



Haemorrhage alleviation with  
tranexamic acid - Intestinal system

# HOW TO SUBMIT DATA AND RESPOND TO QUERIES ONLINE

Protocol Code: ISRCTN11225767

How to submit data and respond to queries online – version 1.0 date 10/05/2013

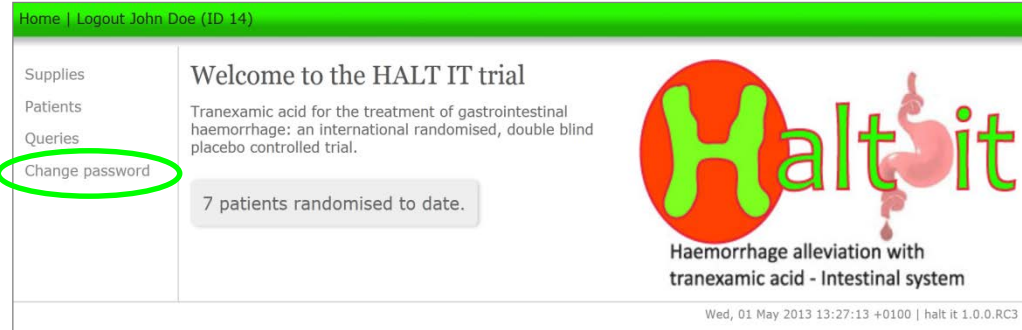
# Online data entry

**You must complete a paper form (entry/outcome)  
before you enter 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 [haltit.data@Lshtm.ac.uk](mailto:haltit.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 14)

Supplies  
Patients  
Queries  
**Change password**

Welcome to the HALT IT trial

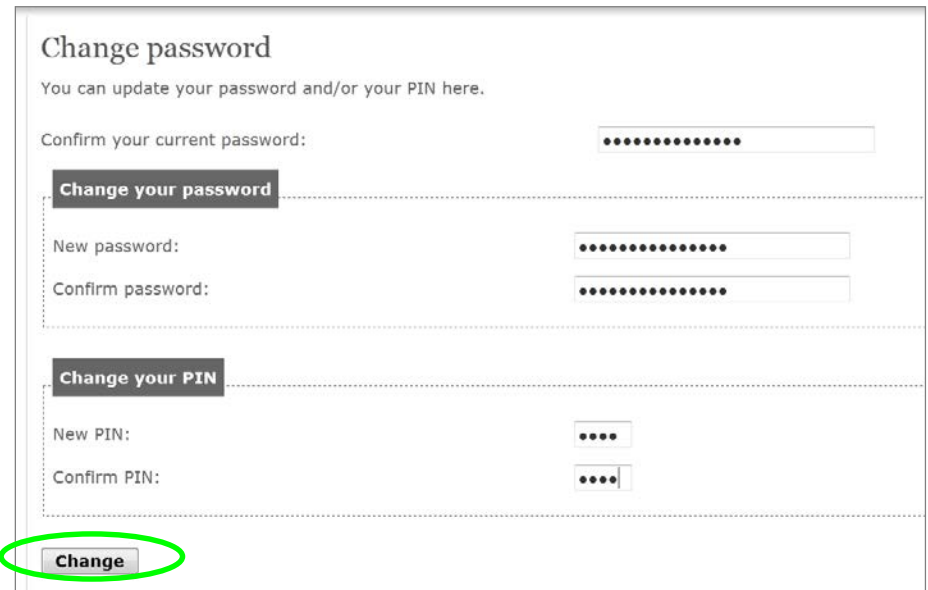
Tranexamic acid for the treatment of gastrointestinal haemorrhage: an international randomised, double blind placebo controlled trial.

7 patients randomised to date.



