UNIVERSITY OF BIRMINGHAM | BCTU Birmingham Clinical Trials Unit

ECUSTEC Trial:

Patient Enrolment and SAE Reporting

Emma Barsoum

Senior Trial Coordinator

ECUSTEC Patient Recruitment

District general hospital (may or not be a PIC)

- STEC HUS is suspected (all inclusion criteria do not need to be met)
- Clinical stabilisation
- Contact the regional paediatric nephrologist on-call at the renal unit

Renal unit

- If diagnosis highly likely to be STEC HUS, will accept the referral and arrange transfer
- If child does not require transfer for clinical purposes, the paediatric nephrologist will explain that transfer will be accepted earlier than usual so that participation in the trial can be offered

Summary Sheet

Information regarding ECUSTEC will be offered pre-transfer if the referring hospital is a PIC

ECUSTEC Screening Patients

- Potential patients undergo eligibility assessment at recruiting centre
- Please note any potential patients onto the ECUSTEC Pre-screening Log
  - Ineligible patients should be noted and the reason why
- Any parents/patients given an ECUSTEC PIS or otherwise approached for potential participation in the trial should be recorded on the ECUSTEC Participant Approach Log
- Screening information will be requested quarterly by the ECUSTEC Trials Team

ECUSTEC Randomisation

- BCTU will provide a secure online randomisation system (https:www.trials.bham.ac.uk/ECUSTEC)
- BCTU will provide usernames and passwords for the online system
- Online randomisation available 24 hours a day, 7 days a week
- Telephone randomisation service available (0800 953 0274) available Monday to Friday from 9am-5pm
- Complete the ECUSTEC Randomisation Notepad prior to randomisation
- The Randomisation Notepad must **be signed by the investigator** to indicate all of the eligibility criteria have been checked
  - Original to be kept in the Site File
  - Copy to be sent to Trials Office

ECUSTEC Approaching Families Tips

- If possible, provide families the PIS to read overnight to allow more time to consider the trial information
- Allow enough time for the families to ask questions

- It works best when the clinician who is has been responsible for the patient's clinical care to approach the family to initiate discussion about the trial
- Point out that they will receive a patient safety card to carry with them at all times containing signs and symptoms of meningococcal disease
- Inform families that eculizumab is currently licenced for a similar disease, atypical HUS

ECUSTEC SAE Reporting

- SAE forms are provided in the Site File and on the ECUSTEC website

- Please complete as soon as you are aware of the SAE
  - Fax/email to the BCTU Trials Team: 0121 415 9135 or ecustec@trials.bham.ac.uk
  - Within 24 hours of research staff becoming aware of the event

- The Trials Team will report all SAEs to the CI and Sponsor

- Current RSI is eculizumab SmPC 28th June 2016 which can be found in the Site File

ECUSTEC Delegation Log

- New staff added to the delegation log:
  - Send recently signed CV, GCP certificate and delegation log to the Trials Team (ecustec@trials.bham.ac.uk)
  - Check all appropriate duties have been circled before forwarding to the Trials Team

- Ward Staff Authorisation and Training Logs can be updated and kept locally in the Site File – Trials Team do not require copies

- Ensure each role on the delegation log is covered by as many members of the research team as possible, as soon as possible

ECUSTEC Delegation Log Completion

This table should include the sub-investigator(s), research nurse(s), trial coordinator(s), data manager(s) and all other clinical staff who routinely see trial subjects or who have specific data collection/interpretation duties. This table should also include any contracted specialists performing protocol-required examinations. Add new or replacement staff as appropriate.

