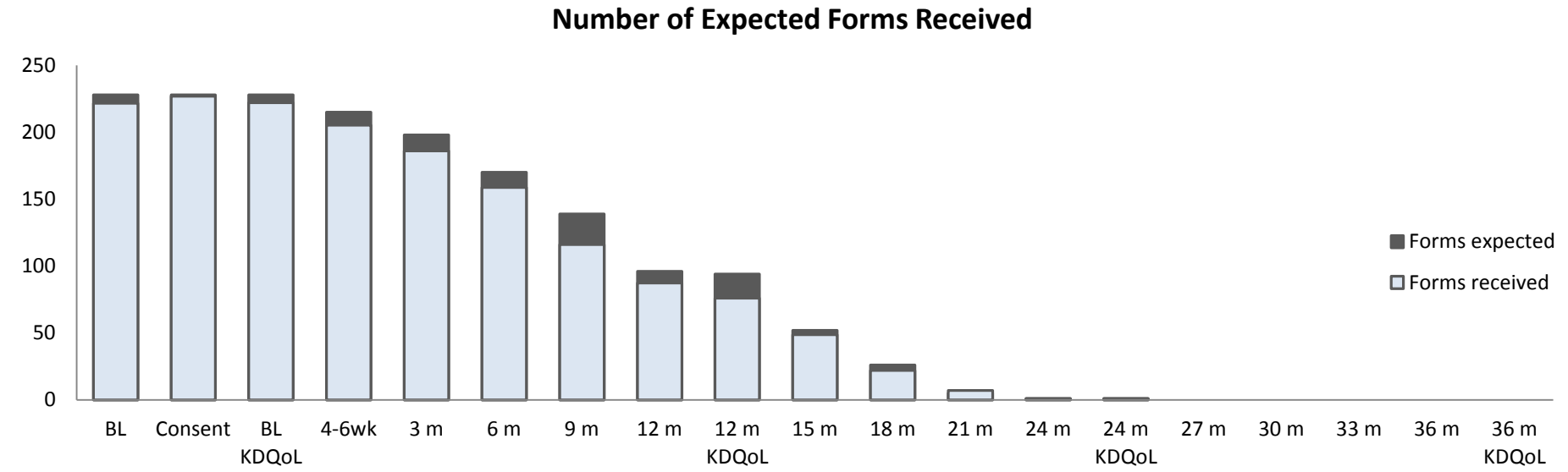
UNIVERSITY OF BIRMINGHAM | BCTU Birmingham Clinical Trials Unit | Hull and East Yorkshire Hospitals NHS Trust | NHS

CRF return rates

Form	Time point	Forms expected	Forms received	Percentage received
Baseline	BL	228	222	97.2
Consent	Consent	228	227	99.6
KDQOLSF	BL KDQoL	228	222	97.4
Phone call	4-6wk	215	205	95.5
Follow Up	3 m	198	186	93.9
Follow Up	6 m	170	159	93.3
Follow Up	9 m	139	116	83.5
Follow Up	12 m	96	87	91.0
KDQOLSF	12 m KDQoL	94	76	80.9
Follow Up	15 m	52	49	93.6
Follow Up	18 m	26	22	84.6
Follow Up	21 m	5	7	140.0
Follow Up	24 m	1	1	100.0
KDQOLSF	24 m KDQoL	1	1	100.0
Follow Up	27 m	0	0	0
Follow Up	30 m	0	0	0
Follow Up	33 m	0	0	0
Follow Up	36 m	0	0	0
KDQOLSF	36 m KDQoL	0	0	0
Totals		**1681**	**1580**	**94.0**

CRF return rates





Common problems with ICFs

ICF not on headed paper

Trial ID not completed

Boxes ticked instead of initialled

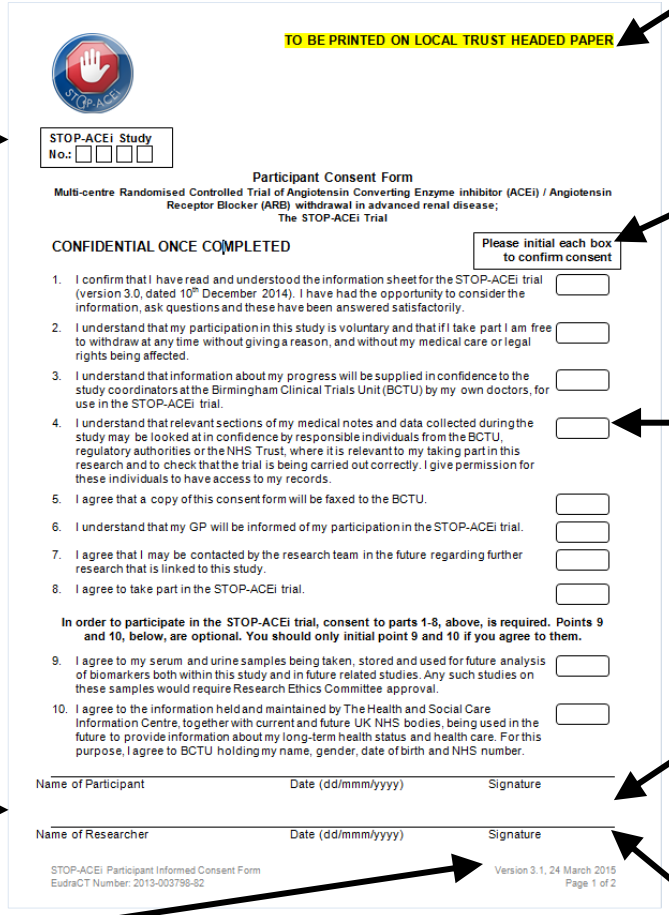
Some required boxes not initialled

Missing signatures / dates

Clinician counter-signing ICF not on del. log.

Incorrect version no.

Clinician counter-signing ICF on different date



TO BE PRINTED ON LOCAL TRUST HEADED PAPER

STOP-ACEi Study No.: ☐☐☐☐

Participant Consent Form

Multi-centre Randomised Controlled Trial of Angiotensin Converting Enzyme inhibitor (ACEi) / Angiotensin Receptor Blocker (ARB) withdrawal in advanced renal disease; The STOP-ACEi Trial

CONFIDENTIAL ONCE COMPLETED

Please initial each box to confirm consent

1. I confirm that I have read and understood the information sheet for the STOP-ACEi trial (version 3.0, dated 10th December 2014). I have had the opportunity to consider the information, ask questions and these have been answered satisfactorily. ☐
2. I understand that my participation in this study is voluntary and that if I take part I am free to withdraw at any time without giving a reason, and without my medical care or legal rights being affected. ☐
3. I understand that information about my progress will be supplied in confidence to the study coordinators at the Birmingham Clinical Trials Unit (BCTU) by my own doctors, for use in the STOP-ACEi trial. ☐
4. I understand that relevant sections of my medical notes and data collected during the study may be looked at in confidence by responsible individuals from the BCTU, regulatory authorities or the NHS Trust, where it is relevant to my taking part in this research and to check that the trial is being carried out correctly. I give permission for these individuals to have access to my records. ☐
5. I agree that a copy of this consent form will be faxed to the BCTU. ☐
6. I understand that my GP will be informed of my participation in the STOP-ACEi trial. ☐
7. I agree that I may be contacted by the research team in the future regarding further research that is linked to this study. ☐
8. I agree to take part in the STOP-ACEi trial. ☐

In order to participate in the STOP-ACEi trial, consent to parts 1-8, above, is required. Points 9 and 10, below, are optional. You should only initial point 9 and 10 if you agree to them.

