



University of  
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**FEED1**

FLUIDS EXCLUSIVELY  
ENTERAL FROM DAY 1

# INSTRUCTIONS FOR DATA ENTRY IN THE MACRO DATABASE SYSTEM

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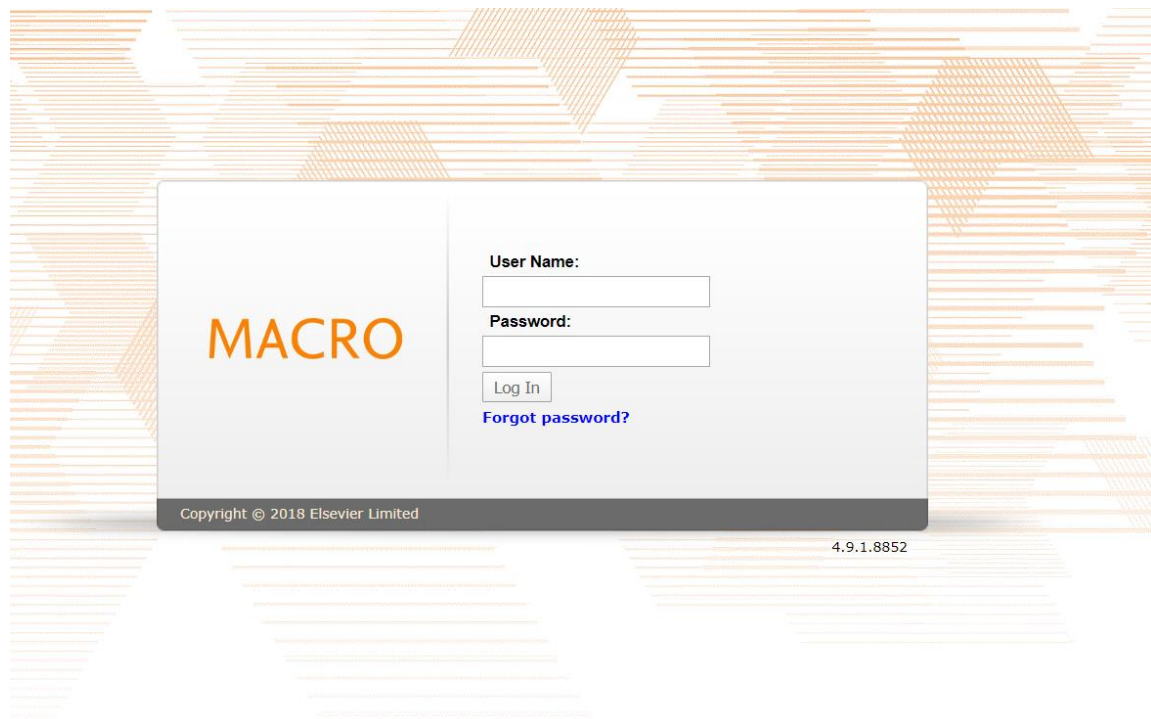
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## LOGGING ONTO THE MACRO DATABASE

Please use the Google Chrome browser or Internet Explorer to access the MACRO database. If you are using Internet Explorer please refer to the Compatibility Issues section of these guidelines (page 22) to ensure compatibility settings are set up correctly.

This is the web address to access MACRO:

<https://macro02.nottingham.ac.uk/>



Enter your user ID and your password that have been supplied to you and then select 'Log in'. The password is case sensitive. When you enter a password, the characters will appear as stars for security purposes.

**You must use your own log-in to enter data, under no circumstances should a log-in be shared with others.**

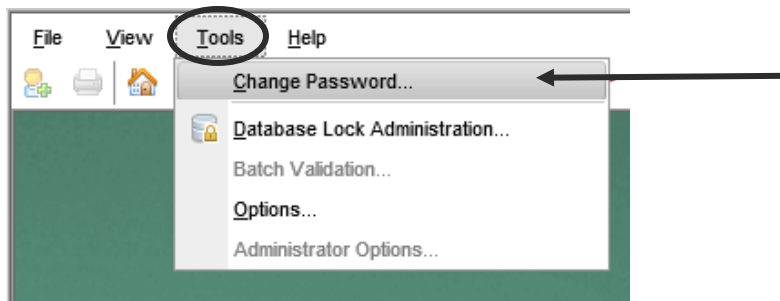
A screen will then appear showing the databases that the user has access to. The user should select the database that they would like to enter and click 'OK'.