Name of Delegate (please PRINT)	**Trial Role** (e.g. Clinician, Research Nurse, Data Manager)	**Tasks Delegated by PI** (see legend)	**Initials of Delegate**	**Signature of Delegate[2] Date of Delegate Signature** (dd-mon-yyyy)	**Status** E = Employed H = Honorary	**Date of Duties**		
						From (dd-mon-yyyy)	**To** (dd-mon-yyyy)	**Initials of PI and Date** (dd-mon-yyyy)
		A B C D E F G H I J K L M N O P Q R S T U V W X Y Z α						
		A B C D E F G H I J K L M N O P Q R S T U V W X Y Z α						
		A B C D E F G H I J K L						

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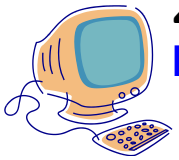
ECUSTEC Trial: Trial Procedures and Case Report Forms

Terry Hughes

ECUSTEC Data Manager

ECUSTEC
Randomisation Procedure



24/7 days
https://www.trials.bham.ac.uk/ECUSTEC

Randomise

Confirmation e-mail

Collect information on randomisation notepad

9am – 5pm, Mon-Fri
0800 953 0274

After randomisation

Remember to send a copy of the following forms to the ECUSTEC study office:

- **Randomisation Notepad**
- **Consent Form**
- **Baseline CRF form**
- **Baseline Quality Of life Questionnaires**

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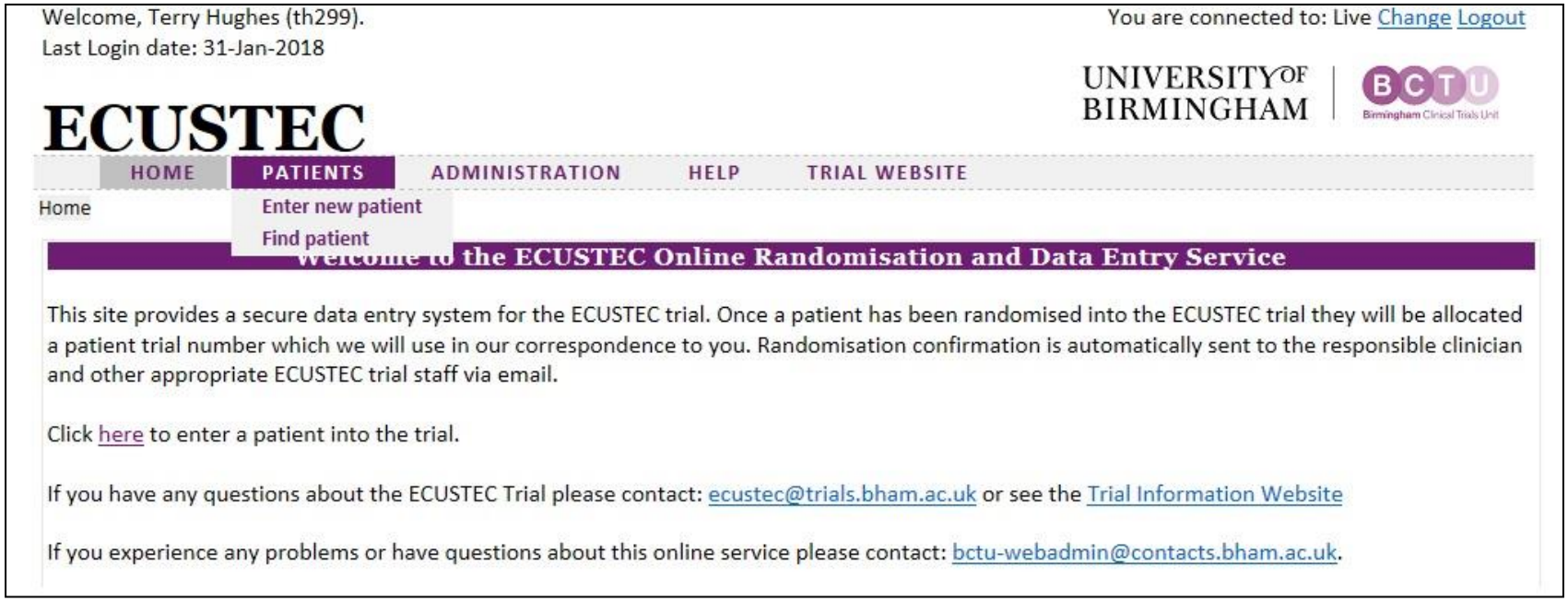
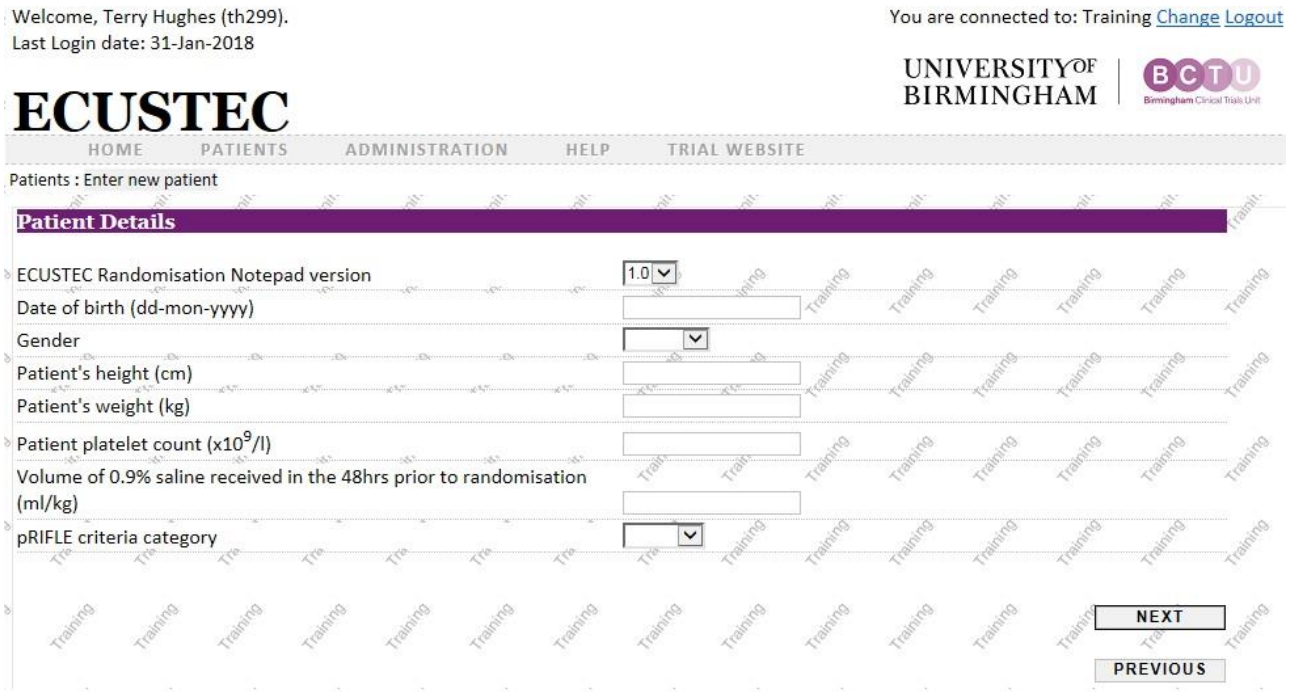
ECUSTEC Randomisation Procedure