9. I agree to my serum and urine samples being taken, stored and used for future analysis of biomarkers both within this study and in future related studies. Any such studies on these samples would require Research Ethics Committee approval. ☐
10. I agree to the information held and maintained by The Health and Social Care Information Centre, together with current and future UK NHS bodies, being used in the future to provide information about my long-term health status and health care. For this purpose, I agree to BCTU holding my name, gender, date of birth and NHS number. ☐

Name of Participant | Date (dd/mmm/yyyy) | Signature

Name of Researcher | Date (dd/mmm/yyyy) | Signature

STOP-ACEi Participant Informed Consent Form
EudraCT Number: 2013-003798-82

Version 3.1, 24 March 2015
Page 1 of 2

Common problems with ICFs

- Participant consent forms should either be faxed or emailed to our NHS email address.

@NHS stop.ace@nhs.net

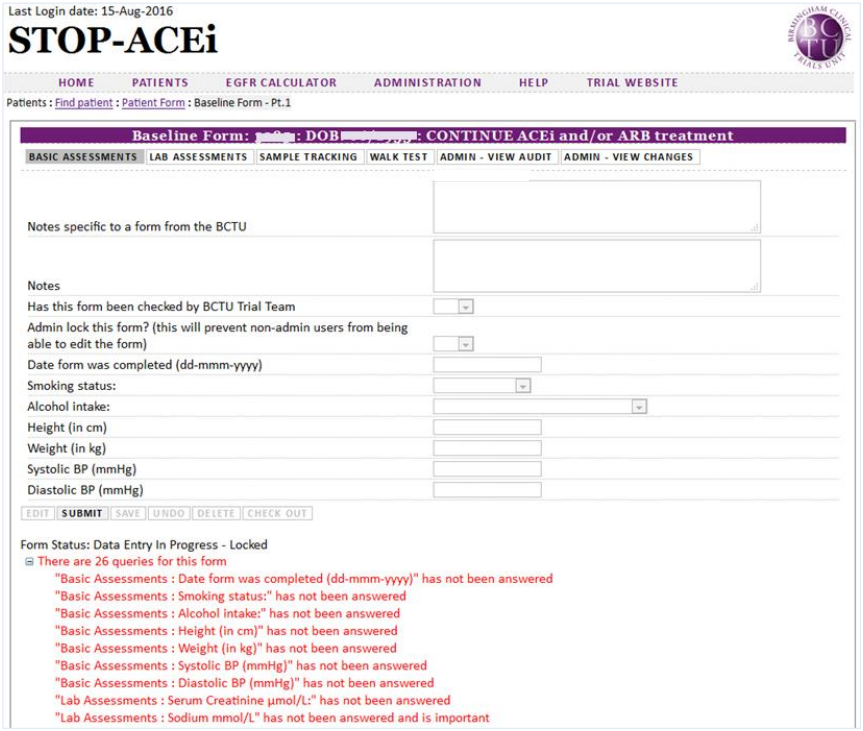
0121 415 9135

CRFs and data entry

- CRFs are in your site file or can be downloaded from the trial website
  - CRF01 – Randomisation Form
  - CRF02 – Baseline assessment
  - CRF03 – Telephone follow-up
  - CRF04 – 3-monthly visits
  - CRF05 – Additional clinical visits
  - CRF06 – Lab results – used by central lab staff
  - CRF10 – SAE form
- Don’t forget KDQOL-SF questionnaires

CRFs and data entry

- Data should be entered directly into online system – will check for errors / omissions



- Please keep originals of CRFs at site.
- You should have corresponding source data which must tally with everything submitted on the CRF.

Login

- You will need:
  - A Unique Username – BCTU will provide after SIV
  - A Unique Password – you will set
- No access until site fully approved
- Once you have your Username and you can set your password at: https://www.trials.bham.ac.uk/password/
- Activate your password by following instructions in e-mail.
- Check your 'Junk Email' folder
  - Can manually add bctu-webadmin@contacts.bham.ac.uk to your list of safe senders in your email clients
- Can then access the STOP-ACEi Online System at: https://www.trials.bham.ac.uk/STOPACEi

Common issues with form completion

The following results and assessments are only required at **baseline** and then again at **months 12, 24 and 36:**

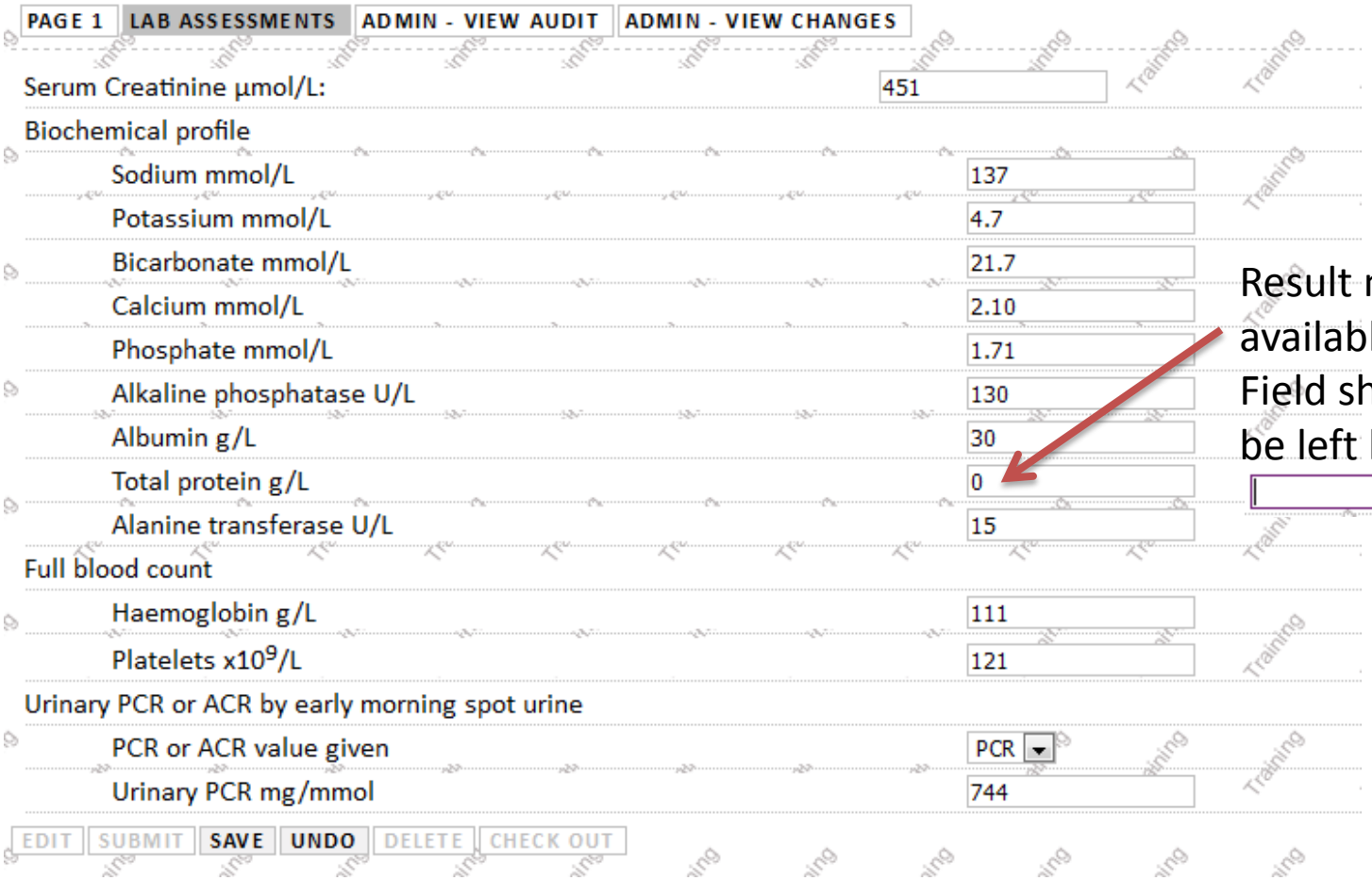
- Weight
- C-reactive Protein (CRP)
- Sample Tracking
- Six-Minute Walk Test
- 12-Lead ECG
- KDQOL-SF questionnaires

