LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

CLINICAL TRIALS UNIT

THE TRIAL DATABASE AND ONLINE DATA QUERIES

Protocol number: ISRCTN62396133
Version 1.0; Date 05 April 2019

THE TRIAL DATABASE

- Data for the WOMAN-2 trial should be sent via **direct data entry online** into the trial database

- Data to be sent within 24 hours of completion:
    - Baseline form *(for both randomised and screen failures)*
    - Outcome form
    - Adverse event form
    - Serious adverse event form

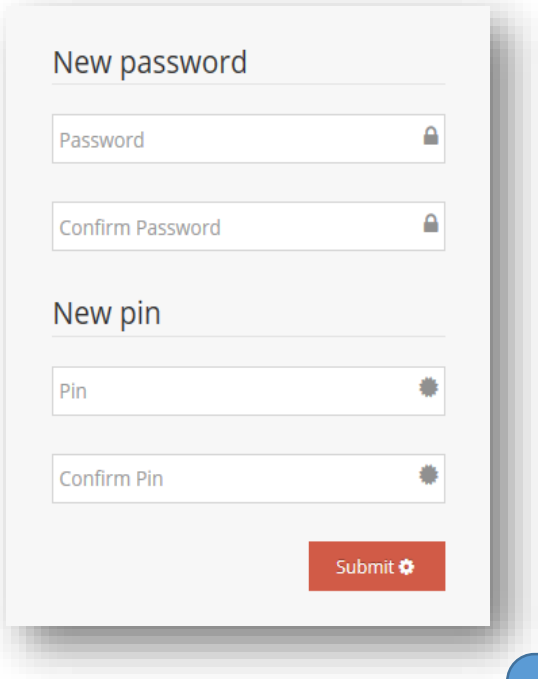
- In rare circumstances where entry online cannot be done, contact the CTU on woman2@Lshtm.ac.uk for advice

OBTAINING ACCESS TO THE DATABASE

A copy of the delegation log **signed** and **dated** by the **Principal Investigator**

A written request for the individual to have database access from the Principal Investigator

Emailed to woman2@Lshtm.ac.uk



Individuals will receive an email with a link to set up unique:
-Password
-Pin number

Log in to the trial database using **username**, **password** and **pin**

Note: Your 'username' is the same email address used to set up pin/password

LOGIN IN DETAILS

- Each staff member with delegated responsibility to enter data must have **their own unique database log in account**

- **Log in details must NOT be shared with anyone**

- Your password should be **memorable but secure** i.e. use a combination of characters, numbers and capital/non-capitals

Forgot your log in details?

- Contact woman2@Lshtm.ac.uk to request a reset

USING THE DATABASE

- Access to database allows:

  - add participant data
  - view of all data entered for your site
  - view of all open and closed queries at site
  - resolution of all open queries

- A practice database is available to familiarise yourself before attempting your first data entry. Email woman2@Lshtm.ac.uk for access

The database will close down after 10 minutes of inactivity – you will lose any unsaved forms and will need to log in again

PARTICIPANT IDENTIFIABLE INFORMATION

- In line with Data Protection Regulations which governs LSHTM, **no identifiable participant data should be submitted to the CTU** including in data entry or in query or email correspondence

- This includes names, date of births or hospital ID numbers

- *Only the consent form which has personal data, should be sent when requested - these are handled separately from the data*

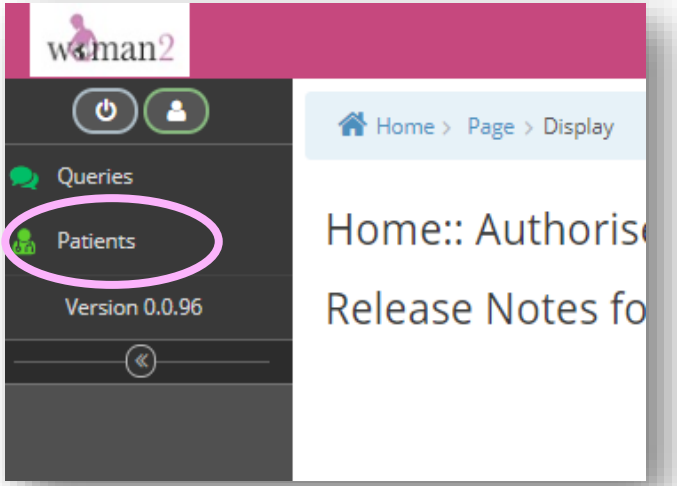
- If identifiable information is sent, this will be a **Data Protection breach**

- **Only screening ID, box-pack number or initials should be used when referring to a participant in data entry, query or email correspondence**