## DATA ENTRY TRAINING

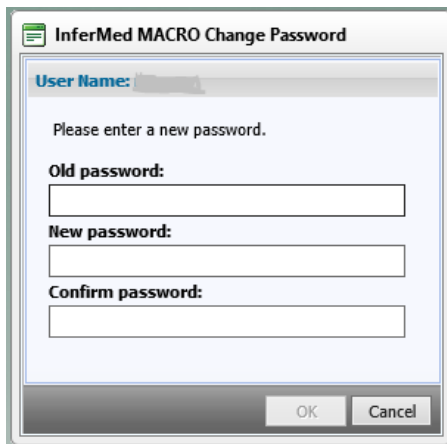
The trial manager will give a general overview of how to use Macro. You will be asked to enter data in to the test centre to learn how the database works and raise any questions that they may have. Only when the trial manager is satisfied that the user has a good understanding of Macro will the user be granted access to the live site in the trial database and real data can be entered onto the live database.

## CHANGING YOUR PASSWORD

Select Tools then 'Change Password'. The Change Password screen is displayed.



Enter your current (old) password. When you enter a password, the characters will appear as stars for security purposes. Then enter the new password that you have chosen. Enter it again for confirmation. This ensures that it is entered correctly.

A dialog box titled 'InferMed MACRO Change Password'. It contains a 'User Name:' field at the top. Below it is the instruction 'Please enter a new password.' followed by three input fields: 'Old password:', 'New password:', and 'Confirm password:'. At the bottom right, there are 'OK' and 'Cancel' buttons.

**Please use a password of exactly 8 characters with at least one numerical value and at least one upper case and one lower case character.**

Click OK to save the change or click Cancel to close the box without saving.

If you click OK, a message will be displayed to inform you that your password has been successfully changed.

## PASSWORD EXPIRY

All passwords expire after a 6 month time period. When the expiry date is near, you will be warned that your password is about to expire and asked if you would like to choose a new one.

Click OK to go to the Change Password screen and follow the steps above.

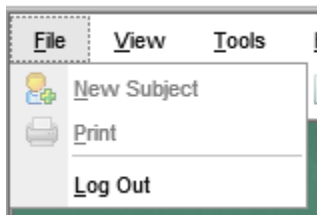
Once your password has expired, you will not be able to log in until you have specified a new one.

## IF YOU HAVE FORGOTTEN YOUR PASSWORD:

If you forget your password, e-mail the trial team with your details, so that a new password can be sent to you.

## EXITING MACRO

To log out, click File then logout.



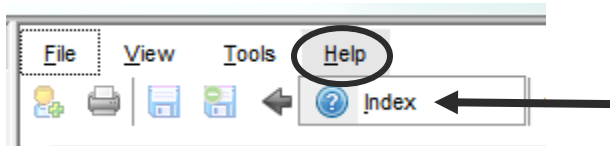
You will be logged out and the login screen will be displayed.

Do not exit the module by closing the browser window. This may lead to problems with locks being created.

## USING THE DATABASE

### 'HELP' FUNCTIONALITY

To get 'Help' on Macro, go to the 'Help' button on the toolbar, then click index.



A new window will open up which will describe the commonly required tasks for someone performing data entry.

The screenshot shows a web browser window with a blue header bar containing the breadcrumb path: [Home](#) > [Entering and Reviewing Data](#) > [Using the Data Entry/Review Module](#). Below the header is a green horizontal bar with the text "Welcome to the help for the Data Entry/Review module". A left-hand navigation menu is visible, listing: Welcome to MACRO, Administration, Designing Studies, Entering and Reviewing Data (highlighted), and Archiving and Extracting Data. The main content area contains a blue link: [Click here for a Quick Start guide to entering data...](#). Below this, a heading reads "Click the links below for help on some basic data entry tasks:" followed by a bulleted list of links: [Creating a new subject](#), [Finding an existing subject](#), [Opening the schedule for a subject](#), [Opening an eForm](#), [Entering data](#), [List of common popup messages](#), [Status and information icons](#), [Searching for response data](#), [Searching for DCRs](#), and [Searching for SDVs](#). Another heading reads "Click the links below to get help on some of the differences between MACRO v3 and MACRO v4:" followed by a bulleted list of links: [Icon Comparison](#) and [Task Comparison](#). At the bottom of the main content area, it says "You can also use the Table of Contents, Index and Search facilities to find help. [More help on these...](#)". A final green horizontal bar contains the heading "Related Topics" and a link: [Using this help system](#).

## TIMEOUT PERIODS

Macro has a system time out period of 20 minutes. If the system is left unused for this timeout period it is assumed that the user has left their computer unattended. Any data that has been entered but not yet saved will be lost, therefore it is advised to save any entered data whenever you take a break from entering data, even briefly. If you are planning on taking a break from entering data it is advisable to logout of MACRO.