There have been a number of six-minute walk tests and questionnaires missed at the month 12 annual follow-ups. This data is important to the trial and should be obtained if possible.

Common issues with form completion

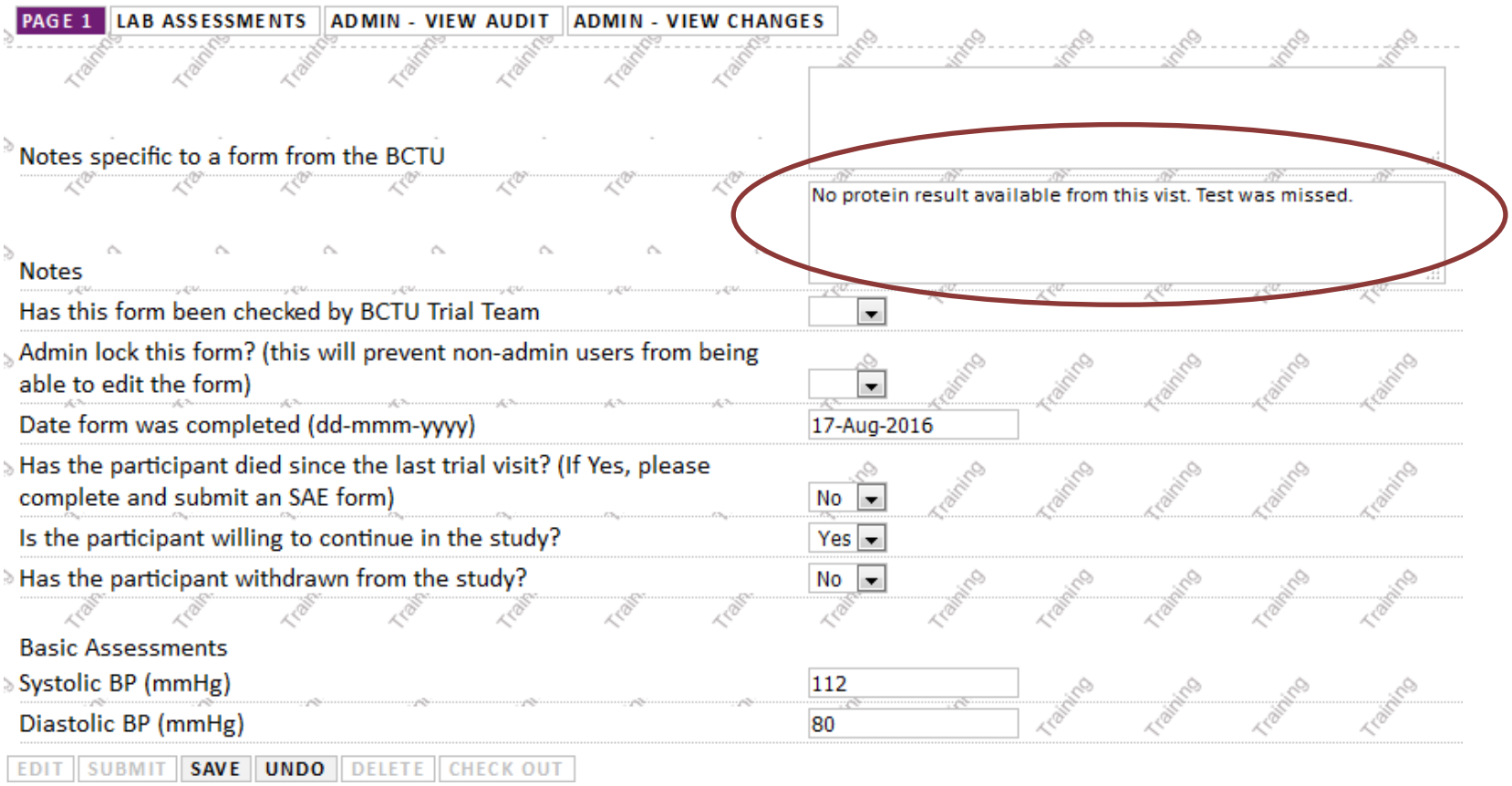
Lab Assessments

If a result is missing please leave the field blank.



Common issues with form completion

Add notes to minimise queries. Note boxes can be found on each part of the eCRF.



Common issues with form completion

Add notes to minimise queries. Note boxes can be found on each part of the eCRF.