**HALT IT**  
Haemorrhage alleviation with tranexamic acid - Intestinal system

Wed, 01 May 2013 13:27:13 +0100 | halt it 1.0.0.RC3



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**

Keep your access details secure  
– do not share with anyone

If you forget your password or PIN,  
email: [haltit.data@Lshtm.ac.uk](mailto:haltit.data@Lshtm.ac.uk)

# 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

John Doe (ID 14)

### Entry Form

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

Code 1061-11 | Daniela Hospital 2 (Site #10), The Bahamas

<< return to patient

This form was created on 1 May 2013 13:53 by John Doe (ID 14)

## Please log in

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

Email address:

Password:

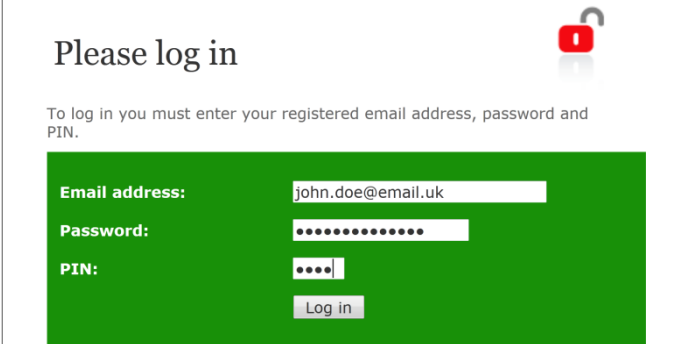
PIN:

Log in

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 <https://ctu4.lshtm.ac.uk/haltit/>
- 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

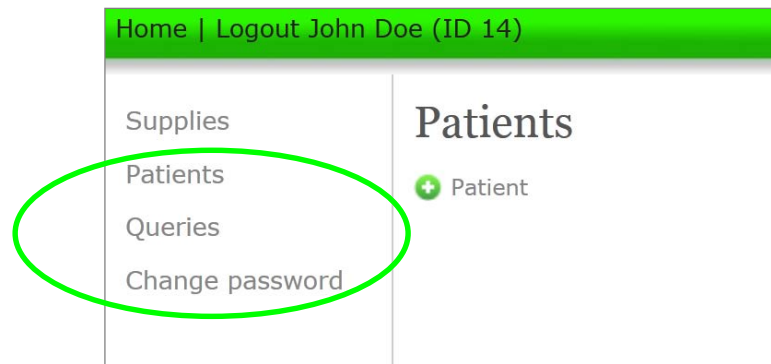
To log in you must enter your registered email address, password and PIN.

Email address: john.doe@email.uk

Password: .....

PIN: ....

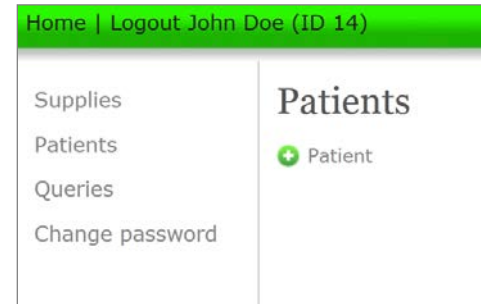
Log in



# 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**



**Entry Form**

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

[<< return to patient](#)

**About the hospital**

2. Hospital code (in your study file)

**About the patient**

3. Patient's initials   
first name/last name

4. Sex  Male  Female

5. Age

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

**11a. Systolic Blood Pressure**

Recorded  
 Too low to be recorded  
 Not recorded/Missing

11b. If recorded, enter value (most recent measurement prior to randomisation)   
mmHg. Number (up to 3 digits)

**12a. Heart Rate**

Recorded  
 Not recorded/Missing

12b. If recorded, enter value (most recent measurement prior to randomisation)   
beats per minute. Number (up to 3 digits)

# Completing the entry form

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

5. Age  Please enter a value between 1 and 100. years. Number (up to 3 digits)

6. Time since onset of GI bleed symptoms  This field is required. hours. In relation to THIS acute episode only

If the patient is not eligible, you are asked to explain why the patient is not eligible in the appropriate field