If you use the arrows to move between e Forms, please note that data will not be saved automatically before moving to the next screen, therefore it is especially important to ensure you save regularly.

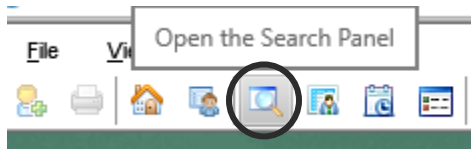
## CREATING A NEW PARTICIPANT

Once a participant has been enrolled/randomised in the randomisation system the MACRO system will automatically be synchronised so the participant will be visible in MACRO.

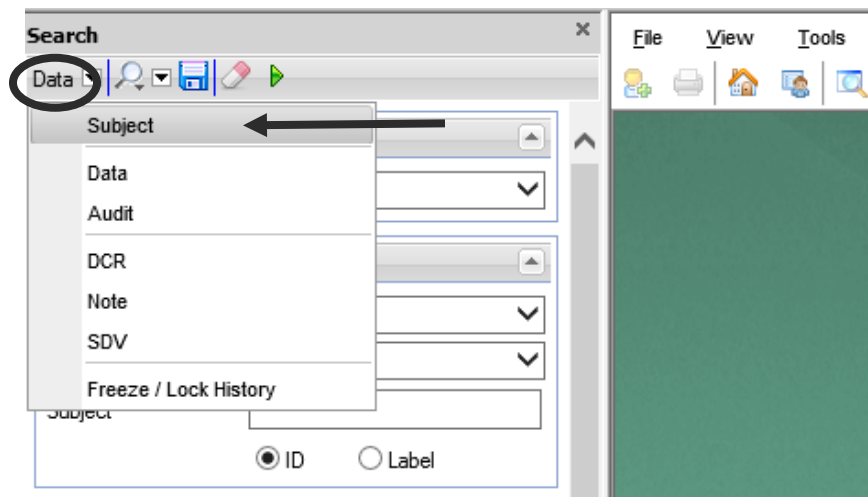
MACRO data entry forms will only open if a date of written consent is entered onto the randomisation system.

## SEARCHING FOR A PARTICIPANT

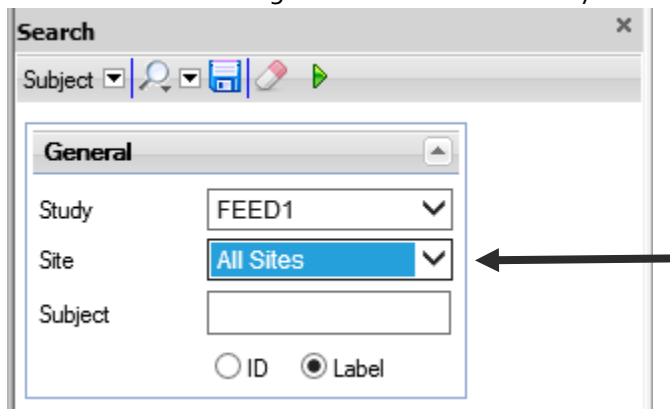
To search for a participant click on the search icon:



This will bring up the search bar. Click on 'Data', then 'subject'



This will then change the search bar so you can select your site from the dropdown list:



Then type in the trial number, MAKE SURE YOU HAVE CLICKED ON LABEL NOT ID:

**Search** [X]

Subject [v] [magnifying glass] [print] [eraser] [play]

---

**General** [up arrow]

Study: FEED1 [v]

Site: s99 [v]

Subject: 99067 [text box]

ID  Label

You can then click the green triangle or press enter to start the search. If the patient exists in MACRO their details will then appear.

Subject [v] [magnifying glass] [print] [eraser] [play]

**General** [up arrow]

Study: FEED1 [v]

Site: All Sites [v]

Subject: 99067 [text box]

ID  Label

| Status       | Study | Site | Subject ID | Subject Label       | Last Modified             |
|--------------|-------|------|------------|---------------------|---------------------------|
| [orange dot] | FEED1 | s99  | 62         | 99067-1 05-SEP-2019 | 2019/09/05 14:32:42 (GMT) |

Double click on the participant to bring up the 'schedule', which shows all the eForms that need to be filled in.

## SEARCHING FOR MULTIPLE BIRTH PARTICIPANTS

A separate subject entry is made for each infant of a multiple birth.

E.g. mother 99030 is randomised, but there are two separate MACRO entries for her twins. Number of infant by birth order is indicated by the number after the subject label (e.g. 99030-1; 99030-2 etc.)