- Ensure PI has signed off eligibility on the Randomisation Form.
- If randomising online, once logged in select the ‘Patients’ tab and go to ‘Enter new patient’.

ECUSTEC Randomisation Procedure



- If any questions are missed, an error message will appear and you will be unable to proceed forward

ECUSTEC Randomisation Procedure

- If any questions are answered in a way that makes the patient ineligible, you will be unable to proceed with the randomisation

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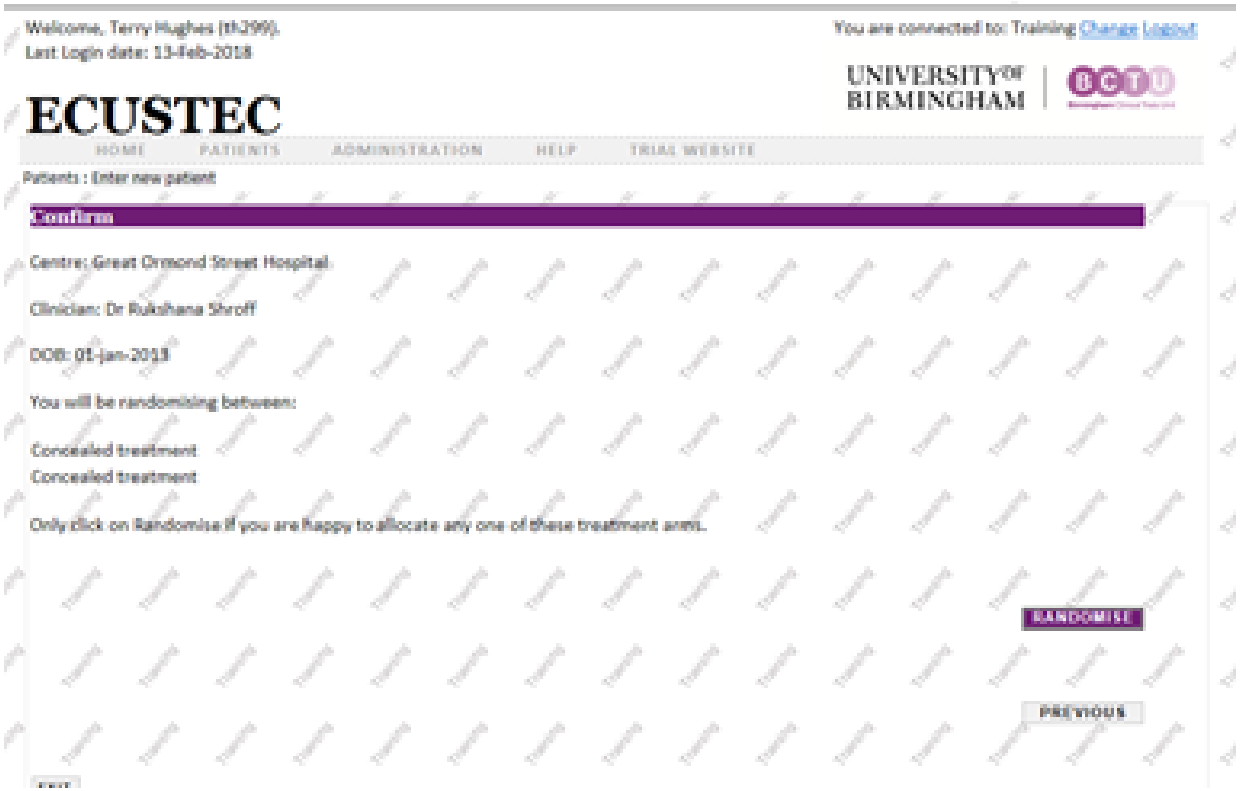
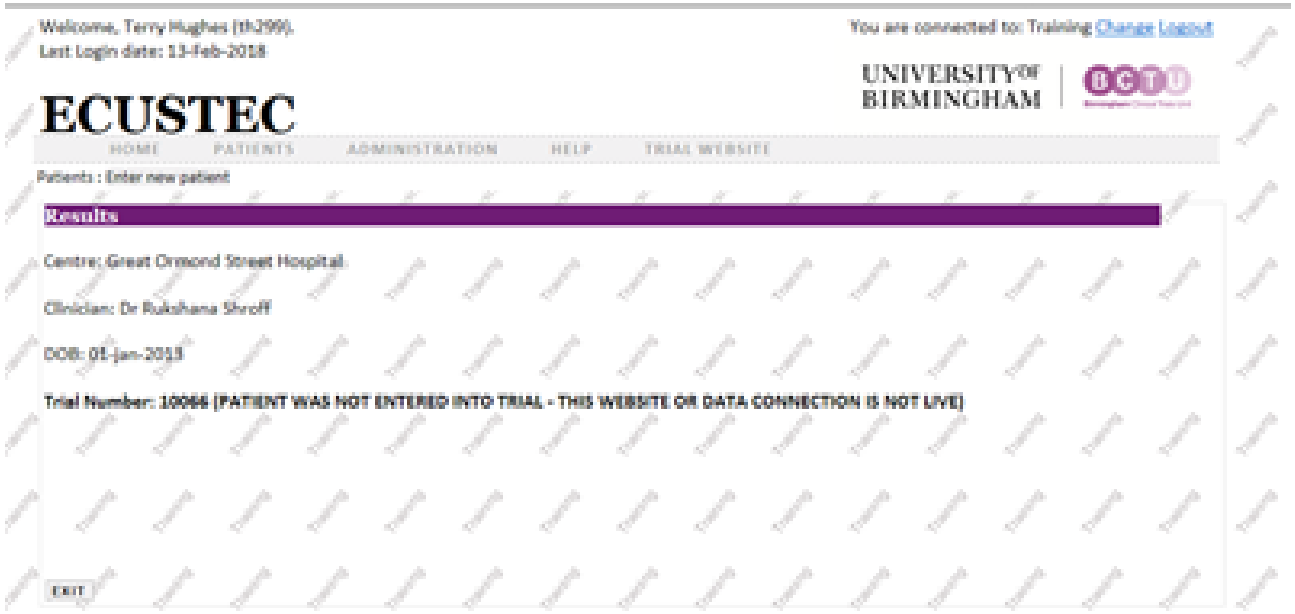
ECUSTEC Randomisation Procedure