Yes

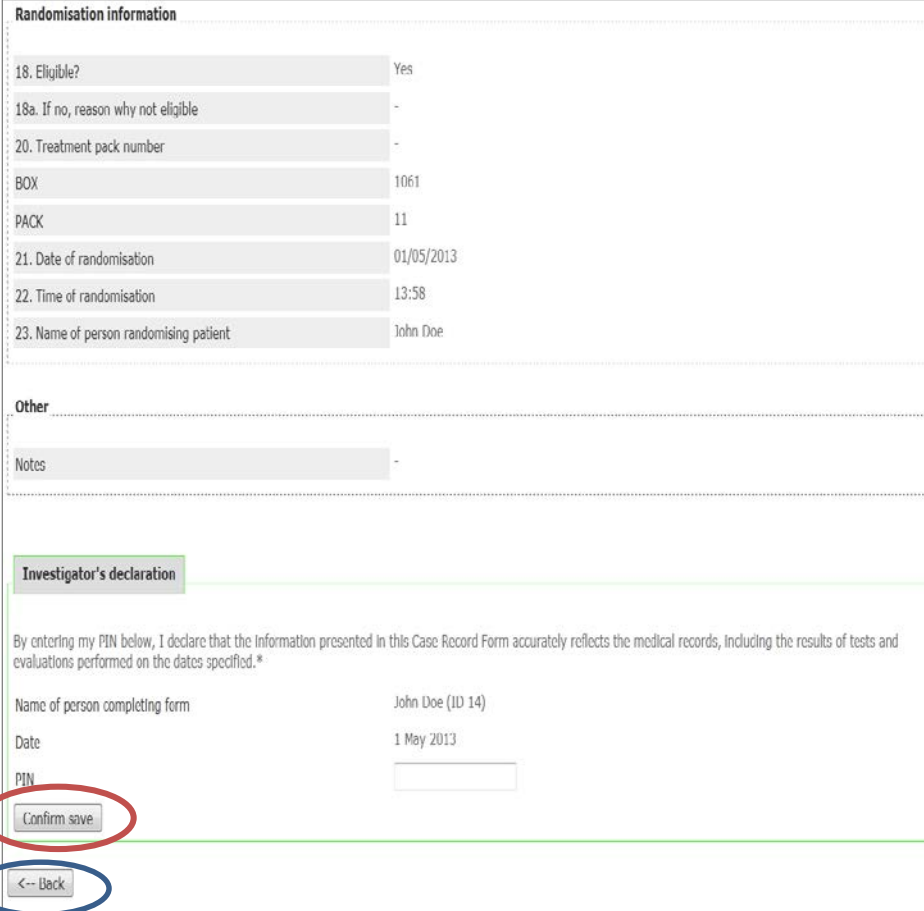
Patient not eligible; please explain in the text box directly below

OK

# 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**

18. Eligible?	Yes
18a. If no, reason why not eligible	-
20. Treatment pack number	-
BOX	1061
PACK	11
21. Date of randomisation	01/05/2013
22. Time of randomisation	13:58
23. Name of person randomising patient	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 14)

Date 1 May 2013

PIN

Confirm save

<-- Back



# 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

Home | Logout John Doe (ID 14)

Supplies  
Patients  
Queries  
Change password

## 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 the hospital**

2. Hospital code (in your study file) 10: Daniela Hospital 2

**About the patient**

### 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 14)  
Date 1 May 2013  
PIN

# Logging out

## Entry Form

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

[<< return to patient](#)

This form was created on 1 May 2013 13:53 by John Doe (ID 14)

- 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 14)**

Supplies	<h2>Welcome to the HALT IT trial</h2> <p>Tranexamic acid for the treatment of gastrointestinal haemorrhage: an international randomised, double blind placebo controlled trial.</p> <p>9 patients randomised to date.</p>
Patients	
Queries	
Change password	

