

How to submit data and respond to queries online

Online data entry

You must complete a paper form (entry/outcome) before you enter any data online

- Online data entry allows you to enter your data directly to the trial database
- All data forms entered will be acknowledged by email
- If you wish to practise before attempting your first entry, please email crash.data@Lshtm.ac.uk for access to the practice database
- Automatic checks in the database will identify data errors / missing data
- Forms can be corrected **before** saving
- All of your data can be viewed by logging in
- Data queries can be viewed and answered online
- You should change your password and PIN as soon as you receive them

Password / PIN

- Online database is held on a secure server with encryption
- Log in – click on **Change password** on the welcome screen
- Change your password and PIN regularly



Home | Logout John Doe (ID 118)

Patients
Queries
Change password

Welcome to the Crash 3 trial

Tranexamic acid for the treatment of significant traumatic brain injury: an international randomised, double blind placebo controlled trial.

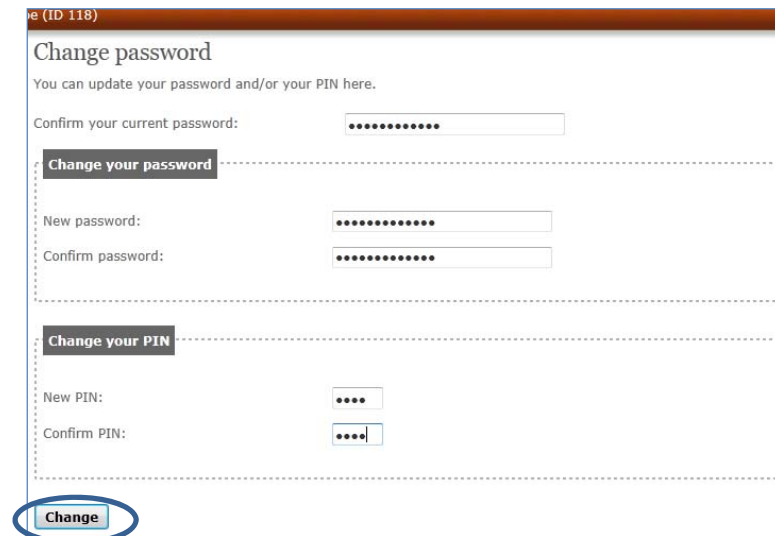
10 patients randomised to date.

Outcome forms overdue

CRASH
Clinical Randomisation of an Antifibrinolytic in Significant Head Injury

Keep your access details secure
– do not share with anyone

If you forget your password or PIN
email crash.data@lshtm.ac.uk



Change password

You can update your password and/or your PIN here.

Confirm your current password:

Change your password

New password:

Confirm password:

Change your PIN

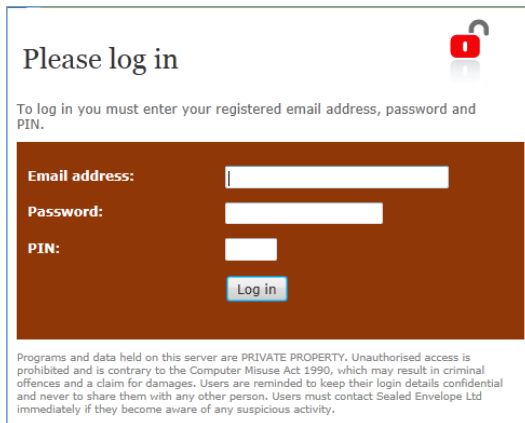
New PIN:

Confirm PIN:

Change

Security

- Each team member with delegated responsibility to enter data must have their own unique username, password and PIN – **DO NOT** share your details
- Only the PI may request database access for team members
- Data will be logged against the name of the person entering



Please log in

To log in you must enter your registered email address, password and PIN.

Email address:

Password:

PIN:

Programs and data held on this server are PRIVATE PROPERTY. Unauthorised access is prohibited and is contrary to the Computer Misuse Act 1990, which may result in criminal offences and a claim for damages. Users are reminded to keep their login details confidential and never to share them with any other person. Users must contact Sealed Envelope Ltd immediately if they become aware of any suspicious activity.



Entry Form

Code 3011-34 | Test Hospital Maria (Site #5), United Kingdom

Please ensure all information below is contained in the medical records.