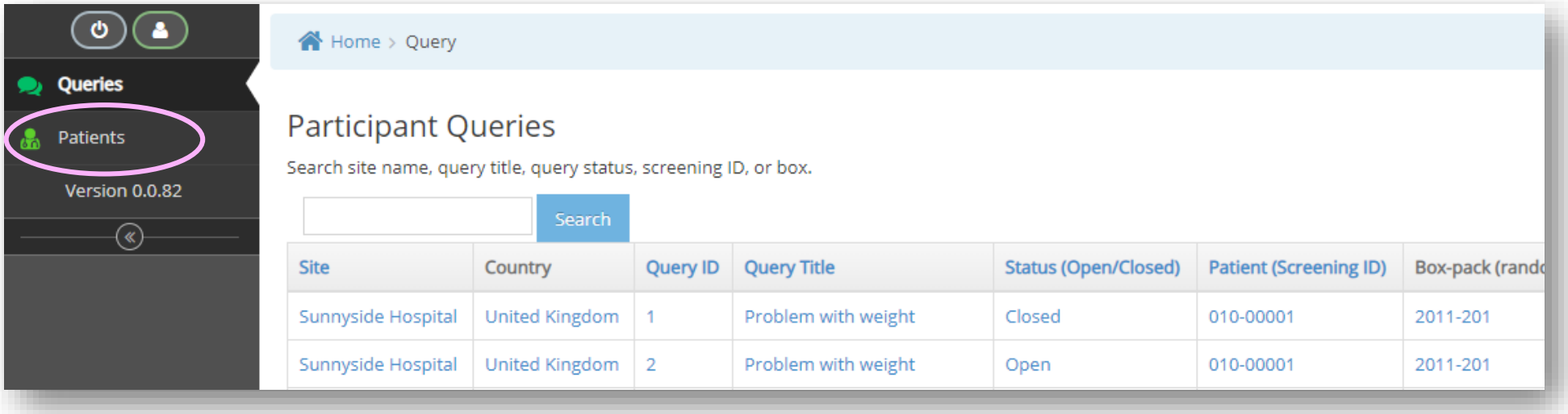
DATABASE WELCOME SCREEN

- The links on the left of the Welcome screen allow you to:

  - Add and view all data at your site (**Patients** tab)

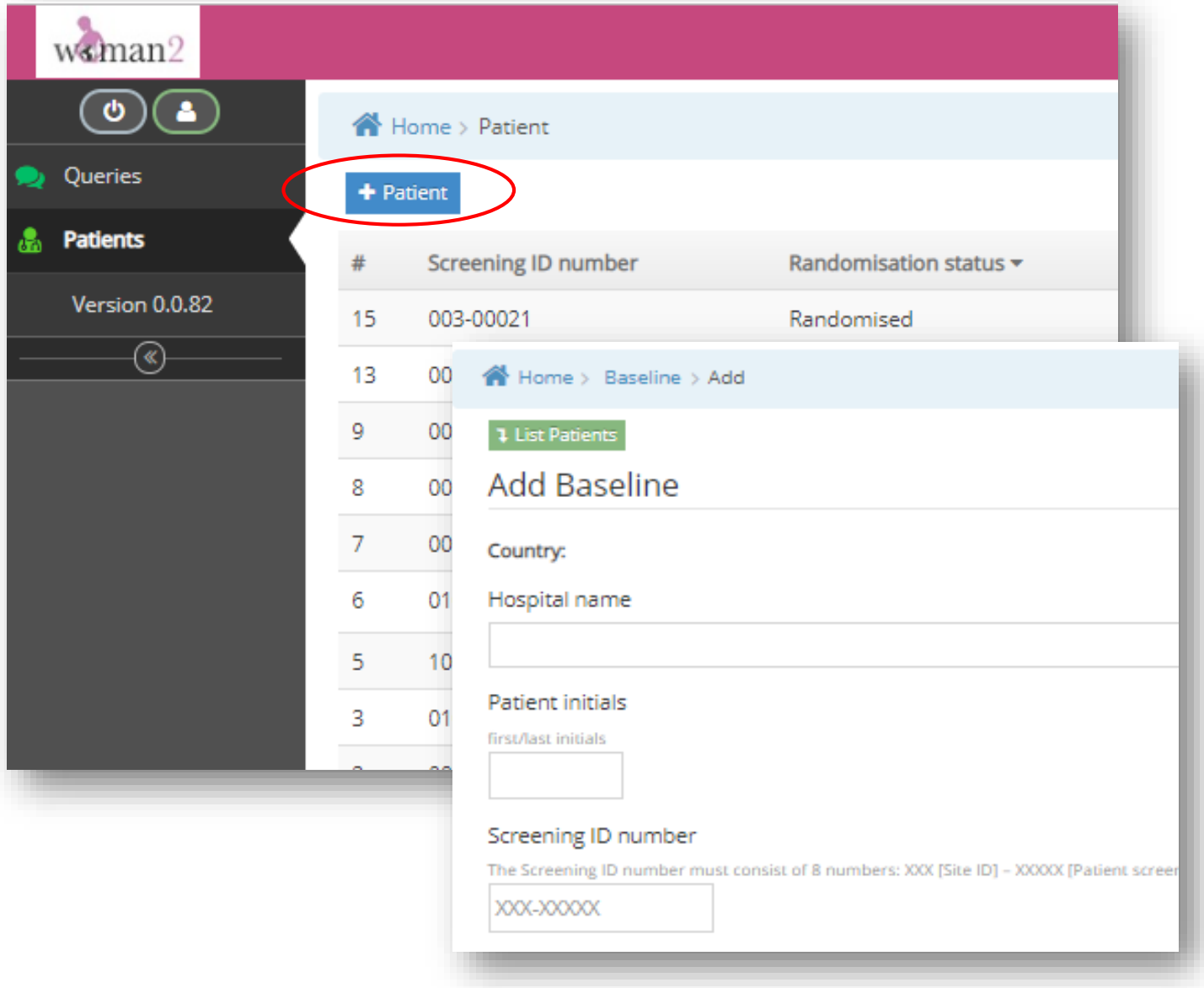


  - View all open/closed queries (**Queries** tab)