Search for the infant using the trial number, and select the correct infant from the panel on the right:

Subject [v] [magnifying glass] [print] [eraser] [play]

**General** [up arrow]

Study: FEED1 [v]

Site: s99 [v]

Subject: 99030 [text box]

ID  Label

| Status       | Study | Site | Subject ID | Subject Label       |
|--------------|-------|------|------------|---------------------|
| [orange dot] | FEED1 | s99  | 23         | 99030-1 20-AUG-2019 |
| [orange dot] | FEED1 | s99  | 24         | 99030-2 20-AUG-2019 |




# NAVIGATION


## NAVIGATING AROUND THE SCHEDULE

Below is a picture showing the Schedule screen for a participant:


| FEED1/s99/99067-1 05-SEP-2019 | Enrolment | Baseline | Logs | Gut Signs | Late-onset invasive infection | SAE |
|-------------------------------|-----------|----------|------|-----------|-------------------------------|-----|
|                               | ✓         | ☀        |      |           |                               |     |
| Enrolment                     | ✓         |          |      |           |                               |     |
| Neonatal                      |           | ☀        |      |           |                               |     |
| Daily feed                    |           |          |      |           |                               |     |
| Hypoglycemia details          |           |          |      |           |                               |     |
| Hospital Discharge            |           |          |      |           |                               |     |
| Hospital Discharge (contd.)   |           |          |      |           |                               |     |
| Transfer                      |           |          |      |           |                               |     |
| Protocol Deviations           |           |          |      |           |                               |     |
| Withdrawal                    |           |          |      |           |                               |     |
| Death                         |           |          |      |           |                               |     |

|  |   |
|--|---|
| Late-onset invasive infection (part 3) |  |
| Antibiotic details                     |  |
| Antifungal details                     |  |
| Sign-off Statement                     |    |


**eForms ready to be filled out** – the eForms that are available to be filled are blue boxes . Double click on the box to open the eForm.

**eForms greyed out** – the eForms that are greyed out  are not available to be entered at the time. This may be due to the participant not requiring those forms, or because the previous forms have not been filled out to unlock them.

**Missing data symbol** – eForms that have an orange symbol have missing data that needs to be addressed.

|          |   |
|----------|---|
| Neonatal |  |
|----------|---|


**Green tick symbols** – the green tick on the schedule shows that the eForm has been completed and that there is no missing data.

|           |   |
|-----------|---|
| Enrolment |  |
|-----------|---|

**Enrolment** – if you double click on the green tick next to Enrolment in the baseline column, you can see the participant details that have synchronized from the randomization system. To return to the schedule, press the cross at the top of the page.

Visit: Enrolment eForm: Enrolment ✓

Visit Date: Laboratory: None selected eForm Date:

**FEED-1** Trial Ref 1704 

**Enrolment** Baby No. 1 Selected Infant 99067-1 05-SEP-2019

**IMPORTANT: information on this form is a read only copy of data entered onto the randomisation system**

Infant's date/time of birth 05-SEP-2019 14:01


Date of Randomisation 05-SEP-2019

Randomisation No. R20055

Written consent date 05-SEP-2019 ✓

Date/time updated from rando system 05-Sep-2019 14:32:37

## NAVIGATING THE EFORM

**FEED-1** Trial Ref 1704 

**Neonatal** Baby No. 2 Selected Infant 99021-2 20-AUG-2019

Was this infant delivered via caesarean section?

Were the membranes ruptured >24 hours before delivery?

Was this infant's heart rate >100 bpm at 5 minutes of age?

What was this infant's temperature when first admitted to the first neonatal unit?  (degrees centigrade)

What was this infant's worst base excess measured within 24 hours of birth?

Was this infant receiving respiratory support at the time of randomisation?

If yes, select support ( all that apply)

Mechanical ventilation

CPAP

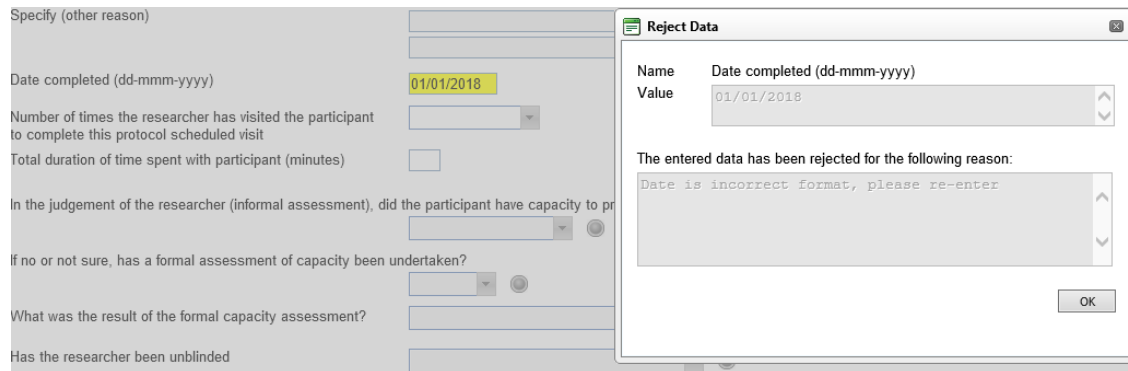
High flow oxygen

Any other supplemental oxygen


Use the dropdown list to select the answers to each field. Fields that have a grey circle next to them are not available to enter data into.