[<< return to patient](#)

This form was created on 11 Jun 2012 10:55 by John Doe (ID 118)

The database will close down if inactive for 15–20 minutes – you will lose any unsaved forms and will need to log in again

Entering data online

- Go to ctu4.Lshtm.ac.uk/crash3
- Enter the log-in details sent to you by the TCC
- With the links on the left of the Welcome screen you can:
 - add and view randomised patients
 - answer queries
 - change password



Please log in

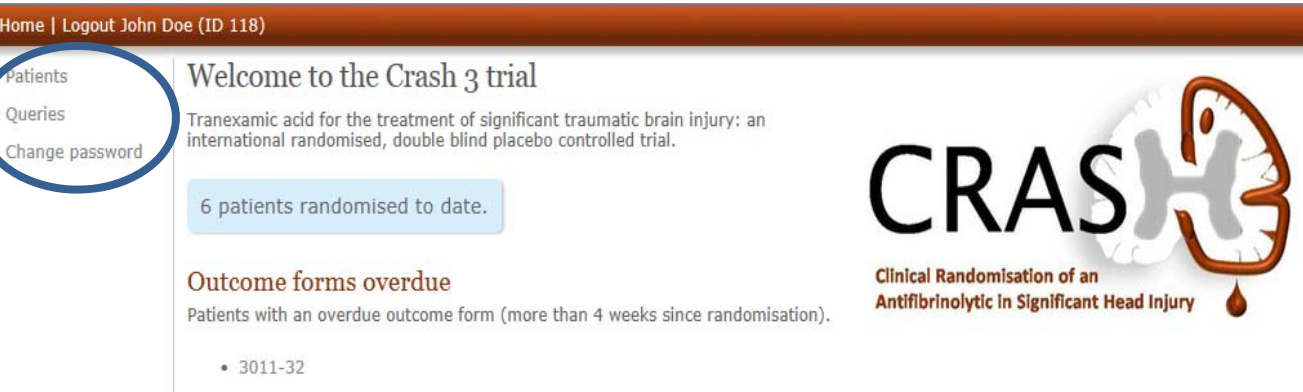
To log in you must enter your registered email address, password and PIN.

Email address: john.doe@blurb.ac.uk

Password:

PIN:

Log in



Home | Logout John Doe (ID 118)

Patients

Queries

Change password

Welcome to the Crash 3 trial

Tranexamic acid for the treatment of significant traumatic brain injury: an international randomised, double blind placebo controlled trial.

6 patients randomised to date.

Outcome forms overdue

Patients with an overdue outcome form (more than 4 weeks since randomisation).

- 3011-32

CRASH
Clinical Randomisation of an
Antifibrinolytic in Significant Head Injury

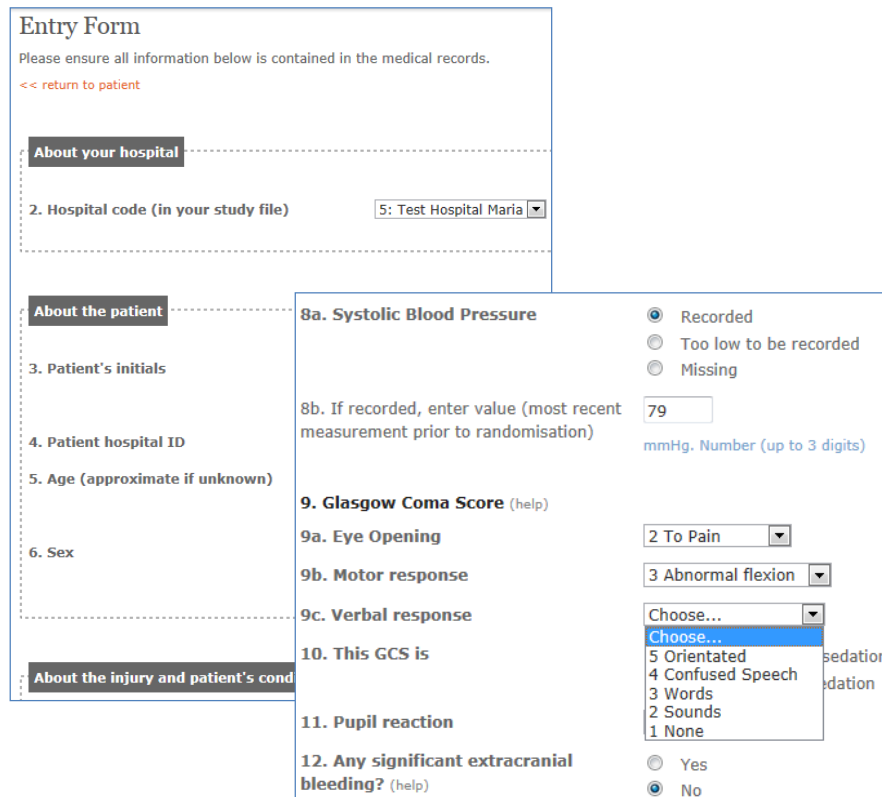
Online entry form

Click on **Patients** on the Welcome screen left hand menu to reveal a new link **+ Patient**