ADDING A PARTICIPANT

- **To add baseline data**
  - Click **+Patient**
  - Blank baseline form will open
  - Complete all fields and submit



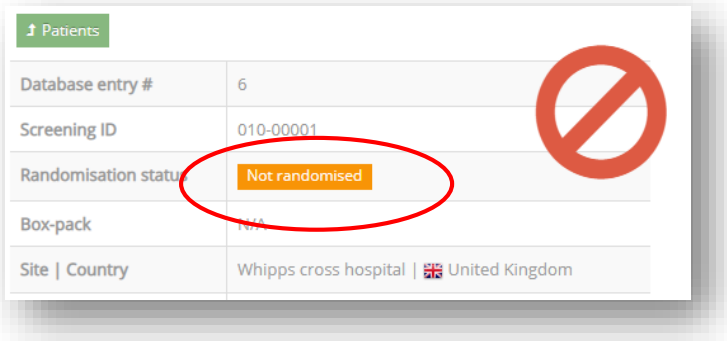
PARTICIPANTS SCREENED BUT NOT RANDOMISED

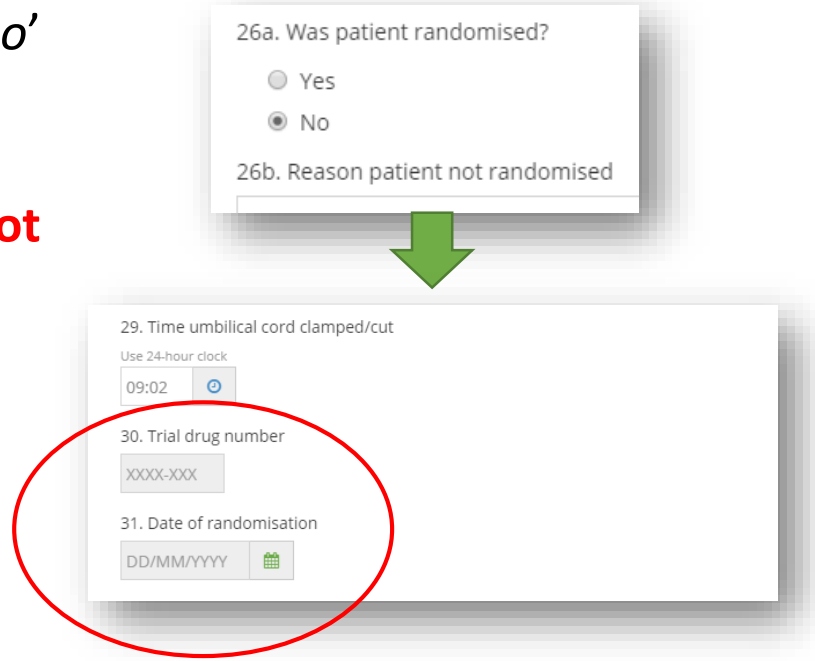
- The database should collect data for all screened participants including those screened but not randomised.

- All baseline screening data collected in the CRF booklet (Sections A-C and D-G (if applicable)) should be entered into the database, even if the participant was not randomised.

- Some fields will be automatically disabled on the baseline data entry form if Q26a '*Was patient randomised?*' is marked as '*No*' e.g. trial drug pack number and date of randomisation.

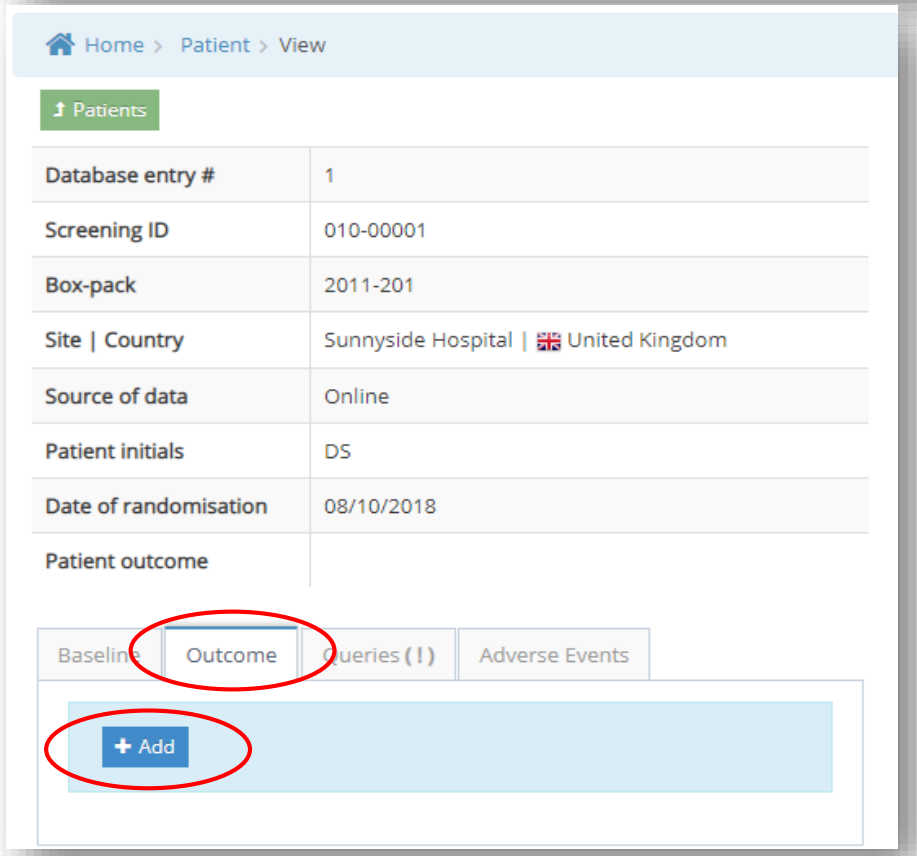
- On submission, the participant will be marked as **'Not randomised'.**