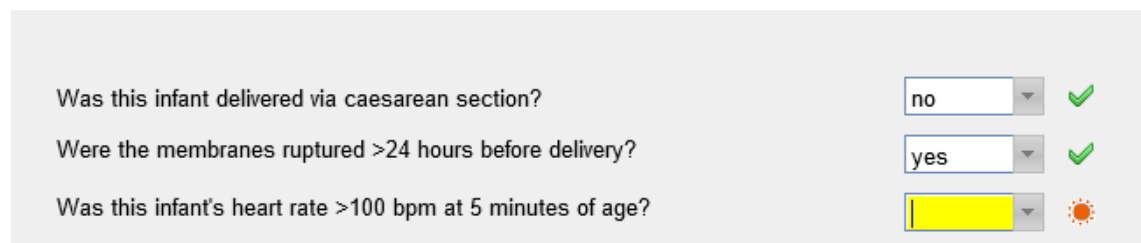
Mechanical ventilation

To enter dates, type in the box using the format DD-MMM-YYYY if this is done incorrectly a warning will occur directing you to change the format.



Click on the save button at the top of the screen to save the data entered in the fields.

Any fields that have not been completed have an orange  warning next to the field, those that are complete have a green tick after the form has been saved.

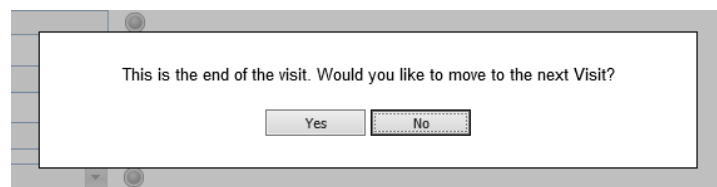


There are four save buttons, the icon on the most left saves the eForm but does not navigate away from the form. The inner left icon next to the arrow saves the data and navigates you back to the last eForm. The inner right icon saves the data and navigates to the next open eForm, and the outer right icon saves the data and navigates you back to the schedule form.



To close the eForm without saving anything click the red cross.

To navigate to the next available eForm without saving use the arrow buttons at the top of the page, or use the arrow keys on your keyboard. If no more eForms are available in that **visit (e.g. baseline)** then you will be asked if you wish to move to the **next visit.**



## QUICK NAVIGATION

To navigate between eForms quickly, you can use the 'Schedule QuickView Panel'.

Click on the icon of a calendar to bring up a list of all eForms for the participant on the left side of the screen.

The screenshot shows the 'Schedule QuickView' panel on the left, listing various eForms for participant 'FEED1/s99/99067-1 05-SEP-2019'. The 'Neonatal' section is expanded, showing a list of eForms with status icons: green checkmarks for completed, yellow triangles for warnings, red suns for missing data, and grey squares for not completed. The main window displays the 'FEED-1 Neonatal' form, showing fields for 'Trial Ref' (1704) and 'Baby No.' (1). The form content includes questions about delivery method, membrane rupture, heart rate, temperature, and respiratory support.

You can then see which forms have been completed ( ✓ ), have a warning ( ⚠ ), missing data ( ☀ ), have not been completed ( □ ), or are not able to open ( ■ ).