- Once you click ‘Randomise’ you cannot amend any information entered

ECUSTEC Randomisation Procedure



- Once randomised, this final page gives the patient's trial number, the allocation is not given as everyone except the pharmacy teams are blinded to the allocation.

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Following Randomisation

- Following randomisation, a confirmation email will be sent to the recruiting consultant and research nurse.
- Pharmacy will receive a confirmation email confirming the patients treatment allocation.
- On the Randomisation Form add the study number, the participant's study number should be added to the completed Parent/ Participant Consent Form, prior to sending the documents to the Trials team at BCTU
- Trial Team will send out additional trial supplies to site
- All participants will be followed-up for 52 weeks. Daily until discharge (reducing to weekly after day 14 if still admitted), then at 30 and 60 days and then 6 and 12 months post randomisation.

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Assessments and Case Report Forms

- Forms are provided in the Site File and on the ECUSTEC website

- Questionnaires are only available from the ECUSTEC Trials Team at BCTU as they are copyrighted
  - CHU-9D has two age related forms
    (under 5 years old) and (5 years and over)
  - PedsQL has six age related forms
    (1-12 Month), (13-24 month), (2-4 years), (5-7 years), (8-12 years) and (13-18 years)
  - ABAS (under 5years) and (over 5 years)
    (These are for 60 day CNS assessment only)

- Copies of the CRFs are required to be sent to the ECUSTEC Trial Office by either fax/email or posted. So the data can be checked and entered onto the ECUSTEC online database.

ECUSTEC

Assessments and Case Report Forms

Forms requires at BCTU for each assessment are:

Baseline Assessment

- Baseline form (V1.0)
- CHU-9D
- PedsQL

- Baseline assessment is due on the same day as consent and randomisation

ECUSTEC

Assessments and Case Report Forms

Day 1

- Day 1 Treatment Forms (V1.0),
- Day 1 Certificate of Vaccination

Day 8

- Day 8 Treatment Forms (V1.0),
- Day 8 Certificate of Vaccination
- CHU-9D
- PedsQL

- Remember Certificates of Vaccination must be sent to pharmacy with the prescription form before treatment allocation is dispensed.

- Day 1 and Pre-Discharge Certificate of Vaccinations are forwarded to both BCTU and Alexion

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Assessments and Case Report Forms

At Discharge

- Initial Admission for Trial Treatment Form (V1.0) is completed when the patient is discharged.
- Discharge Certificates of Vaccination

Day 30

- Day 30 & 60 Follow Up Form (V1.0),
- Stool Sample Result Form (V1.0)
- CHU-9D
- PedsQL
- If there are primary care visits, etc. to record there is an additional form called ECUSTEC Healthcare Contacts Form (V1.0).