Use notes to tell us that a medication has stopped or a dose has been changed:

Notes

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

A lab result is from a different date to the assessment:

Notes

Urinary PCR result from 2 weeks prior to trial visit (22-May-2016)

You're not sure of something:

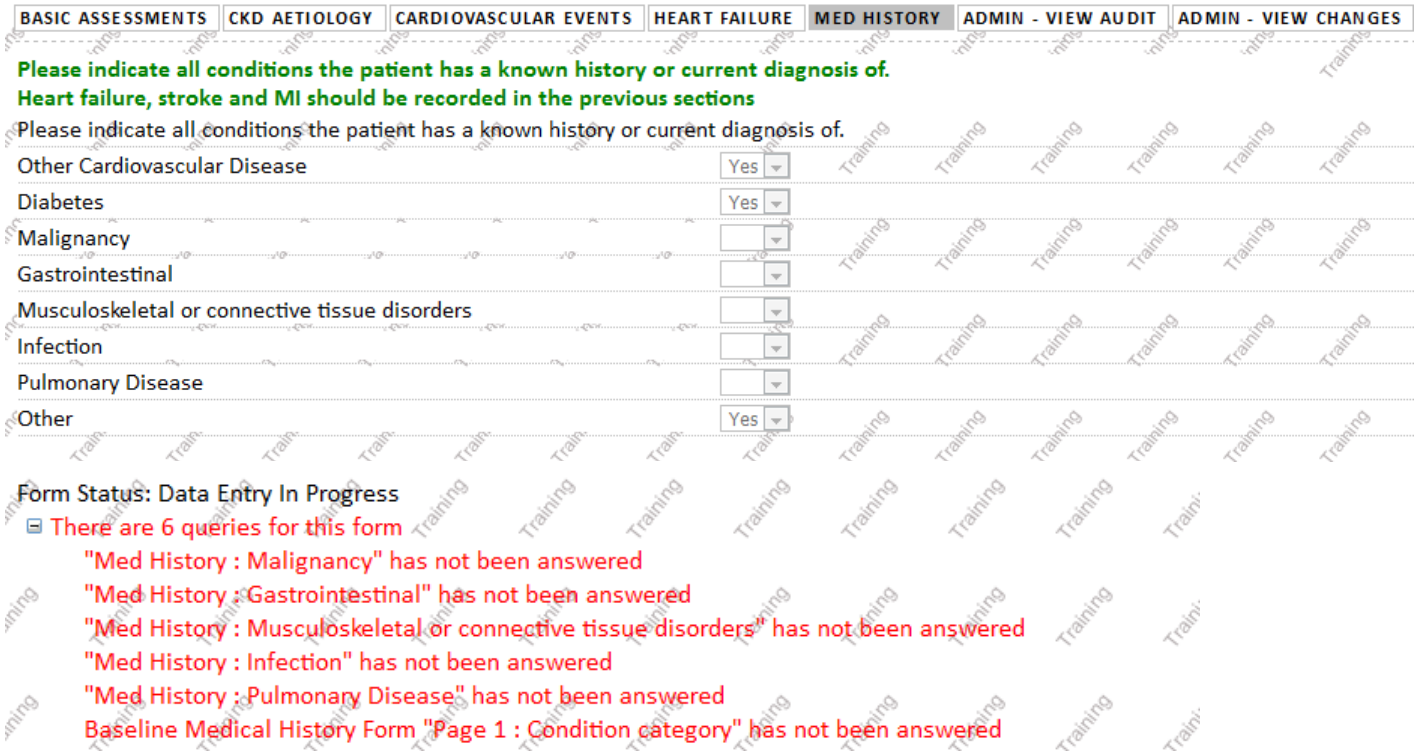
Notes

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

Notes are really helpful to me and help to minimise queries.

Common issues with form completion

Please complete all drop down boxes.



The system will query missing data.

Common issues with form completion

A lot of queries are around medications with no corresponding medical condition. Please ensure that the patient's full medical history is present at baseline and new conditions are added as the trial progresses.

Common issues with form completion

PAGE 1 | MEDICATION | ANTIHYP 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
Bisphoshonate	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

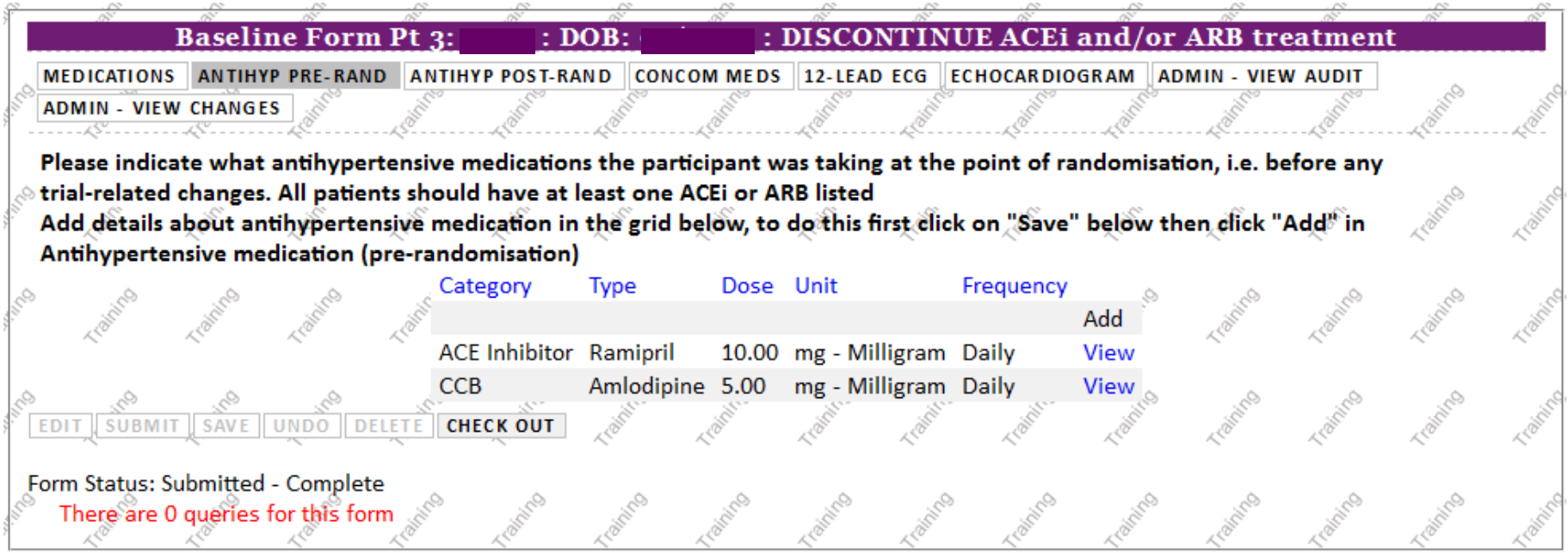
Gout

Common issues with form completion

Antihypertensive Medications at Baseline

If the patient has been randomised to discontinue ACEi/ARB the pre-randomisation and post-randomisation tabs should be completed as follows:

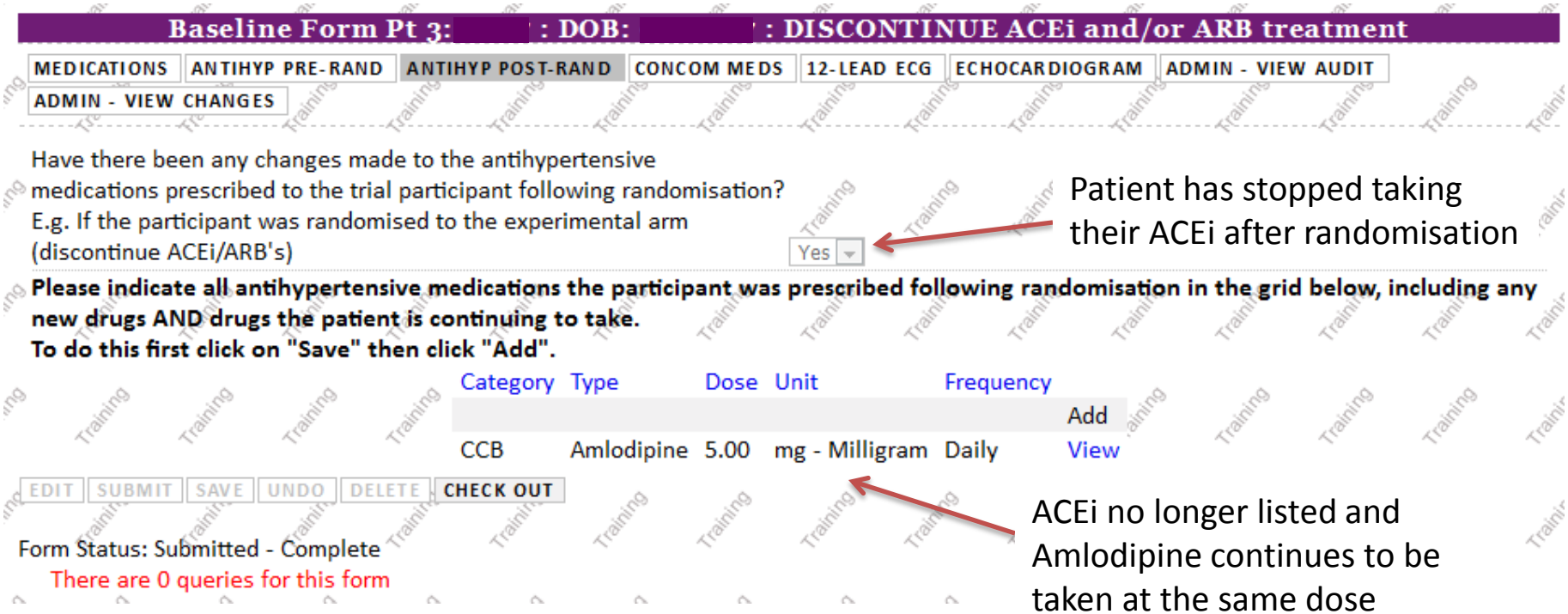
Pre-randomisation:



Common issues with form completion

Antihypertensive Medications at Baseline

Post-randomisation:



Patient has stopped taking their ACEi after randomisation

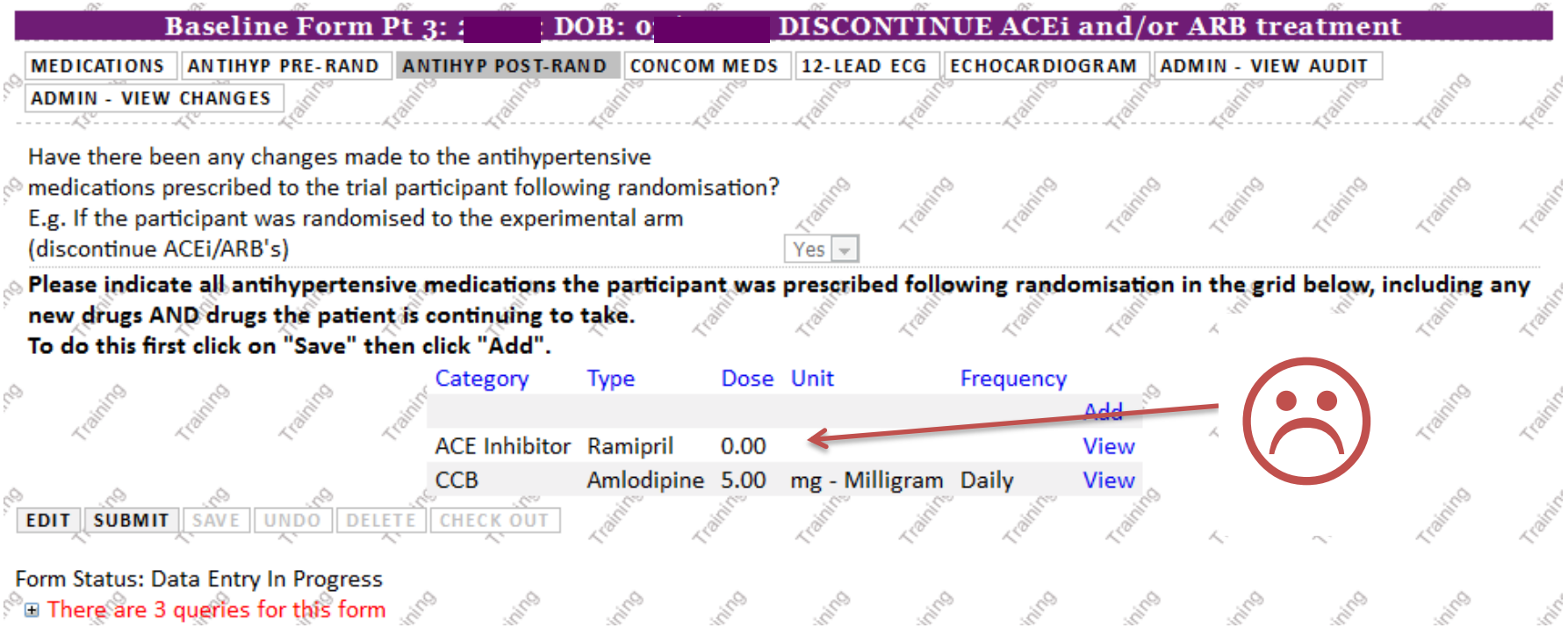
ACEi no longer listed and Amlodipine continues to be taken at the same dose

