

LONDON
SCHOOL of
HYGIENE
& TROPICAL
MEDICINE



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

The screenshot shows a web form with the following sections:

- New password:** Two input fields labeled "Password" and "Confirm Password", each with a lock icon on the right.
- New pin:** Two input fields labeled "Pin" and "Confirm Pin", each with a gear icon on the right.
- Submit:** A red button with the text "Submit" and a gear icon.

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

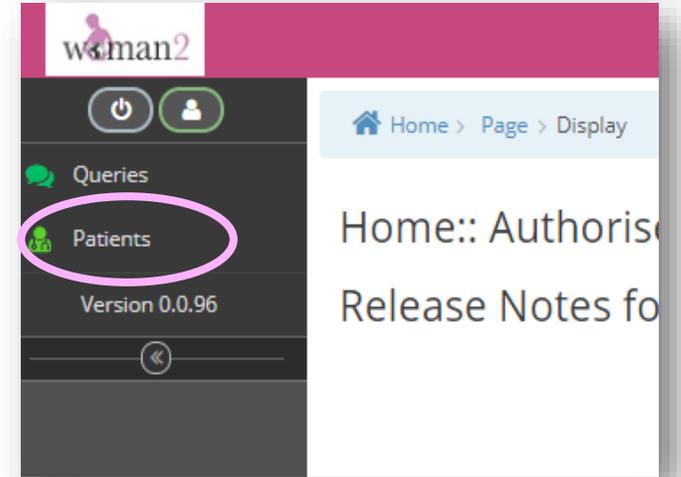
PARTICIPANT IDENTIFIABLE INFORMATION

- 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)

A screenshot of the 'Participant Queries' screen. The left sidebar is dark grey with a white 'woman2' logo at the top. Below the logo are two circular icons: a power button and a user profile icon. The sidebar contains two main menu items: 'Queries' with a speech bubble icon and 'Patients' with a person icon. The 'Patients' item is circled in pink. Below the menu items is the text 'Version 0.0.82' and a back arrow icon. The main content area is white with a blue header bar containing a home icon and the text 'Home > Query'. Below the header bar, the text 'Participant Queries' is displayed. Underneath is a search bar with the placeholder text 'Search site name, query title, query status, screening ID, or box.' and a blue 'Search' button. Below the search bar is a table with the following data:

Site	Country	Query ID	Query Title	Status (Open/Closed)	Patient (Screening ID)	Box-pack (rand
Sunnyside Hospital	United Kingdom	1	Problem with weight	Closed	010-00001	2011-201
Sunnyside Hospital	United Kingdom	2	Problem with weight	Open	010-00001	2011-201

ADDING A PARTICIPANT

- To add baseline data

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

The screenshot displays the 'woman2' mobile application interface. The top navigation bar is pink with the 'woman2' logo. Below it, a dark sidebar contains icons for 'Queries' and 'Patients', with 'Patients' selected. The main content area shows a list of patients with columns for '#', 'Screening ID number', and 'Randomisation status'. A blue '+ Patient' button is circled in red. An overlay form titled 'Add Baseline' is open, showing fields for 'Country', 'Hospital name', 'Patient initials', and 'Screening ID number'. The 'Screening ID number' field includes a placeholder 'XXX-XXXX' and a note: 'The Screening ID number must consist of 8 numbers: XXX [Site ID] - XXXXX [Patient screen]'.

#	Screening ID number	Randomisation status
15	003-00021	Randomised
13	00	
9	00	
8	00	
7	00	
6	01	
5	10	
3	01	
2	00	

Home > Patient

+ Patient

Home > Baseline > Add

List Patients

Add Baseline

Country:

Hospital name

Patient initials

first/last initials

Screening ID number

The Screening ID number must consist of 8 numbers: XXX [Site ID] - XXXXX [Patient screen]

XXX-XXXX

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'**.

26a. Was patient randomised?

Yes

No

26b. Reason patient not randomised



29. Time umbilical cord clamped/cut

Use 24-hour clock

09:02

30. Trial drug number

XXXX-XXX

31. Date of randomisation

DD/MM/YYYY

↑ Patients

Database entry #	6
Screening ID	010-00001
Randomisation status	Not randomised
Box-pack	1000
Site Country	Whipps cross hospital United Kingdom

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

The screenshot displays a web application interface for patient management. The top section shows a breadcrumb trail 'Home > Patient' and a '+ Patient' button. Below this is a table with columns: '#', 'Screening ID number', 'Box', 'Packs', and 'Hospital name'. Two rows are visible, with a mouse cursor pointing at the first row's 'Screening ID number' (010-00001).

The bottom section shows a 'View' page for a patient, with a breadcrumb trail 'Home > Patient > View' and a '+ Patients' button. It contains a table with the following data:

Database entry #	1
Screening ID	010-00001
Box-pack	2011-201
Site Country	Sunnyside Hospital United Kingdom
Source of data	Online
Patient initials	DS
Date of randomisation	08/10/2018
Patient outcome	

At the bottom, there are four tabs: 'Baseline', 'Outcome', 'Queries (1)', and 'Adverse Events'. The 'Outcome' tab is selected and circled in red. Below the tabs is a large light blue area with a '+ Add' button, also circled in red.