## 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 14)

Supplies

**Patients**

Queries

Change password

+ Patient

Number	Box	Pack	Site	Country
8	1061	11	Daniela Hospital 2	The Bahamas
9	1061	12	Daniela Hospital 2	The Bahamas

# Adding an outcome form

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

Patients  Search

+ Patient

Number	Box	Pack	Site	Country
8	1061	11	Daniela Hospital 2	The Bahamas

[View details](#) 1061 12 Daniela Hospital 2 The Bahamas

**Patient details**

**Number** 8

**Box-pack** 1061-11

**Site** Daniela Hospital 2 (Site #10), The Bahamas

**Source of data** Online

**Patient initials** BS

**Gender** Male

**Queries**

**CRFs**

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

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

# Completing the outcome form

- Complete the outcome form and press **Save form**
- You will be prompted for any missing or incorrect data

Outcome Form

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

[<< return to patient](#)

**2. Patient details**

a) Initials   
first name/last name

b) Age at entry   
years. Number (up to 3 digits)

c) Written consent obtained from patient or representative?  Yes  
 No

d) If no written consent, give reason

a) Diagnostic endoscopic procedure  Yes  
 No

b) Therapeutic endoscopic procedure  Yes  
 No

c) Diagnostic radiological procedure  Yes  
 No

This field is required.

**3.1 Death in hospital**

a) Date of death   Date must be after 01/05/2013

dd/mm/yyyy

## 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

The screenshot shows a web form titled "Investigator's declaration" enclosed in a light green border. The form contains a declaration text, a "Confirm save" button, and a "<-- Back" button. The "Back" button is circled in blue. The form fields are as follows:

<b>Investigator's declaration</b>	
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 14)
Date	1 May 2013
PIN	<input type="text"/>
<input type="button" value="Confirm save"/>	
<input type="button" value=" &lt;-- Back"/>	

# 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

Code 1061-11 | Daniela Hospital 2 (Site #10), The Bahamas

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

### Review and sign

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

#### 2. Patient details

a) Initials	BS
b) Age at entry	60
c) Written consent obtained from patient or representative?	Yes

### 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 14)

Date      1 May 2013

PIN

# 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 14)

Supplies  
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## Outcome Form

Complete at discharge from the randomising hospital, death in hospital or 28 occurs first

**<< return to patient**

---

### 2. Patient details

a) Initials	BS
b) Age at entry	60
c) Written consent obtained from patient or representative?	Yes
d) If no written consent, give reason	-

Home | Logout John Doe (ID 14)

Supplies  
Patients  
Queries  
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## Patients