Day 30 are due within +/- 1 weeks of the due date

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Assessments and Case Report Forms

Day 60

- Day 30 & 60 Follow Up Form(V1.0),
- CHU-9D
- PedsQL
- If there are primary care visits, etc. to record there is an additional form called ECUSTEC Healthcare Contacts form(V1.0).

- Day 60 are due within -3/+7 days of the due date

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Assessments and Case Report Forms

Week 26 & 52

- Week 26 & 52 Follow Up Form(V1.0),
- CHU-9D
- PedsQL
- If there are primary care visits, etc. to record there is an additional form called ECUSTEC Healthcare Contacts form(V1.0).

- Week 26 and Week 52 are due within +/- 1 weeks of the due date

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Assessments and Case Report Forms

Tips

- If a question has Yes/No boxes please mark all the fields and not just the one which should be answered ‘Yes’.
  This will reduce the amount of DCF form sent to site for clarification

- Before sending any CRF to BCTU please check all the trial information box has been added

- Hand writing on CRF forms

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Data Clarification Form (DCF)

- Data Clarification Forms (DCF) is how the ECUSTEC trial processes discrepancies on any CRF.
- A single DCF per CRF
- CRFs do not need updating
- Critical Data Query Items which need confirming will be chased until resolved.
- Non Critical Data Items which need confirming will only be chased twice.
- Ensure DCF form is signed by PI so they have confirmed the corrections.

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Data Clarification Form (DCF)

Outstanding Critical Data Queries by Patient

Centre: Bristol Royal Hospital for Children

Site Principal Investigator Sign-off

I understand that the information provided within the following Data Clarifications Report (consisting of **3 Pages** and generated on **7-Mar-18** is true and correct to my knowledge and that the report has been completed by a member of my research team duly delegated on the Site delegation Log within the ECUSEC ISF.

Site Principal Investigator Comments (e.g. concerning completeness of report):

Principal Investigator:_____ Date:_____ Sign:_____

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Data Clarification Form (DCF)

Outstanding Critical Data Queries by Site

Centre Name	Bristol Royal Hospital for Children			Raised By	Terry Hughes
Query Number	250	Query Raised	7-Mar-18		
Participant Number	10033	CRF	Baseline		
	Part		Time point	BL	

Details of query

ECUSTEC Baseline Form

1. **Part A: Recent Medical History**
   "Eligible on arrival at the renal unit?" has not been answered but marked "Unknown", as "If no, state date and time eligibility confirmed" as been answered
   Please confirm you are happy to answer "Eligible on arrival at the renal unit?" as "No"
2. **Part G: Quality of Life Questionnaires**
   Have the standardised, parent/patient completed, questionnaires been completed at Baseline? CHU-9d and PedsQL has not been answered
   As we have received these questionnaires
   Please confirm these can be answered "Yes"
3. **Part H: Samples** (Please indicate which baseline samples have been collected and complete the samples log in the site file)
   "Not Optional Blood EDTA— genetics" has not been answered? But you have a note stating 4ml take next week.
   Please can you confirm if this was taken and sent off with the window up to day 8?
4. **Part H: Samples** (Please indicate which baseline samples have been collected and complete the samples log in the site file)
   Optional Blood (EDTA)
   Optional Blood (Lithium heparin)
   Optional Urine
   These samples were also not answered?
   Please confirm if they were taken or Not at Baseline?

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Data Clarification Form (DCF)

Response from site
1.
2.
3.
4.
5.
6.
7..

Completed by:_____Date:_____Sign:_____

ECUSTEC
Data Clarification Form (DCF)

1. Print the DCF.
2. Write the response to each query on the DCF itself. Please do not amend your original paper CRF.
3. Print your name, sign and date at the bottom of the DCF. Please note, in doing this you are confirming the data provided is correct, and are granting permission for the Renal Trials Team at BCTU to amend the online database accordingly
4. Ensure DCF top page is signed by PI so they have confirmed the corrections
5. Photocopy/scan the completed DCF.
6. Send a copy of the completed DCF to BCTU (ECUSTEC@bham.ac.uk) via email, fax or post (please see email signature for contact details).
7. Attach the original DCF to the back of the original paper CRF.