Common issues with form completion

Antihypertensive Medications at Baseline

Please **do not** enter a medication that has been stopped with a '0' dose

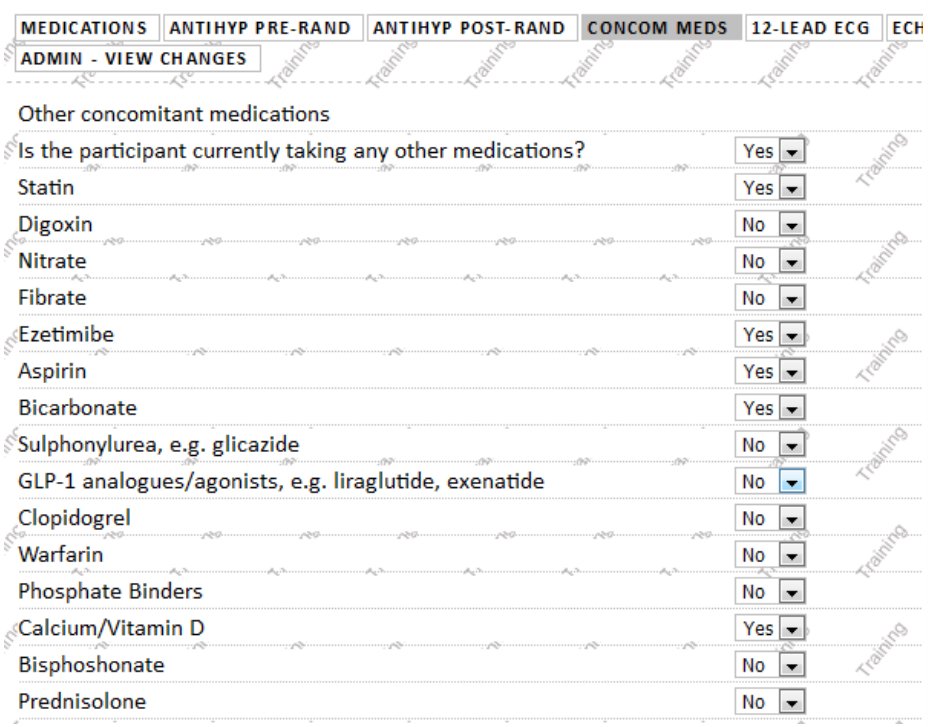
Post-randomisation:

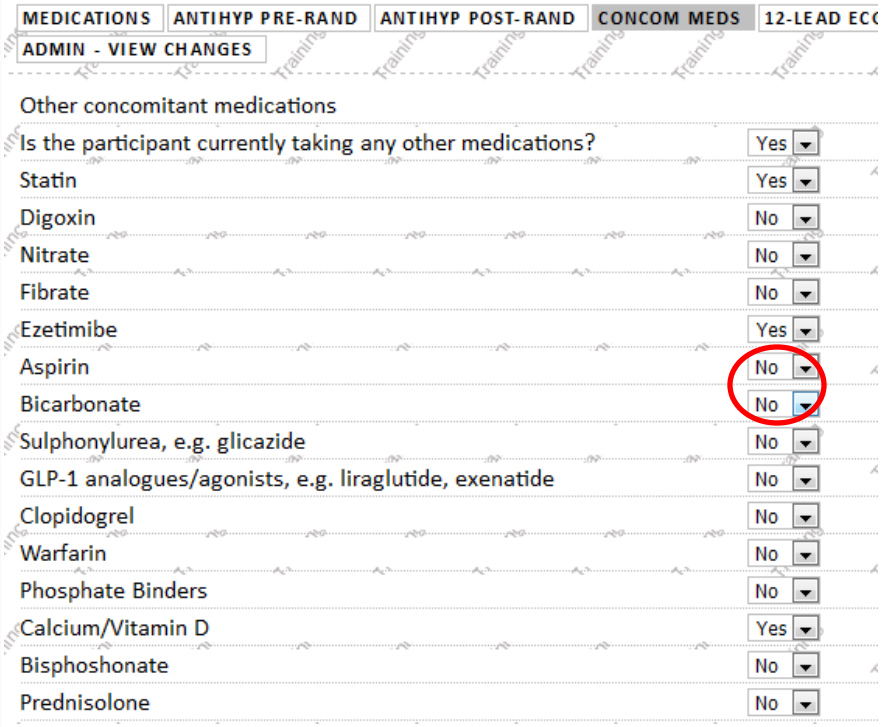


Common issues with form completion

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).

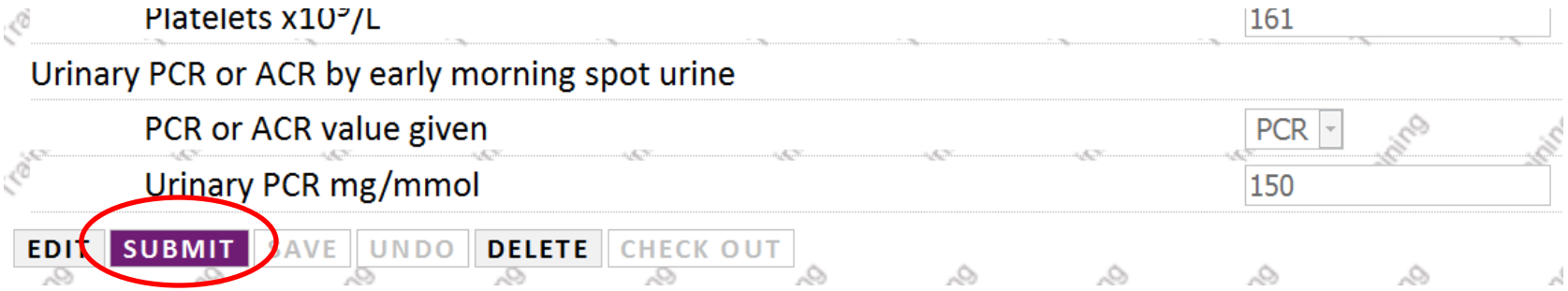




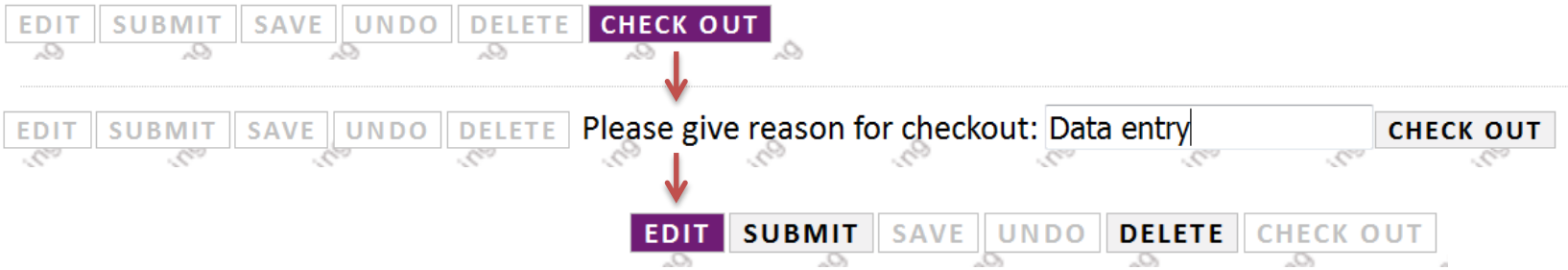
Common issues with form completion

Please remember to submit eCRFs when completed

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



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



STOP-ACEi website

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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 (BCTU)
- **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