ADDING AN OUTCOME/ADVERSE EVENT FORM

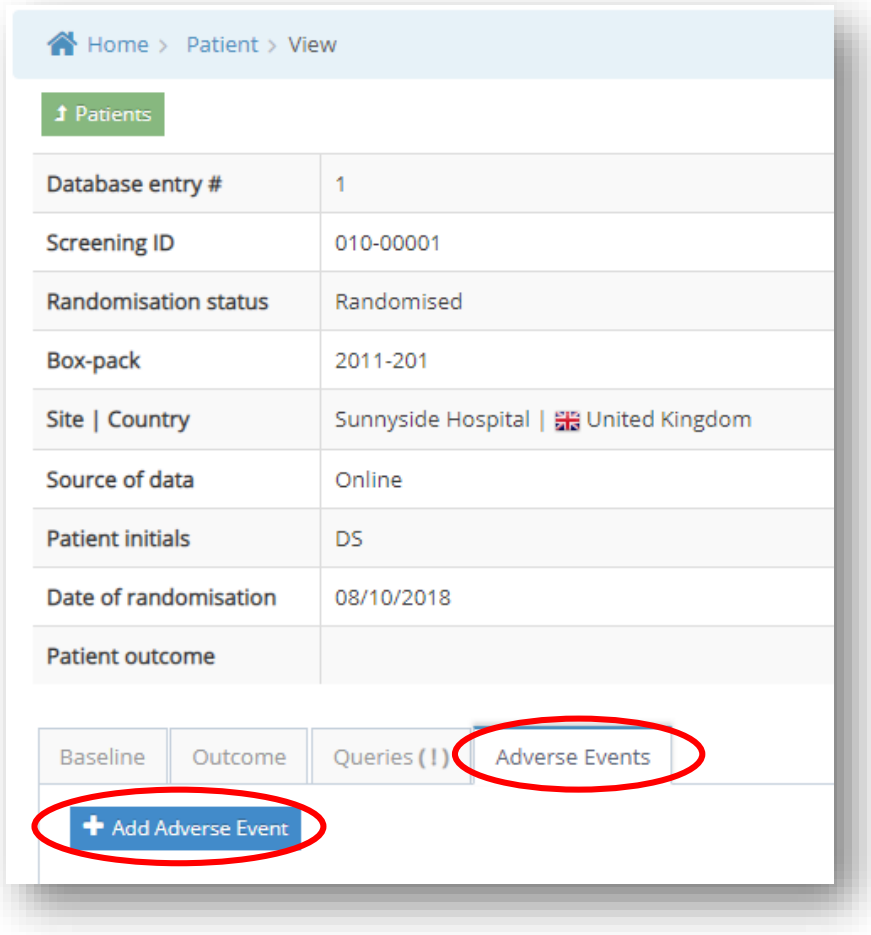
- Click on **Patients** on left hand panel
- Find the participant using the Screening ID or Randomisation Number
- Select **Outcome** or **Adverse Events** tab
- Click **+ Add**
- Complete all fields and submit



ADDING ADVERSE EVENT DATA

- Complete Q1-7 of the data form only for ‘Adverse Event’

- Complete Q1-20 of the data form (additional fields will open based if any of the ‘serious’ criteria is selected) for ‘Serious Adverse Event’