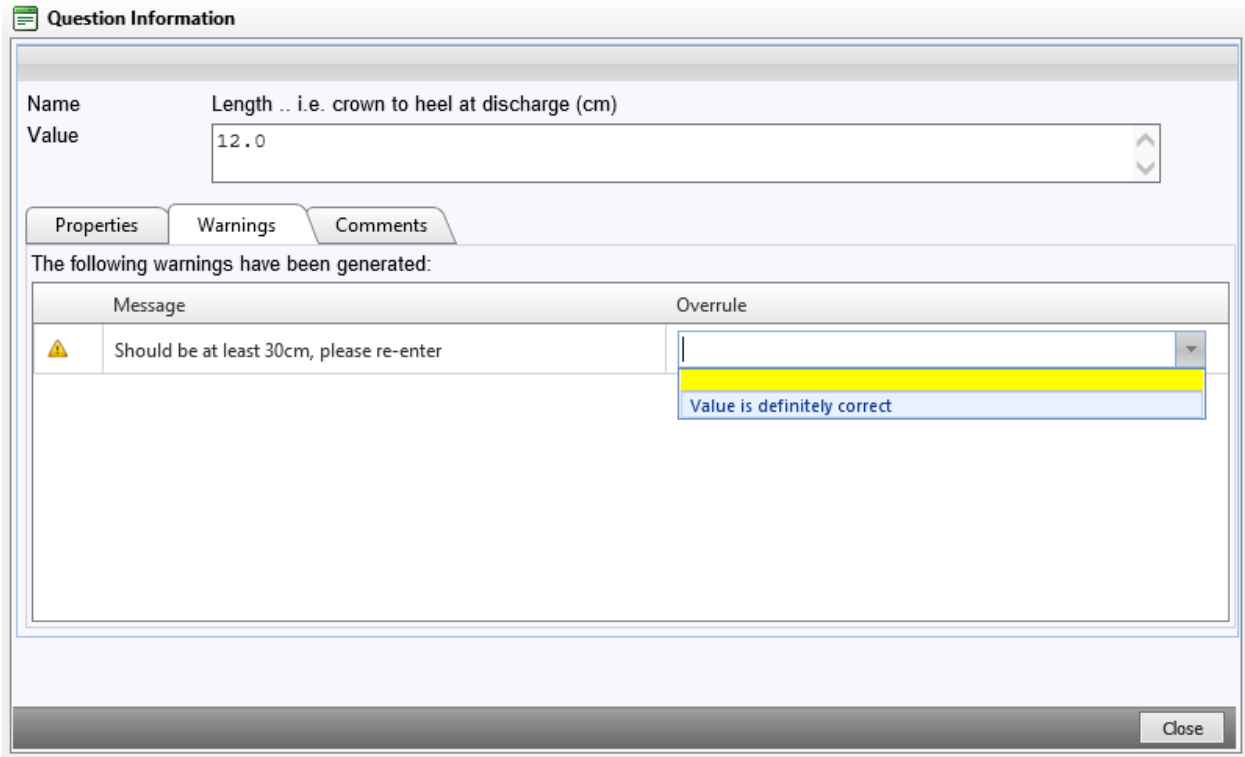
## OTHER SYMBOLS ON EFORMS

### WARNINGS

If a field contains an unexpected value, a warning symbol will appear.

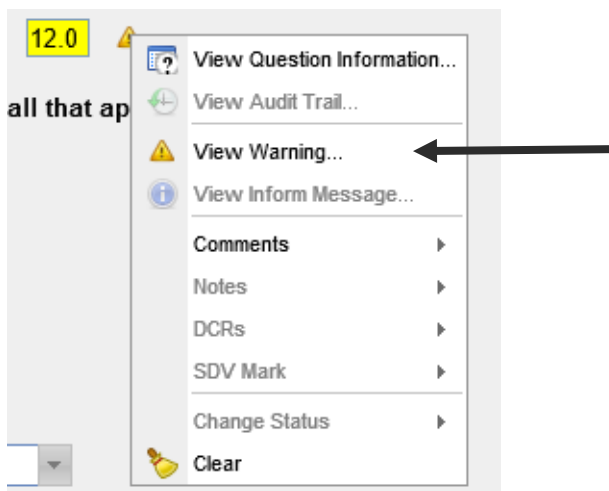
Length of infant i.e. crown to heel at discharge (cm)  ⚠

You will be asked to overrule the warning when it is first entered. An example is given below, click on 'value is definitely correct,' to overrule the warning if the data is correct. Please review the data to ensure it is correct before you overrule the warning.



If the warning is not overruled when first entered, it can still be overruled at a later date. When reviewing the data, the data team at the NCTU will raise a query to check the data asking for this to be ammended or overruled.

Right click on the warning symbol, then click on 'view warning'.



The warning screen from before will then appear for you to then overrule the warning.

## FROZEN/LOCKED DATA

Participants' data can be frozen or locked by the NCTU to prevent anyone making changes to it. You cannot make any changes to locked/ frozen data or add comments.

Frozen data are indicated by the freeze icon ❄️ on an eForm and in the schedule, and also by green text in the Data Browser.

Locked data are indicated by the lock icon 🗝️ on an eForm and in the schedule, and also by red text in the Data Browser.

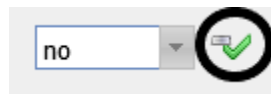
If you need to make a change to data to that has already been frozen, please contact the NCTU to request the data be unfrozen/unlocked.

## CHANGES TO RESPONSE DATA

If you change the data in a field in an eForm, a message will appear asking you to give a reason why the answer has changed.

Select from the dropdown menu the reason for the change and click OK.