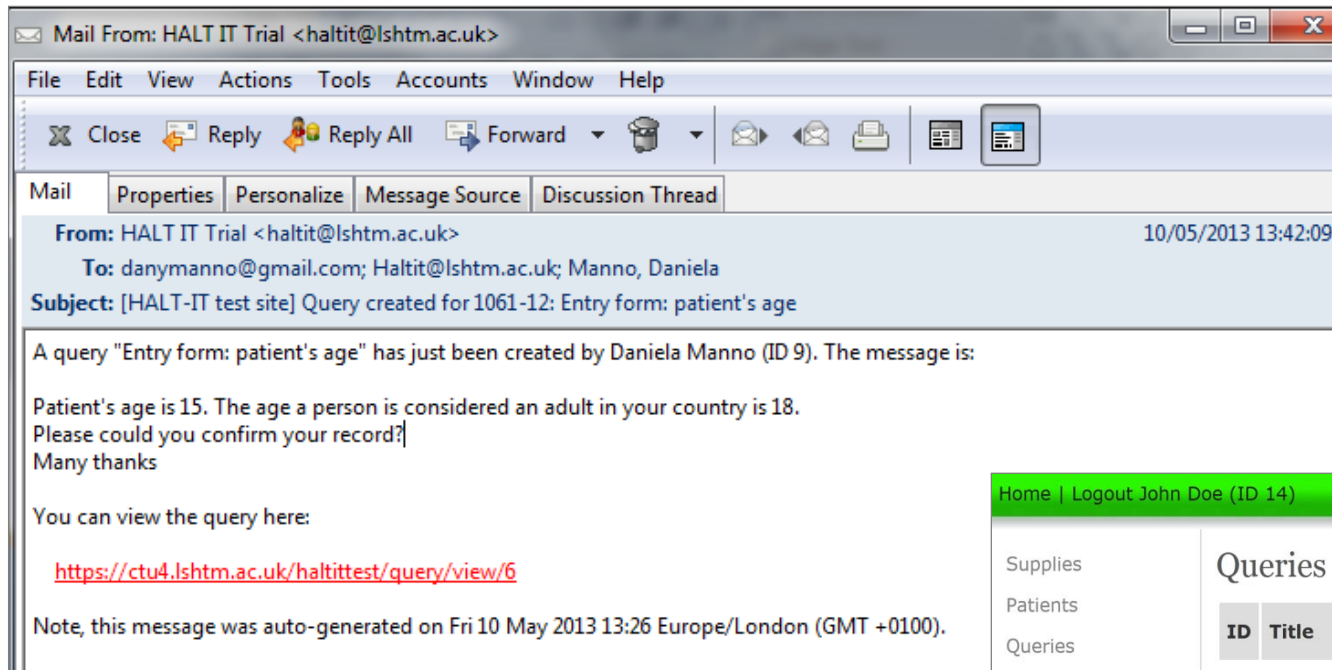
+ Patient

Number	Box	Pack	Site	Country
8	1061	11	Daniela Hospital 2	The Bahamas
9	1061	12	Daniela Hospital 2	The Bahamas
10	1061	13	Daniela Hospital 2	The Bahamas



# 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



Mail From: HALT IT Trial <haltit@lshtm.ac.uk>

File Edit View Actions Tools Accounts Window Help

Close Reply Reply All Forward

Mail Properties Personalize Message Source Discussion Thread

**From:** HALT IT Trial <haltit@lshtm.ac.uk> 10/05/2013 13:42:09  
**To:** danymanno@gmail.com; Haltit@lshtm.ac.uk; Manno, Daniela  
**Subject:** [HALT-IT test site] Query created for 1061-12: Entry form: patient's age

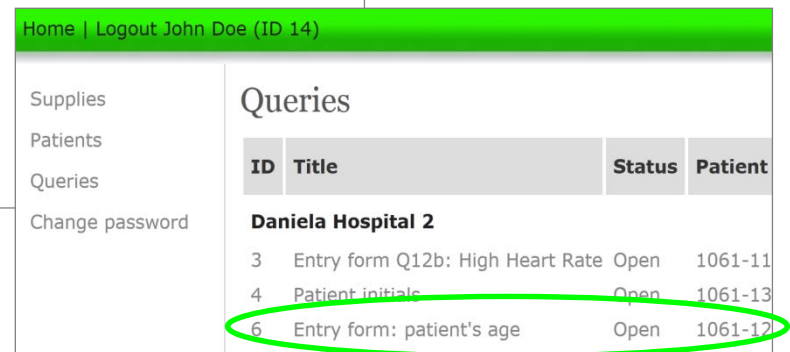
A query "Entry form: patient's age" has just been created by Daniela Manno (ID 9). The message is:

Patient's age is 15. The age a person is considered an adult in your country is 18.  
Please could you confirm your record?  
Many thanks

You can view the query here:

<https://ctu4.lshtm.ac.uk/haltittest/query/view/6>

Note, this message was auto-generated on Fri 10 May 2013 13:26 Europe/London (GMT +0100).