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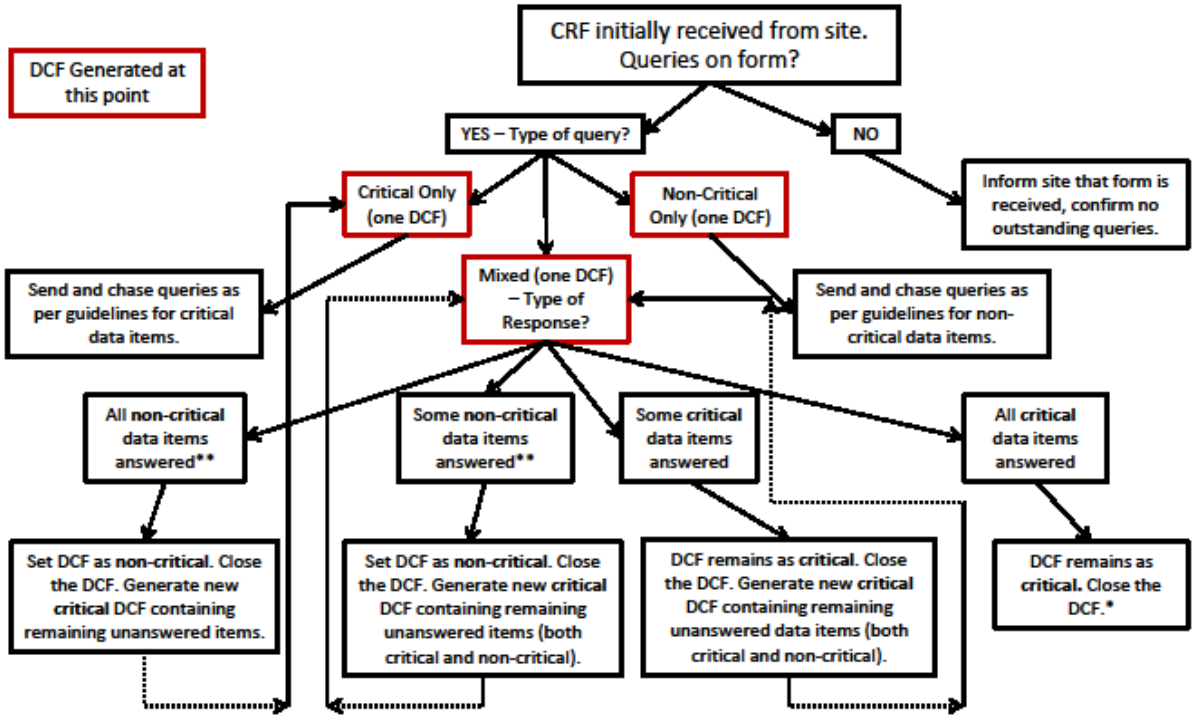
Data Clarification Form (DCF)



*If non-critical queries remain on the form and have not reached the specified chase limit, these should be sent again in a new DCF until either; the chase limit is reached, or they are answered.

ns answered.

ECUSTEC
CRF UPDATE

- CRF V2.0 in development process

- Main features include
  - Splitting the 30 and 60 day CRF to two separate forms
  - Removing duplicate questions on certain forms
  - Ensuring the CRFs incorporate the new V4.0 of the Protocol

ECUSTEC

Trial Team Information

General Trial Website: http://www.birmingham.ac.uk/ECUSTEC
Secure Trial Website for Randomisation:
https://www.trials.bham.ac.uk/ECUSTEC
Email: ECUSTEC@trials.bham.ac.uk
Tel: +44 (0)121 415 9130
Fax: +44 (0)121 415 9135
Postal Address: ECUSTEC Trial Office, Birmingham Clinical Trials Unit (BCTU), Institute of Applied Health Research, Public Health Building , College of Medical and Dental Sciences , University of Birmingham, Edgbaston, Birmingham, B15 2TT


Thank You!