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'

The screenshot shows a patient data form with the following fields:

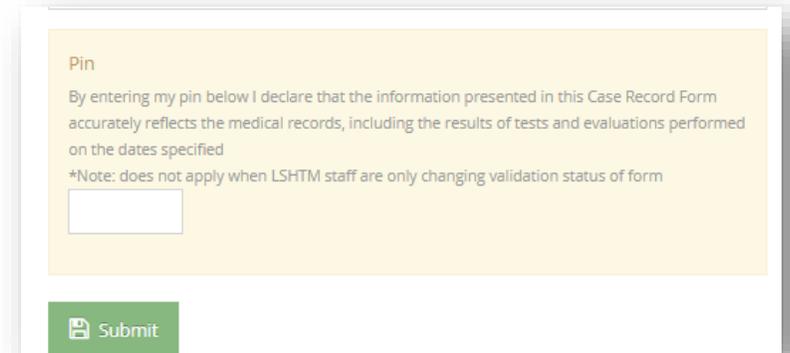
Database entry #	1
Screening ID	010-00001
Randomisation status	Randomised
Box-pack	2011-201
Site Country	Sunnyside Hospital United Kingdom
Source of data	Online
Patient initials	DS
Date of randomisation	08/10/2018
Patient outcome	

Below the form, there is a navigation bar with the following tabs: Baseline, Outcome, Queries (1), and Adverse Events. The 'Adverse Events' tab is highlighted with a red circle. Below the navigation bar, there is a blue button with a white plus sign and the text '+ Add Adverse Event', which is also highlighted with a red circle.

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

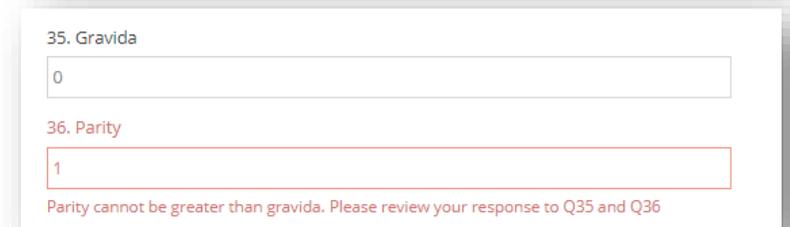


Pin

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

*Note: does not apply when LSHTM staff are only changing validation status of form

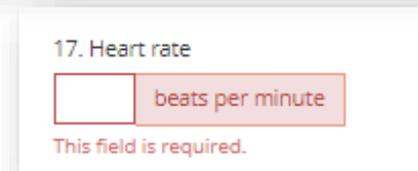
Submit



35. Gravida

36. Parity

Parity cannot be greater than gravida. Please review your response to Q35 and Q36



17. Heart rate

beats per minute

This field is required.

AFTER DATA ENTRY

Once data has been saved:

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

AE ID #4 - Patient Trial ID: 2011-201

Patient Details

Country	United Kingdom
Site & Site ID	Sunnyside Hospital, #10
Patient Initials	DS
Patient Trial ID (Participant ID)	2011-201
DOB or Age	(age 19)

Adverse Event Report Form [Queries](#)

[Edit](#) [Versions](#)

Patient Screening ID	010-00001
Site	Sunnyside Hospital
Site ID	10
Country	United Kingdom
Participant ID (patient trial ID)	2011-201

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



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

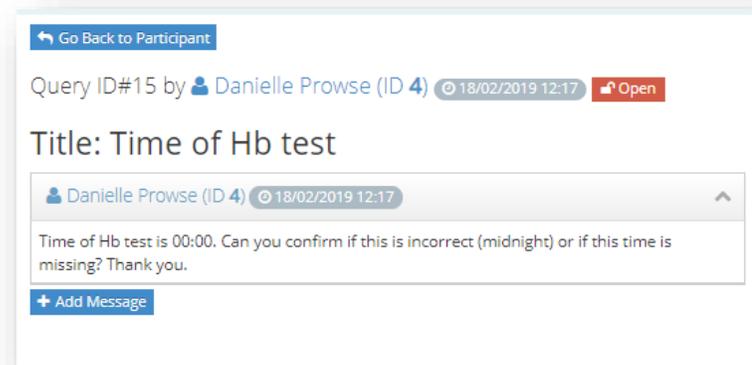
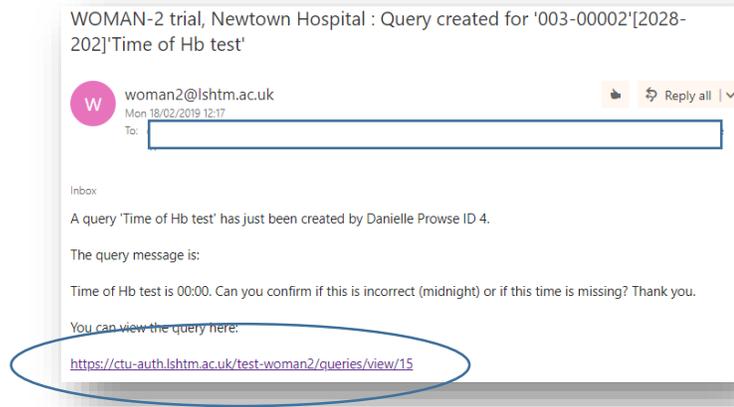