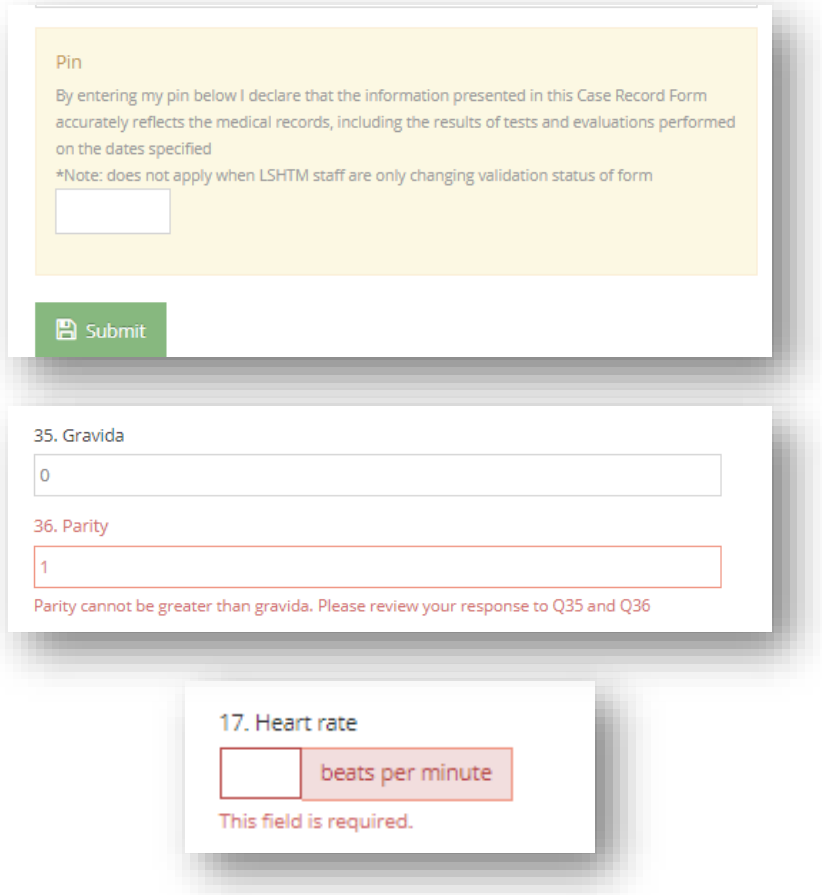


SUBMITTING DATA

Ensure the paper CRF is fully complete before starting data entry – the database does not allow part completion

- The PIN number entered at login is required to submit data

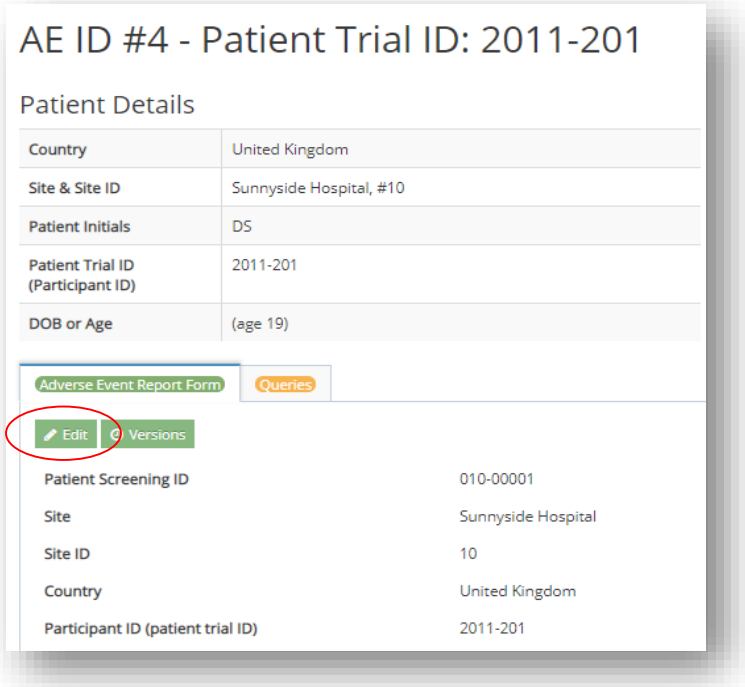
- Cannot submit data if any missing/incorrect data
  - Database will flag these in red
  - Alert messages may also pop up for the user to read



AFTER DATA ENTRY

Once data has been saved:

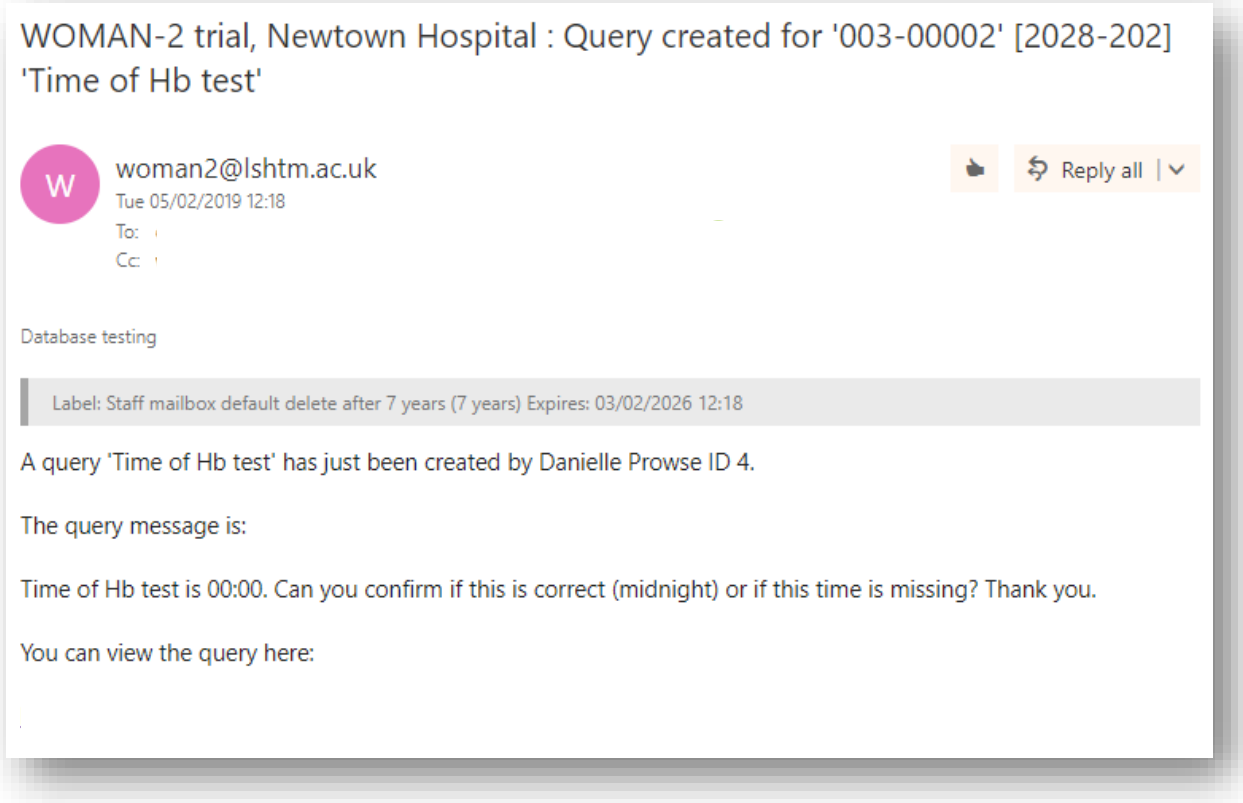
- The CTU will acknowledged by email all data forms entered
- Baseline and outcome data can be viewed once submitted, but cannot be edited
- If data amendment is requireed to Baseline and Outcome Forms, a written request must be sent to the CTU data team
- Adverse event data **<u>can</u>** be edited by investigators, to allow status updates until locked by the CTU