- blank entry form opens
- complete all fields
- click **Save form**



Number	Box	Pack	Site	Country
5	3011	31	Test Hospital Maria	United Kingdom
6	3011	32	Test Hospital Maria	United Kingdom



Entry Form
Please ensure all information below is contained in the medical records.
[<< return to patient](#)

About your hospital

2. Hospital code (in your study file)

About the patient

3. Patient's initials

4. Patient hospital ID

5. Age (approximate if unknown)

6. Sex

8a. Systolic Blood Pressure Recorded
 Too low to be recorded
 Missing

8b. If recorded, enter value (most recent measurement prior to randomisation)
mmHg. Number (up to 3 digits)

9. Glasgow Coma Score (help)

9a. Eye Opening

9b. Motor response

9c. Verbal response

10. This GCS is
sedation
dation

11. Pupil reaction


12. Any significant extracranial bleeding? (help) Yes
 No

Questions can be

- ❖ Yes or No
- ❖ Date and time
- ❖ Specific data (eg SBP)
- ❖ Choice of options from a drop-down list
- ❖ Automatic error checking will inform about out-of-range or incorrect data

Completing the entry form

- Missing/incorrect data will be flagged in red
- Please fill in or correct the data as required and **Save** again



9. Glasgow Coma Score (help)

9a. Eye Opening 3 To Sound

9b. Motor response 5 Localising

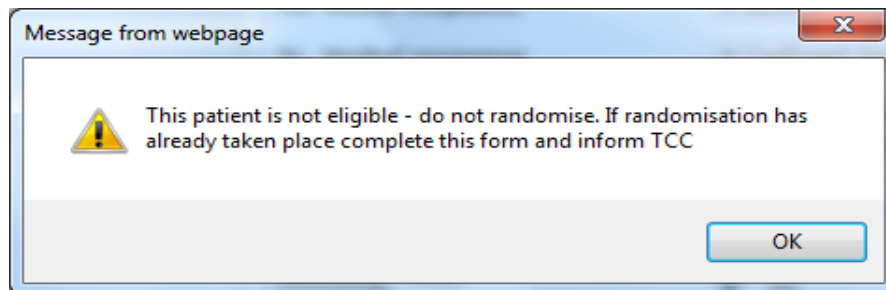
9c. Verbal response 4 Confused Speech

10. This GCS is

Before intubation/sedation
 After intubation/sedation

This field is required.

11. Pupil reaction One Reacts



If the alert message states the patient is not eligible **and you have already randomised the patient**, please **COMPLETE** the on-line form and inform TCC.

Correcting the entry form

- When all fields completed click on **Save** form
- Check data against the original paper form
- If errors found, do not click on Confirm save
- Click on the <-- **Back** button – form opens for editing

BEFORE CLICKING Confirm save – if you see an error eg time of randomisation should be 19:46, use the <-- **Back** button to open the form for editing.

Randomisation information	
15. Eligible?	Yes
15A. If no, reason why not eligible	-
16. Consent process used for entry used?	Waiver
17. Insert treatment pack number here	-
BOX	3011
PACK	33
18. Date of randomisation	10/01/2012
19. Time of randomisation	09:46
20. Name of person randomising	John Doe

Other	
Notes	-

Investigator's declaration	
By entering my PIN below, I declare that the information presented in this Case Record Form accurately reflects the medical records, including the results of tests and evaluations performed on the dates specified.*	
Name of person completing form	John Doe (ID 118)
Date	13 Feb 2012
PIN	<input type="text"/>
<input type="button" value="Confirm save"/>	

Saving the entry form

When form is complete and correct you will be prompted to sign the declaration

- scroll to bottom of form and enter your unique PIN
- click **Confirm save**
- data form will be entered directly into the trial database

oe (ID 118)

Entry Form

Please ensure all information below is contained in the medical records.