After the eForm has been saved, you will notice a grey bar next to the form you have changed. This is for the NCTU to track how many changes have been made to a field.



This bar may be one 📄, two 📄, or three 📄 bars high signalling whether the field has been changed once, twice, or three or more times respectively.

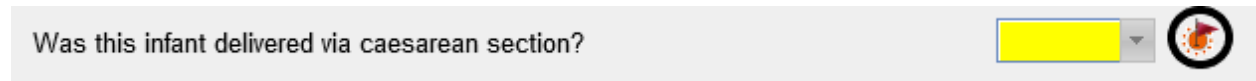
## DATA CLARIFICATION RECORDS (DCRS)

A DCR is a query raised at the NCTU against an individual question. The trial/data manager may be concerned about the accuracy, completeness or validity of the data, or may require additional explanations regarding a warning overrule or other action undertaken by data entry staff.

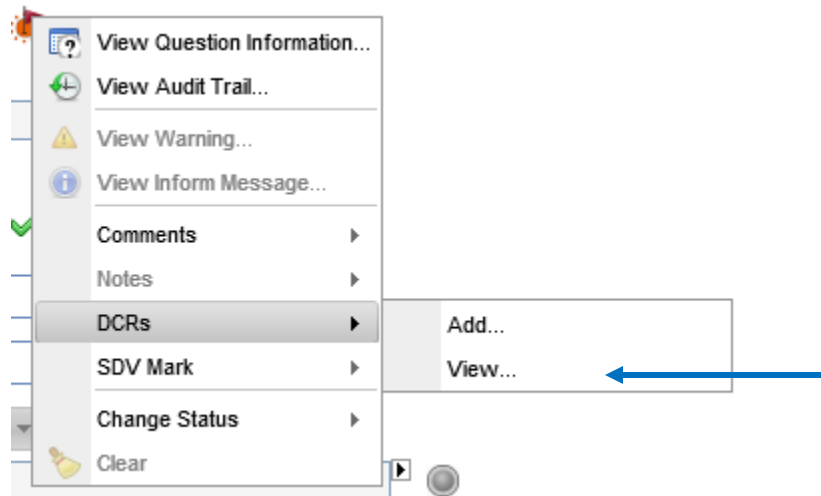
## ANSWERING A DCR

A DCR is shown by a flag.

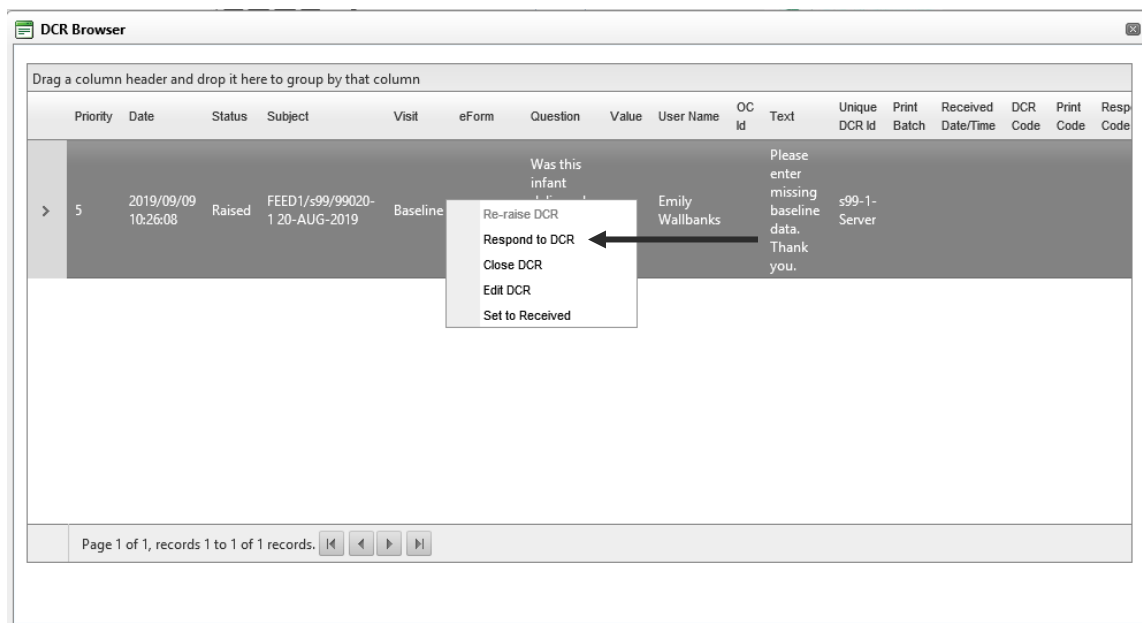
A red flag is a query from the NCTU to be answered by the site user (you).