DATA QUERIES

- CTU staff may raise **data queries** to resolve any questions about the data entered in the trial database

- If a query is raised, all users at site with database access will receive an email notification of this



WOMAN-2 trial, Newtown Hospital : Query created for '003-00002' [2028-202] 'Time of Hb test'

W

woman2@lshtm.ac.uk

Tue 05/02/2019 12:18

To:

Cc:

Reply all

Database testing

Label: Staff mailbox default delete after 7 years (7 years) Expires: 03/02/2026 12:18

A query 'Time of Hb test' has just been created by Danielle Prowse ID 4.

The query message is:

Time of Hb test is 00:00. Can you confirm if this is correct (midnight) or if this time is missing? Thank you.

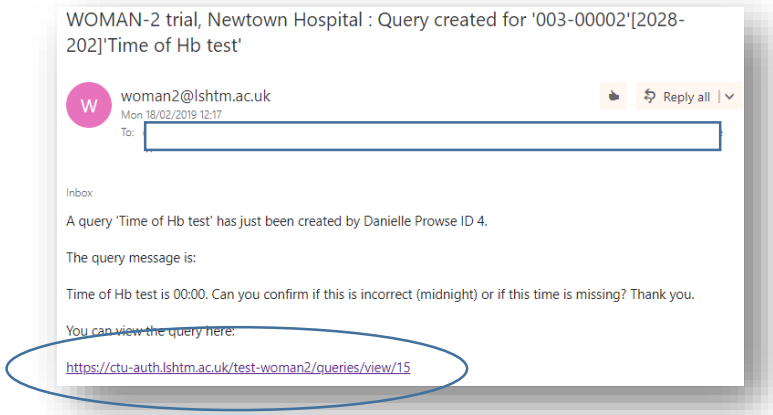
You can view the query here:

Please respond to all queries as soon as possible

RESPONDING TO DATA QUERIES

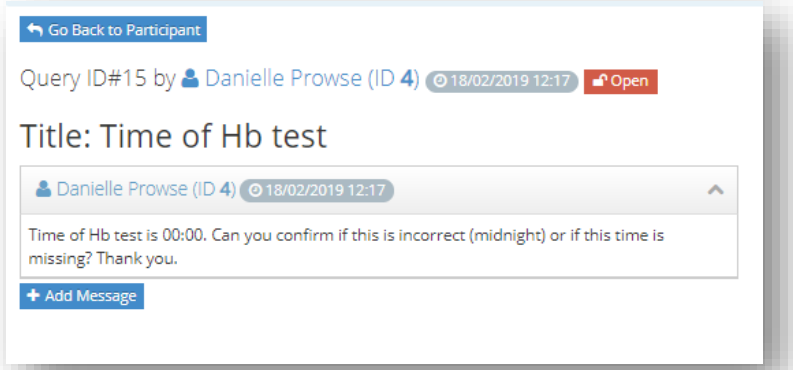
1. Notification of a new query received by email

2. Click link in email

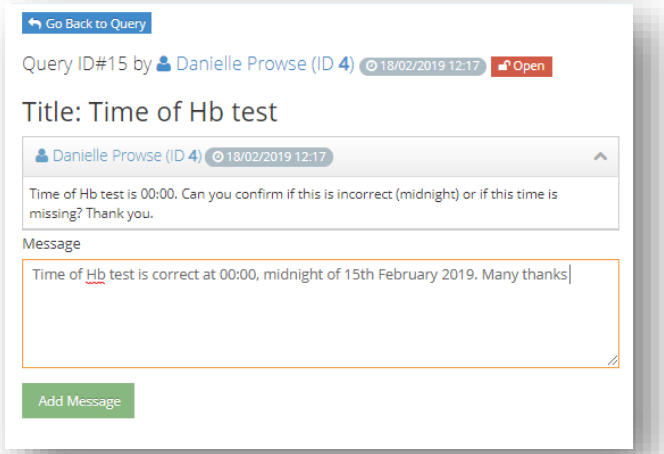


3. Prompted to log in to database

4. Automatically direct you to the query to view



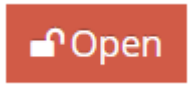
5. Provide response to query by clicking 'add message' then submit