Review and sign

This form has not yet been saved. Please complete the declaration below to save the form.

About your hospital

2. Hospital code (in your study file) 5: Test Hospital Maria

About the patient

3. Patient's initials MN
4. Patient hospital ID 456320
5. Age (approximate if unknown) 34
6. Sex Male

Investigator's declaration

By entering my PIN below, I declare that the information presented in this Case Record Form accurately reflects the medical records, including the results of tests and evaluations performed on the dates specified.*

Name of person completing form John Doe (ID 118)
Date 11 Jun 2012
PIN

Confirm save

Logging out

e (ID 118)

Entry Form

Please ensure all information below is contained in the medical records.

[<< return to patient](#)

Code 3011-33 | Test Hospital Maria (Site #5), United Kingdom

This form was created on 13 Feb 2012 18:16 by John Doe (ID 118)

- The saved form is shown on screen
- Click on **<< return to patient** to exit the form
- To enter more forms click on **+ Patient**
- To exit, click on **Logout** – this closes the database

Home | [Logout John Doe \(ID 118\)](#)

Patients
Queries
Change password

Welcome to the Crash 3 trial

Tranexamic acid for the treatment of significant traumatic brain injury: an international randomised, double blind placebo controlled trial.

10 patients randomised to date.

Outcome forms overdue

Patients with an overdue outcome form (more than 4 weeks since randomisation).




Logged out

Thank you. You are now logged out. Click [here](#) to log in again.

Online outcome form

- Outcome form can be added as soon as the patient has been entered in the database
- Click on **Patients** to show a list of all the patients entered for your hospital



Home | Logout John Doe (ID 118)

Patients
Queries
Change password

Patients

+ Patient

Number	Box	Pack	Site	Country
5	3011	31	Test Hospital Maria	United Kingdom
6	3011	32	Test Hospital Maria	United Kingdom

Adding an outcome form

- Click on the Box/pack number where you want to add an outcome form
- Click **Add** an outcome form

The screenshot shows a web interface for patient management. On the left, a table lists patients with columns for Number, Box, Pack, Site, and Country. The row for patient 6 is highlighted in yellow, and the 'Box' cell (3011) is also highlighted. A tooltip 'View details' is visible over the 'Pack' cell (32). On the right, the 'Patient details' panel shows information for patient 6, including Box-pack (3011-32), Site (Test Hospital Maria), Source of data (Online), Patient initials (PL), and Gender (Male). At the bottom of the details panel, there are sections for 'Entry form' and 'Outcome form', each with 'Add', 'View', and 'Edit' links. The 'Add' link for the Outcome form is circled in blue. A search bar and a '+ Patient' button are at the top left of the interface.

Number	Box	Pack	Site	Country
5	3011	31	Test Hospital Maria	United Kingdom
6	3011	32	Test Hospital Maria	United Kingdom
7	3011	33	Test Hospital Maria	United Kingdom

Patient details

Number 6

Box-pack 3011-32

Site Test Hospital Maria (Site #5), United Kingdom

Source of data Online

Patient initials PL

Gender Male

Queries

CRFs

Entry form [Add](#) [View](#) [Edit](#)

Outcome form [Add](#) [View](#) [Edit](#)

[View log entries for this patient](#)

Completing the outcome form

3.4c. Pain/Discomfort

3.4d. Anxiety

3.4e. Agitation/Aggression

3.4f. Fatigue

4. Management

4a. Days in Intensive Care Unit
(if no ICU or not admitted to ICU, write '0' here)

4b. Type of neurosurgical operation

4bi. Haematoma evacuation Yes
 No

4bii. Other Yes
 No

4c. Blood loss during neurosurgical operation
Estimated volume, ml. Number (up to 4 digits)

5. Trial Treatment

5a. Loading dose given Yes
 No

5b. Maintenance dose given Yes
 No

➤ Complete the outcome form and press **Save form**

➤ You will be prompted for any missing or incorrect data

6f. Sepsis Yes
 No
This field is required.

6g. Seizure Yes
 No

6h. Gastro intestinal bleeding Yes
 No

Outcome Form Code 3011-34 | Test Hospital Maria (Site #5), United Kingdom

Complete at discharge from the randomising hospital, death in hospital or 28 days after injury, whichever occurs first

[<< return to patient](#)

Some errors occurred!