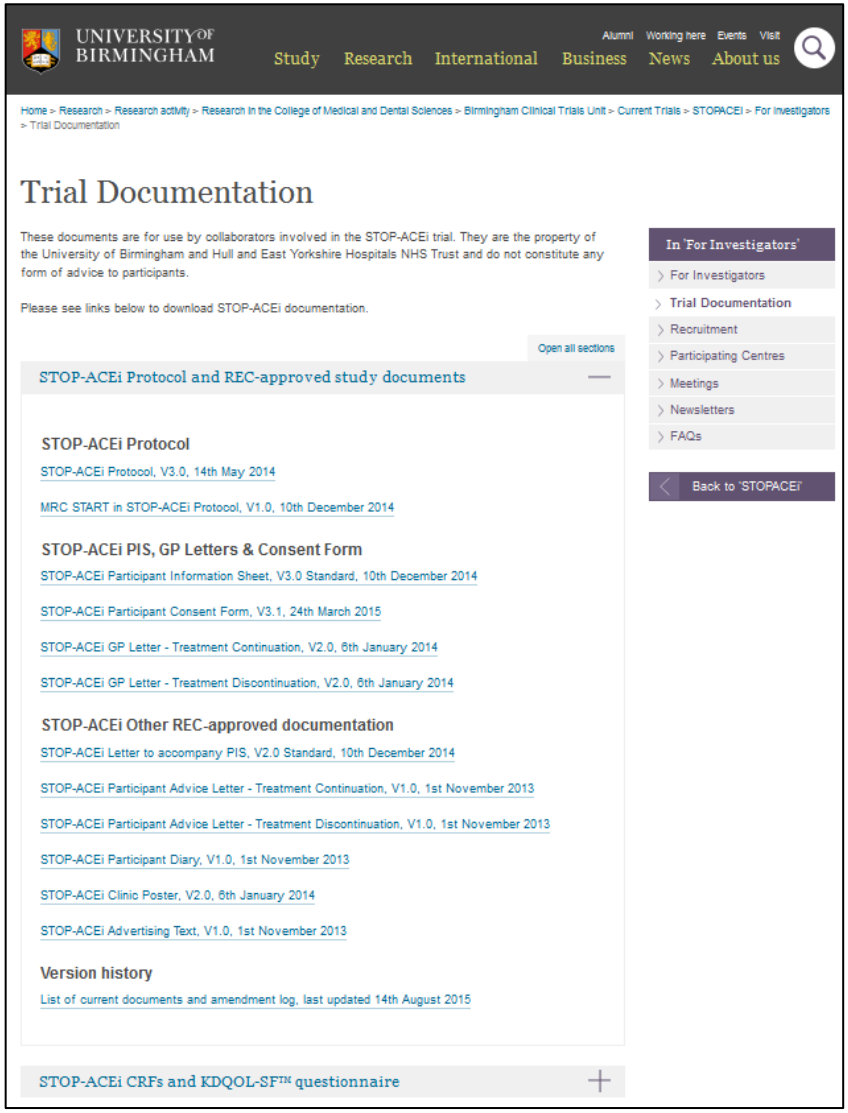
Short Title: The STOP-ACEi Trial

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).

Study 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 website



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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

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 2015

STOP-ACEi CRFs and KDQOL-SF™ questionnaire

In 'For Investigators'

- For Investigators
- Trial Documentation
- Recruitment
- Participating Centres
- Meetings
- Newsletters
- FAQs

Back to 'STOPACEI'

STOP-ACEi website

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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 18 August 2016

STOP-ACEi is open to recruitment. We aim to recruit 410 patients over a period of 2 years from approximately 20 centres across the UK.

Overview

Date first participant randomised	11 Jul 2014
Total recruitment to date	230
Total number of centres with full approval	33

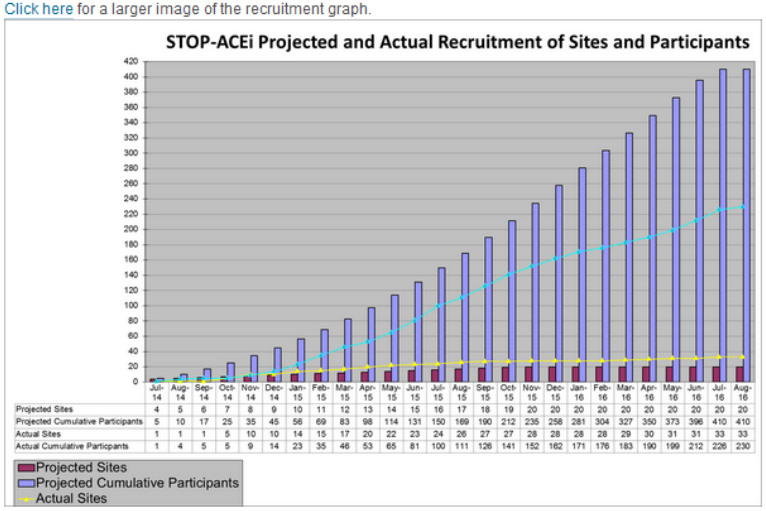
In 'For Investigators'

- For Investigators
- Trial Documentation
- Recruitment
- Participating Centres
- Meetings
- Newsletters
- FAQs

Back to 'STOPACEi'

STOP-ACEi Patient Recruitment

Click here for a larger image of the recruitment graph.



STOP-ACEi Twitter

Join over 100 other Twitter users and Follow us @STOPACEi_trial

STOP-ACEi Twitter

@STOPACEi_trial

STOP-ACEi Trial @STOPACEi_trial · Jun 14

We are now half way there with patient recruitment for #STOPACEi! Well done to the team @SheffieldHosp for recruiting the 205th patient.

1 6

STOP-ACEi Trial @STOPACEi_trial · Mar 16

#STOPACEi trial reaches the landmark of 180 patients! Thank you to all the patients and research teams.

2

Remember to register for one of the #STOPACEi investigator meetings - 1st & 2nd Sep 2016: birmingham.ac.uk/STOPACEi/meeti… @UKRenalResearch