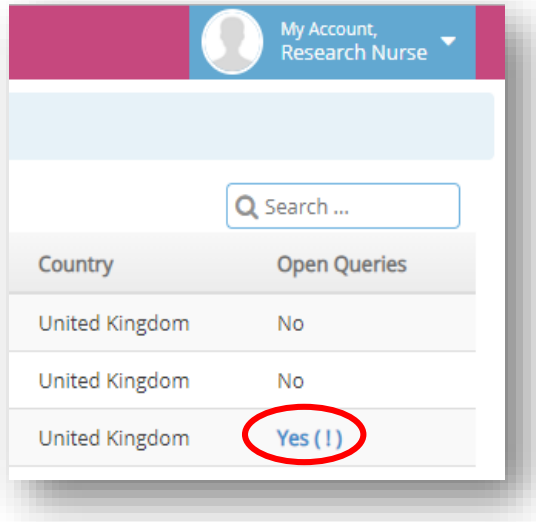
- CTU staff will review responses. Further clarification may be required
- CTU will close the query once resolved

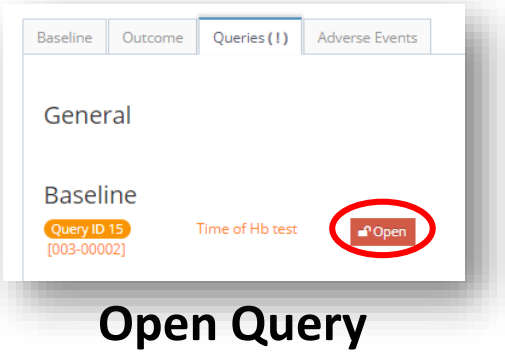
Please respond to all queries as soon as possible

MANAGING DATA QUERIES

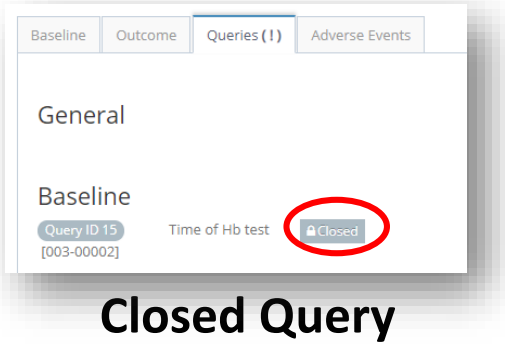
- Participant records with queries will be flagged as Open queries? [**Yes(!)**] on the patient homepage
- All open and closed queries for each participant will also be listed under the 'queries' tab for that participant
- All open queries are marked 