3.2ai. Date or date of discharge: '7 Jun 2012' is not between '13 Feb 2012' and '12 Mar 2012', inclusively

Questions can be

- ❖ Yes or No
- ❖ Date and time
- ❖ Specific data (eg days in ICU)
- ❖ Choice of options from a drop-down list
- ❖ Automatic error checking will inform about out-of-range or incorrect data

Correcting the outcome form

- When all fields completed click on **Save form**
- Review the data by checking against the original paper form
- If errors found, do not click on Confirm save
- Click on the **<-- Back** button – form opens for editing

Investigator's declaration

By entering my PIN below, I declare that the information presented in this Case Record Form accurately reflects the medical records, including the results of tests and evaluations performed on the dates specified.*

Name of person completing form	John Doe (ID 118)
Date	11 Jun 2012
PIN	••••

Saving the outcome form

When the form is complete and correct you will be prompted to sign the declaration:

- scroll to bottom of form and enter your unique PIN
- click **Confirm save**
- form will be entered directly into the trial database and further edits can only be done by TCC

Outcome Form (ID 118)

Code 3011-31 | Test Hospital Maria (Site #5), United Kingdom

Complete at discharge from the randomising hospital, death in hospital or 28 days after injury, whichever occurs first

Review and sign

This form has not yet been saved. Please complete the declaration below to save the form.

2. Patient

c) Patient's initials

Investigator's declaration

By entering my PIN below, I declare that the information presented in this Case Record Form accurately reflects the medical records, including the results of tests and evaluations performed on the dates specified.*

Name of person completing form John Doe (ID 118)

Date 11 Jun 2012

PIN

Confirm save

<-- Back

Logging out

- The saved form is shown on screen
- Click on **<< return to patient** to exit the form
- To exit, click on **Logout** – this closes the database

Home | Logout John Doe (ID 118)

Patients
Queries
Change password

Outcome Form

Code 3011-31 | Test Hospital Maria (Site #5), United Kingdom

Complete at discharge from the randomising hospital, death in hospital or 28 days after injury, whichever occurs first

[<< return to patient](#)

This form was created on 12 Jun 2012 14:21 by John Doe (ID 118)

2. Patient

c) Patient's initials

3.1 Death in hospital

3.1a. Date of death -
3.1b. Time of death -
3.1c. Primary cause of death -
3.1d. Describe here - ONLY ONE cause of death should be entered -

Home | Logout John Doe (ID 118)

Patients
Queries
Change password

Welcome to the Crash 3 trial

Tranexamic acid for the treatment of significant traumatic brain injury: an international randomised, double blind placebo controlled trial.

10 patients randomised to date.

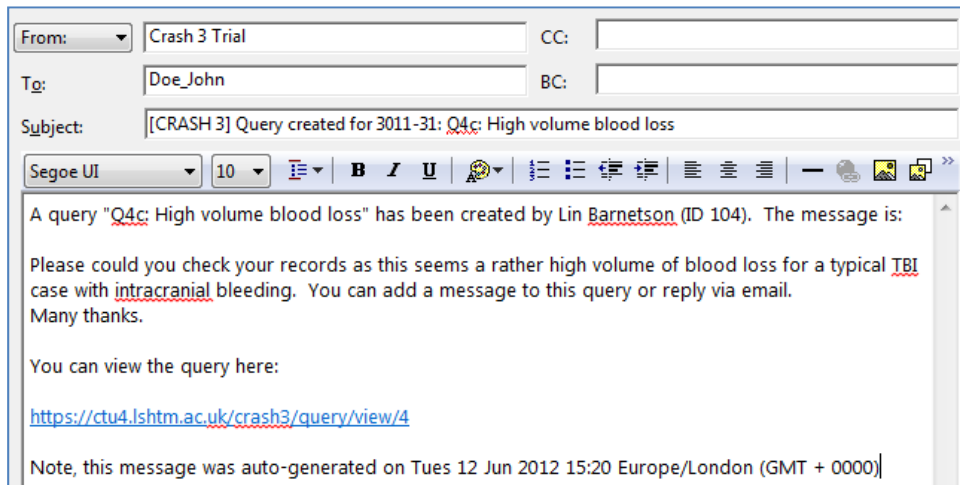
Outcome forms overdue

Patients with an overdue outcome form (more than 4 weeks since randomisation).