Home | Logout John Doe (ID 14)

Supplies  
Patients  
Queries  
Change password

## Queries

ID	Title	Status	Patient
<b>Daniela Hospital 2</b>			
3	Entry form Q12b: High Heart Rate	Open	1061-11
4	Patient initials	Open	1061-13
6	Entry form: patient's age	Open	1061-12

# Answering queries


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

➤ Click on **+ Add message**

Daniela Manno (ID 9) on 10 May 2013 at 01:26:09 PM Action: Open

Patient's age is 15. The age a person is considered an adult in your country is 18. Please could you confirm your record? Many thanks

**+ Add message**

Query ID 6: 1061-12:  [Edit]

Entry form: patient's age

Current status: Open

[View patient](#)

**Messages**

Action: Open. Daniela Manno (ID 9) on 10 May 2013 at 01:26:09 PM

Patient's age is 15. The age a person is considered an adult in your country is 18. Please could you confirm your record? Many thanks

Fri, 10 May 2013 13:38:12 +0100 | halt it 1.0.0.RC4

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

Daniela Manno (ID 9) on 10 May 2013 at 01:26:09 PM Action: Open

Patient's age is 15. The age a person is considered an adult in your country is 18. Please could you confirm your record? Many thanks

**Message**

This was a data entry error. Please change 15 to 45. 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

Home | Logout John Doe (ID 14)

Supplies  
Patients  
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Change password

## Queries

ID	Title	Status	Patient
<b>Daniela Hospital 2</b>			
3	Entry form Q12b: High Heart Rate	Open	1061-11
4	Patient initials	Open	1061-13
6	Entry form: patient's age	Closed	1061-12

Query ID 6: 1061-12: Entry form: patient's age [\[Edit\]](#)

Current status: Closed  
[View patient](#)

**Messages**

Action: Open. Daniela Manno (ID 9) on 10 May 2013 at 01:26:09 PM

Patient's age is 15. The age a person is considered an adult in your country is 18. Please could you confirm your record?  
Many thanks

Action: None. John Doe (ID 14) on 10 May 2013 at 03:14:35 PM

This was a data entry error. Please change 15 to 45.  
Thank you

Action: Close. Daniela Manno (ID 9) on 10 May 2013 at 03:16:57 PM

Correction to patient's age has been made.  
No further action required.  
Thanks

# 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
8	1061	11	Daniela Hospital 2	The Bahamas
9	1061	12	Daniela Hospital 2	The Bahamas
10	1061	13	Daniela Hospital 2	The Bahamas
11	1061	14	Daniela Hospital 2	The Bahamas

Queries			
ID	Title	Status	Patient
<b>Daniela Hospital 2</b>			
3	Entry form Q12b: High Heart Rate	Open	1061-11
4	Patient initials	Open	1061-13
6	Entry form: patient's age	Closed	1061-12

- 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 [haltit.data@Lshtm.ac.uk](mailto:haltit.data@Lshtm.ac.uk) if you have any data related questions

Query ID 6: 1061-12: Entry form:  [Edit]

patient's age

Current status: Closed

[View patient](#)

**Messages**

Action: Open. Daniela Manno (ID 9) on 10 May 2013 at 01:26:09 PM

Patient's age is 15. The age a person is considered an adult in your country is 18.  
Please could you confirm your record?  
Many thanks

Action: None. John Doe (ID 14) on 10 May 2013 at 03:14:35 PM

This was a data entry error. Please change 15 to 45.  
Thank you

Action: Close. Daniela Manno (ID 9) on 10 May 2013 at 03:16:57 PM

Correction to patient's age has been made.  
No further action required.  
Thanks

# JOIN THE GLOBAL COLLABORATION

[haltit.Lshtm.ac.uk](http://haltit.Lshtm.ac.uk)

Trial Coordinating Centre  
London School of Hygiene & Tropical Medicine  
Room 180, Keppel Street, London WC1E 7HT

Tel +44(0)20 7299 4684  
Fax +44(0)20 7299 4663  
Email: [haltit@Lshtm.ac.uk](mailto:haltit@Lshtm.ac.uk)