3. Prompted to log in to database

4. Automatically direct you to the query to view



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

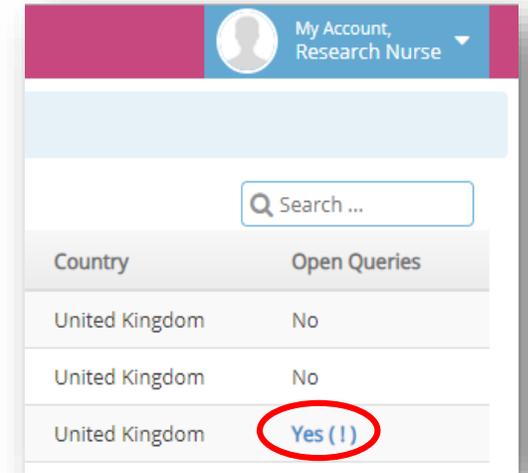


- CTU staff will review responses. Further clarification may be required
- CTU will close the query once resolved

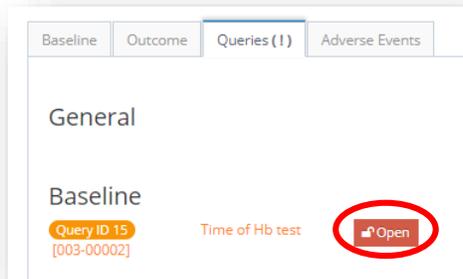
Please respond to all queries as soon as possible

MANAGING DATA QUERIES

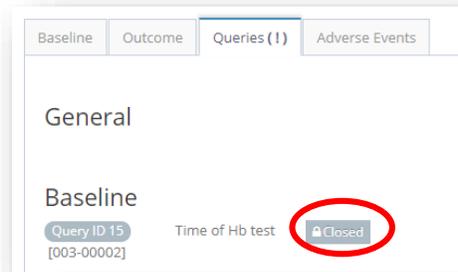
- Participant records with queries will be flagged as Open queries? [Yes(!)] on the patient homepage
- All open and closed queries for each participant will also be listed under the 'queries' tab for that participant
- All open queries are marked  Open
- Once a query is resolved, CTU will mark as closed 



Country	Open Queries
United Kingdom	No
United Kingdom	No
United Kingdom	Yes (!)

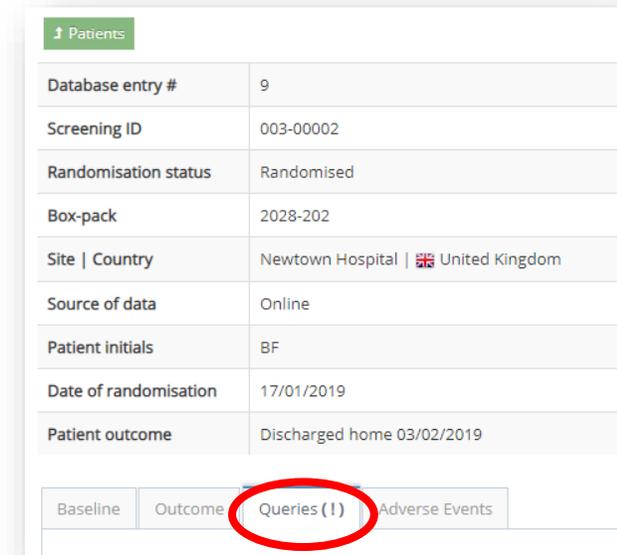


Open Query



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)



↑ Patients	
Database entry #	9
Screening ID	003-00002
Randomisation status	Randomised
Box-pack	2028-202
Site Country	Newtown Hospital  United Kingdom
Source of data	Online
Patient initials	BF
Date of randomisation	17/01/2019
Patient outcome	Discharged home 03/02/2019

Baseline Outcome **Queries (1)** Adverse Events

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 woman2

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
FINAL v1.0: 05 January 2019 Protocol Number: ISRCTN62396133 Page 1 of 10

WOMAN-2 How to use the trial database and send trial data
FINAL v1.0: 05 January 2019 Protocol Number: ISRCTN62396133 Page 2 of 10

WOMAN-2 How to use the trial database and send trial data
FINAL v1.0: 05 January 2019 Protocol Number: ISRCTN62396133 Page 4 of 10



Clinical Trials Unit
London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT

Tel: +44(0)20 7299 4684
Email: woman2@Lshtm.ac.uk
Website: woman2.Lshtm.ac.uk



LONDON
SCHOOL of
HYGIENE
& TROPICAL
MEDICINE