CRASH
Clinical Randomisation of an Antifibrinolytic in Significant Head Injury

Data queries

- If we create a query you will receive an automatic email alert
- Click on the link inside the email, log in and you will be directed to the query

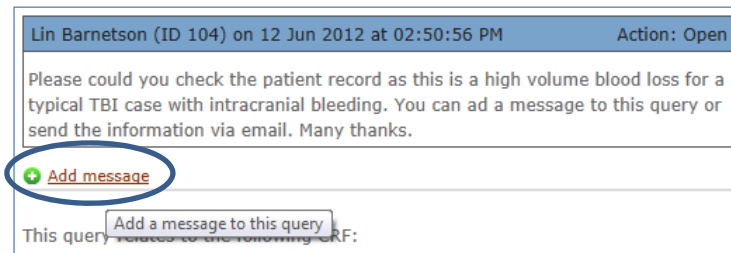


Queries			
ID	Title	Status	Patient
Test Hospital Maria			
5	Q4c: High volume blood loss reported	Open	3011-31
6	Q4c - blood loss during neurosurgical operation	Open	3011-32
2	Q4 Patient	Closed	3011-31

Answering queries

➤ Click on the query title or select **Edit**

➤ Click on **+ Add message**



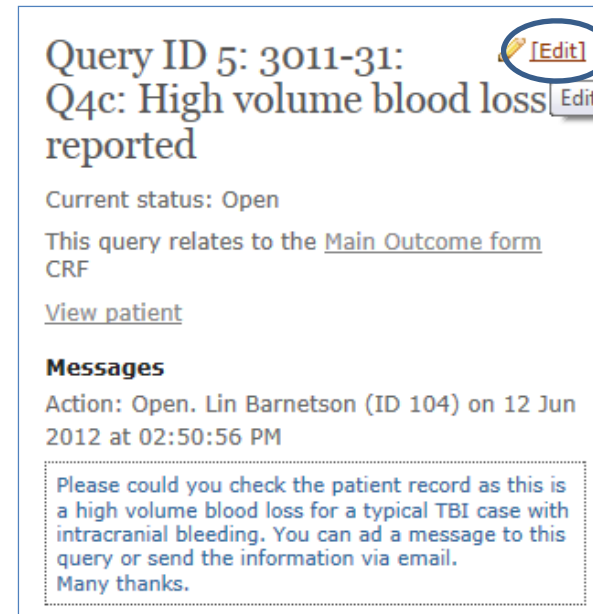
Lin Barnetson (ID 104) on 12 Jun 2012 at 02:50:56 PM Action: Open

Please could you check the patient record as this is a high volume blood loss for a typical TBI case with intracranial bleeding. You can ad a message to this query or send the information via email. Many thanks.

+ Add message

Add a message to this query

This query relates to the following CRF:



Query ID 5: 3011-31: **[Edit]**
Q4c: High volume blood loss reported **Edit**

Current status: Open

This query relates to the [Main Outcome form](#) CRF

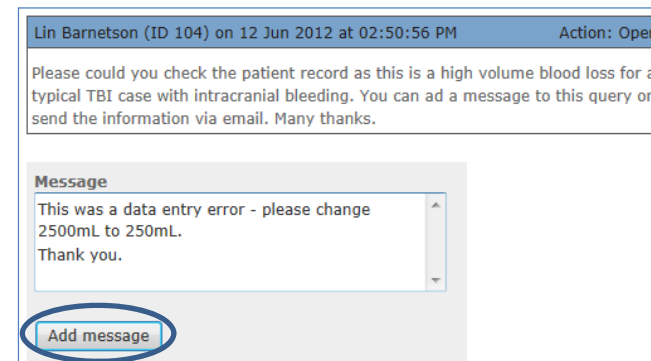
[View patient](#)

Messages

Action: Open. Lin Barnetson (ID 104) on 12 Jun 2012 at 02:50:56 PM

Please could you check the patient record as this is a high volume blood loss for a typical TBI case with intracranial bleeding. You can ad a message to this query or send the information via email. Many thanks.

➤ Enter your response to the query and click on **Add message**



Lin Barnetson (ID 104) on 12 Jun 2012 at 02:50:56 PM Action: Open

Please could you check the patient record as this is a high volume blood loss for a typical TBI case with intracranial bleeding. You can ad a message to this query or send the information via email. Many thanks.

Message

This was a data entry error - please change 2500mL to 250mL.
Thank you.