RETWEETS 3 LIKES 3

Contact details

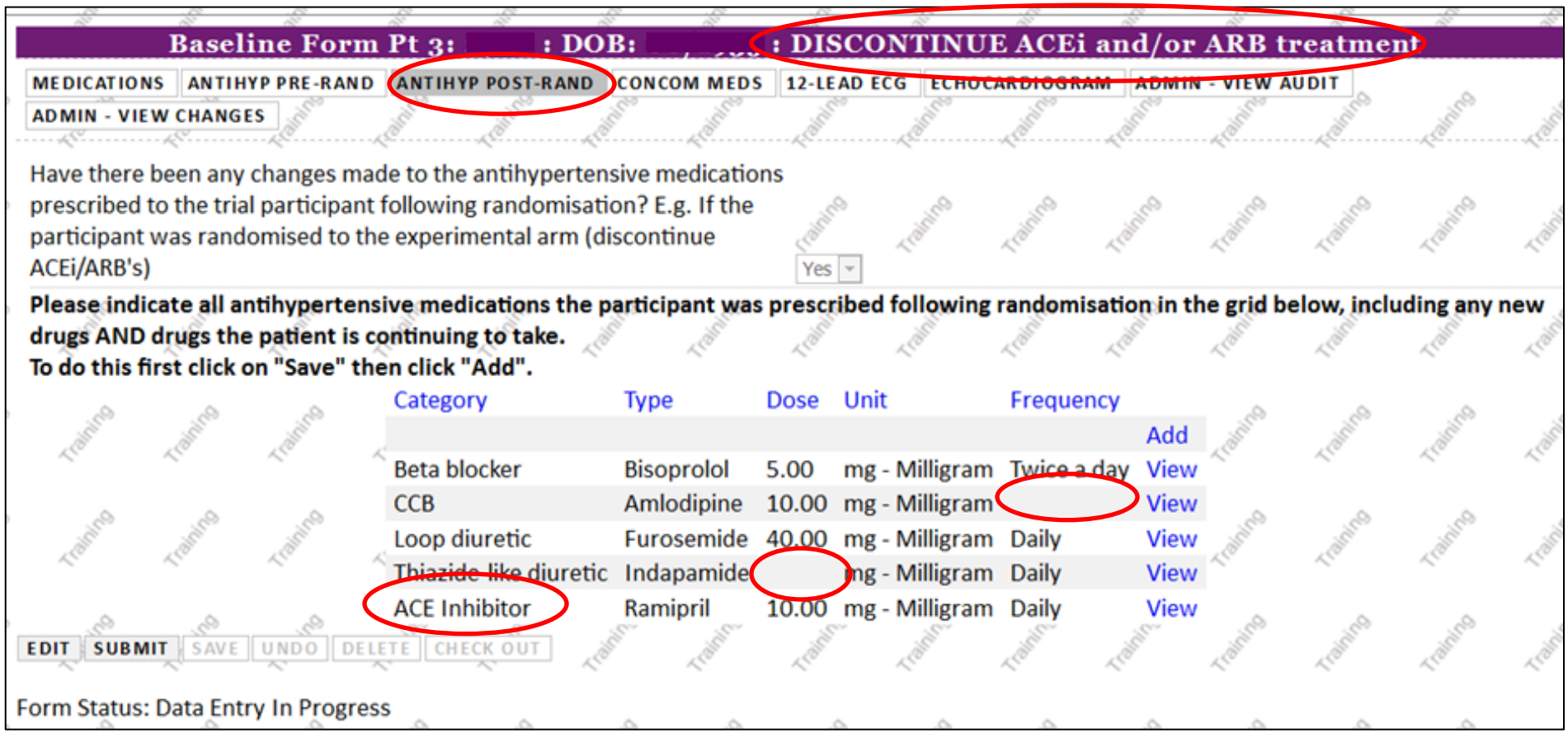
Trial website:	www.birmingham.ac.uk/STOPACEi
Online randomisation & data entry:	www.trials.bham.ac.uk/STOPACEi
E-mail:	STOPACEi@bham.ac.uk STOP.ACE@nhs.net
Telephone:	0121 415 9133
Fax:	0121 415 9135
Post:	Birmingham Clinical Trials Unit Public Health Building University of Birmingham Edgbaston B15 2TT
STOP-ACEi staff:	Marie Valente, Trial Coordinator Jamie Godsall, Data Manager

Data Manager Training – Spot the difference

Is the participant currently on ESA treatment?	Yes
Epoetin alfa (e.g. eprex)	No
Epoetin beta (NeoRecormon®)	No
Darbepoetin alfa (Aranesp®)	Yes
Darbepoetin alfa: Dose	60.00
Darbepoetin alfa: Unit	mcg - Microgram
Darbepoetin alfa: Frequency	Twice a day
Darbepoetin alfa: Route	Subcutaneous
Mircera	No
Other	No

Is the participant currently on ESA treatment?	Yes
Epoetin alfa (e.g. eprex)	No
Epoetin beta (NeoRecormon®)	No
Darbepoetin alfa (Aranesp®)	Yes
Darbepoetin alfa: Dose	600.00
Darbepoetin alfa: Unit	mg - Milligram
Darbepoetin alfa: Frequency	Twice a day
Darbepoetin alfa: Route	Subcutaneous
Mircera	No
Other	

Data Manager Training – Find the queries



Baseline Form Pt 3: : DOB: : DISCONTINUE ACEi and/or ARB treatment

MEDICATIONS | ANTIHYP PRE-RAND | ANTIHYP POST-RAND | CONCOM MEDS | 12-LEAD ECG | ECHOCARDIOGRAM | ADMIN - VIEW AUDIT | ADMIN - VIEW CHANGES

Have there been any changes made to the antihypertensive medications prescribed to the trial participant following randomisation? E.g. If the participant was randomised to the experimental arm (discontinue ACEi/ARB's) Yes

Please indicate all antihypertensive medications the participant was prescribed following randomisation in the grid below, including any new drugs AND drugs the patient is continuing to take.
To do this first click on "Save" then click "Add".

Category	Type	Dose	Unit	Frequency	
					Add
Beta blocker	Bisoprolol	5.00	mg - Milligram	Twice a day	View
CCB	Amlodipine	10.00	mg - Milligram		View
Loop diuretic	Furosemide	40.00	mg - Milligram	Daily	View
Thiazide-like diuretic	Indapamide		mg - Milligram	Daily	View
ACE Inhibitor	Ramipril	10.00	mg - Milligram	Daily	View

EDIT | SUBMIT | SAVE | UNDO | DELETE | CHECK OUT

Form Status: Data Entry In Progress

Data Manager Training – Find the queries

BASIC ASSESSMENTS | LAB ASSESSMENTS | SAMPLE TRACKING | WALK TEST | ADMIN - VIEW AUDIT | ADMIN - VIEW CHANGES

Notes	No protein result for this patient. Test not done.
Admin lock this form? (this will prevent non-admin users from being able to edit the form)	Yes
Date form was received (dd-mmm-yyyy)	04-Dec-2014
Date form was completed (dd-mmm-yyyy)	24-Nov-2014
Smoking status:	Ex-Smoker
Alcohol intake:	None
Height (in cm)	165.0
Weight (in kg)	82.80
Systolic BP (mmHg)	144
Diastolic BP (mmHg)	89

Data Manager Training – Find the queries

BASIC ASSESSMENTS | LAB ASSESSMENTS | SAMPLE TRACKING | WALK TEST | ADMIN - VIEW AUDIT | ADMIN - VIEW CHANGES

Serum Creatinine µmol/L:	663
Biochemical profile	
Sodium mmol/L	136
Potassium mmol/L	
Bicarbonate mmol/L	19.6
Calcium mmol/L	2.22
Phosphate mmol/L	1.59
Alkaline phosphatase U/L	66
Albumin g/L	36
Total protein g/L	0
Alanine transferase U/L	15

Before you leave

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