- Once a query is resolved, CTU will mark as closed 

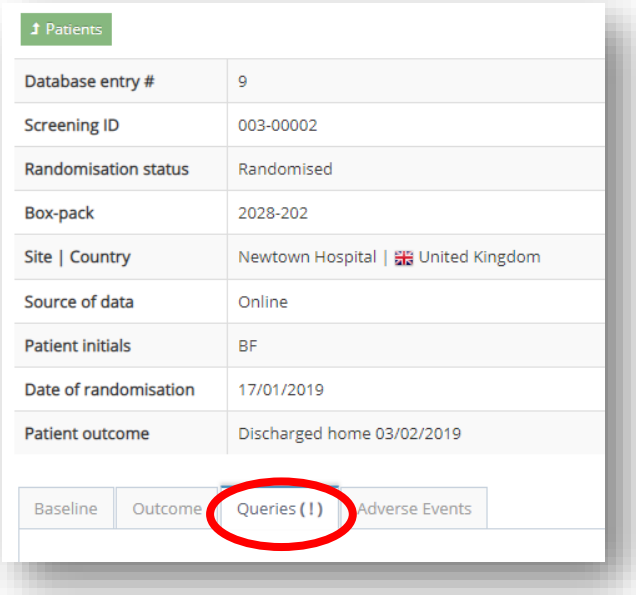




Open Query



Closed Query

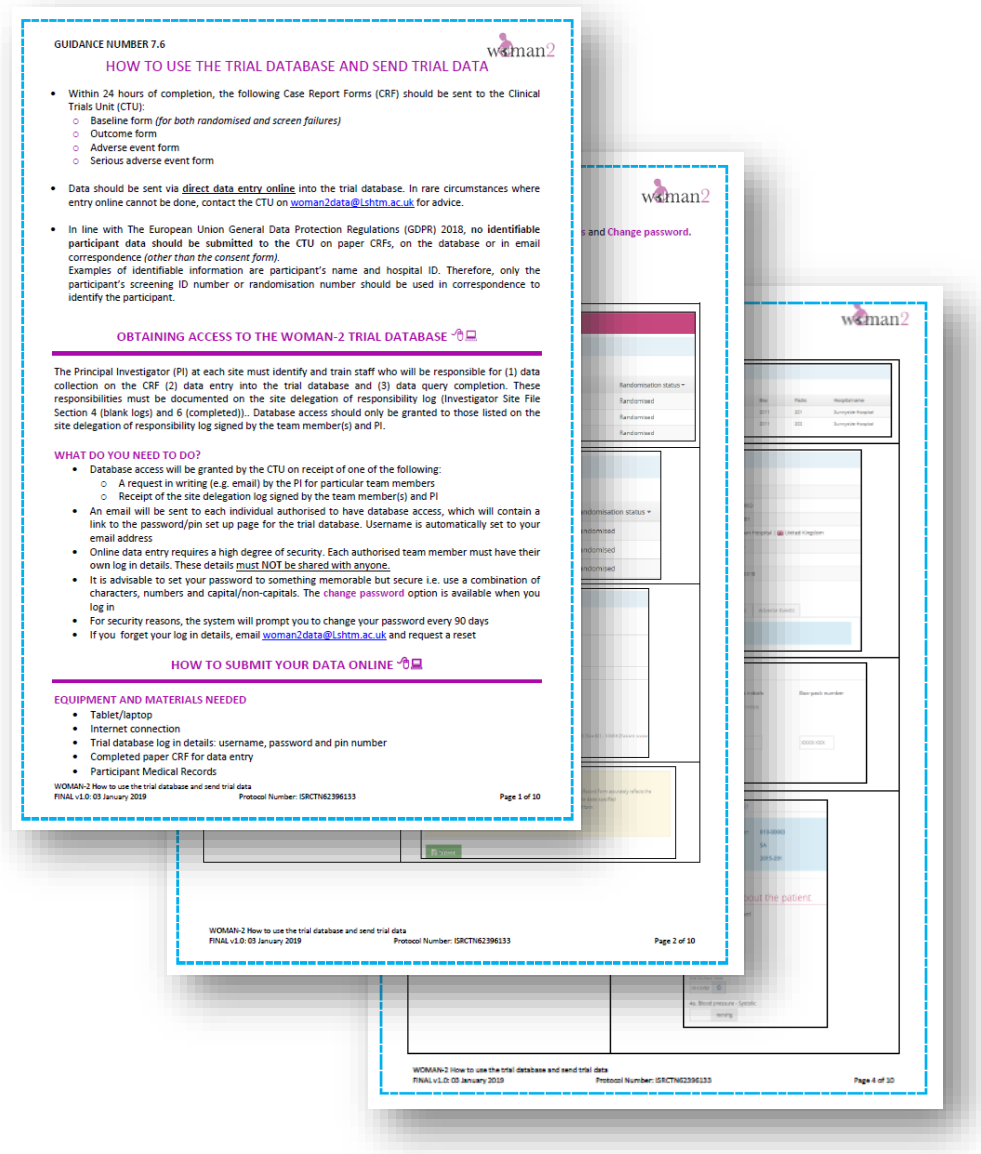


To ensure there is an audit trail of all queries and corrections made on the database, all email correspondence or query chains must be printed and stored in the Investigator Site File, box file 1, with the original Case Report Form (CRF)

FOR FURTHER GUIDANCE SEE:

The Trial Procedures File, section 7:

- How to use the trial database and send trial data, guidance number 7.6



GUIDANCE NUMBER 7.6

HOW TO USE THE TRIAL DATABASE AND SEND TRIAL DATA

- Within 24 hours of completion, the following Case Report Forms (CRF) should be sent to the Clinical Trials Unit (CTU):
  - Baseline form *(for both randomised and screen failures)*
  - Outcome form
  - Adverse event form
  - Serious adverse event form
- Data should be sent via **direct data entry online** into the trial database. In rare circumstances where entry online cannot be done, contact the CTU on woman2data@lshtm.ac.uk for advice.
- In line with The European Union General Data Protection Regulations (GDPR) 2018, **no identifiable participant data should be submitted to the CTU** on paper CRFs, on the database or in email correspondence *(other than the consent form)*.
  Examples of identifiable information are participant's name and hospital ID. Therefore, only the participant's screening ID number or randomisation number should be used in correspondence to identify the participant.

OBTAINING ACCESS TO THE WOMAN-2 TRIAL DATABASE

The Principal Investigator (PI) at each site must identify and train staff who will be responsible for (1) data collection on the CRF (2) data entry into the trial database and (3) data query completion. These responsibilities must be documented on the site delegation of responsibility log (Investigator Site File Section 4 (blank logs) and 6 (completed)).. Database access should only be granted to those listed on the site delegation of responsibility log signed by the team member(s) and PI.

WHAT DO YOU NEED TO DO?

- Database access will be granted by the CTU on receipt of one of the following:
  - A request in writing (e.g. email) by the PI for particular team members
  - Receipt of the site delegation log signed by the team member(s) and PI
- An email will be sent to each individual authorised to have database access, which will contain a link to the password/pin set up page for the trial database. Username is automatically set to your email address
- Online data entry requires a high degree of security. Each authorised team member must have their own log in details. These details must NOT be shared with anyone.
- It is advisable to set your password to something memorable but secure i.e. use a combination of characters, numbers and capital/non-capitals. The change password option is available when you log in
- For security reasons, the system will prompt you to change your password every 90 days
- If you forget your log in details, email woman2data@lshtm.ac.uk and request a reset

HOW TO SUBMIT YOUR DATA ONLINE

EQUIPMENT AND MATERIALS NEEDED

- Tablet/laptop
- Internet connection
- Trial database log in details: username, password and pin number
- Completed paper CRF for data entry
- Participant Medical Records

WOMAN-2 How to use the trial database and send trial data
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