Add message

Closing queries

- Only TCC can close a query
- As soon as you add a response an email alert will go to TCC and to your account
- If TCC require further information they will add a message
- If the query is resolved TCC will close the query

Queries

ID	Title	Status	Patient
Test Hospital Maria			
6	Q4c - blood loss during neurosurgical operation	Open	3011-32
2	Q4 Patient hospital ID number	Closed	3011-31
5	Q4c: High volume blood loss reported	Closed	3011-31

Query ID 5: 3011-31: [Edit]

Q4c: High volume blood loss reported

Current status: Closed

This query relates to the [Main Outcome form](#) CRF

[View patient](#)

Messages

Action: Open. Lin Barnetson (ID 104) on 12 Jun 2012 at 02:50:56 PM

Please could you check the patient record as this is a high volume blood loss for a typical TBI case with intracranial bleeding. You can add a message to this query or send the information via email. Many thanks.

Action: None. John Doe (ID 118) on 12 Jun 2012 at 04:58:12 PM

Apologies - this was a data input error. Please change 2500mL to 250mL. Thank you

Action: Close. Lin Barnetson (ID 104) on 13 Jun 2012 at 11:22:20 AM

Correction to estimated blood loss has been made. No further action required. Thank you.

Managing data queries

- You can see which patients have open queries at any time by logging in and selecting **Patients**
- Patient records with open queries are marked with a yellow flag

Patients				
+ Patient				
Number	Box	Pack	Site	Country
5	3011	31	Test Hospital Maria	United Kingdom
6	3011	32	Test Hospital Maria	United Kingdom
7	3011	33	Test Hospital Maria	United Kingdom
10	3011	34	Test Hospital Maria	United Kingdom

Queries			
ID	Title	Status	Patient
Test Hospital Maria			
6	Q4c - blood loss during neurosurgical operation	Open	3011-32
2	Q4 Patient hospital ID number	Closed	3011-31
5	Q4c: High volume blood loss reported	Closed	3011-31

- Click on the box/pack number and edit the query by adding a response message
- Email alerts will automatically go to TCC and to your account stating that the query has been updated
- When TCC closes the query the flag will disappear from the record and the query will be listed as **Closed**

Viewing queries

- Log in and select **Queries** from the left hand menu
- All open and closed queries will be listed
- You may add responses to the open queries to resolve them and you may add messages to the closed queries if you have further information
- Contact crash.data@Lshtm.ac.uk if you have any data related questions

Patients
Queries
Change password

Query ID 5: 3011-31: Q4c:
High volume blood loss reported

Code 3011-31 | Test Hospital Mar

Current status: Closed

[<< return to patient](#)
[<< return to query](#)

Lin Barnetson (ID 104) on 12 Jun 2012 at 02:50:56 PM Action: Open

Please could you check the patient record as this is a high volume blood loss for a typical TBI case with intracranial bleeding. You can add a message to this query or send the information via email. Many thanks.

John Doe (ID 118) on 12 Jun 2012 at 04:58:12 PM Action: None

Apologies - this was a data input error. Please change 2500mL to 250mL. Thank you

Lin Barnetson (ID 104) on 13 Jun 2012 at 11:22:20 AM Action: Close

Correction to estimated blood loss has been made. No further action required. Thank you.

John Doe (ID 118) on 13 Jun 2012 at 01:13:19 PM Action: None

There was an error in our earlier message - the estimated volume blood loss was 200mL not 250mL. Please effect the correction.

[+ Add message](#)

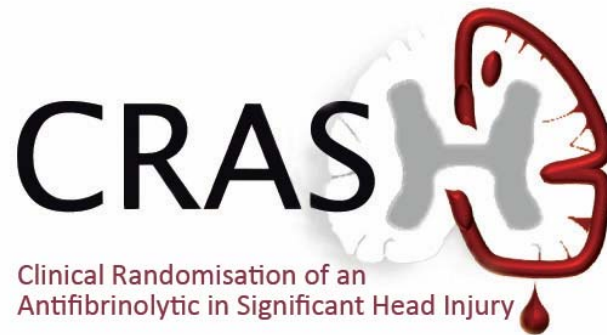
This query relates to the following CRF:

Outcome Form

Code 3011-31 | Test Hospital Mar

Complete at discharge from the randomising hospital, death in hospital or 28 days after injury, whichever occurs first

[<< return to patient](#)



Clinical Randomisation of an
Antifibrinolytic in Significant Head Injury

Trial Coordinating Centre

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