To answer this query, right click on the flag, and click on 'DCR', then view.

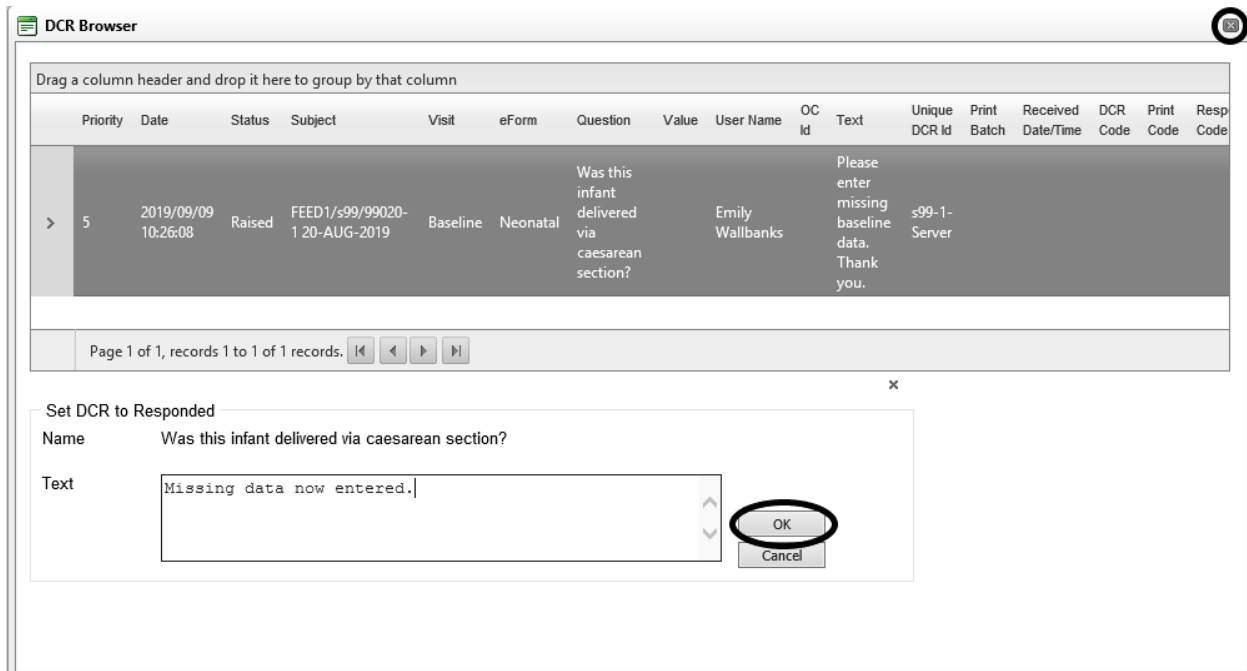


Right click on the DCR then click on Respond to DCR.

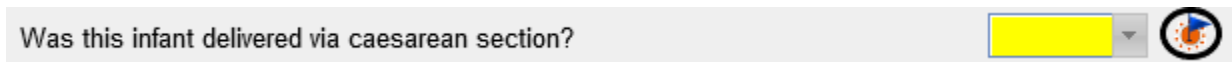




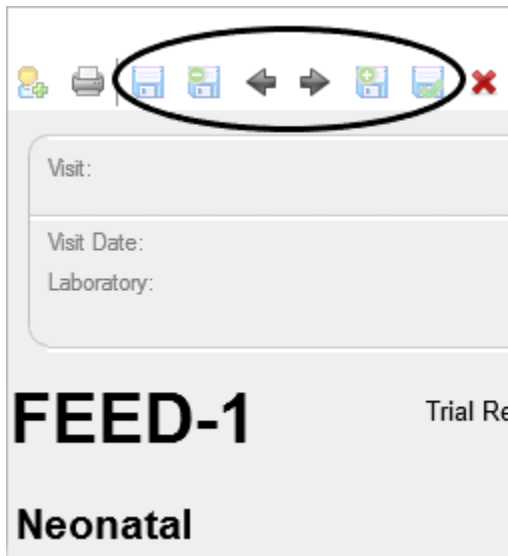
You can then enter text to respond to the DCR. Click OK to submit. Exit the DCR by clicking on the X in the top right corner of the DCR screen. You can then update the database accordingly with the DCR request.




The DCR flag has now changed from red to blue signalling that the DCR has been responded to.




Once finished save the form using the save button at the top of the screen.



A green flag represents when NCTU has closed the query because they are happy with the data provided.

Was this infant delivered via caesarean section?  

If they are not happy, NCTU will re-raise the query and the flag will return to red that you need to respond to.

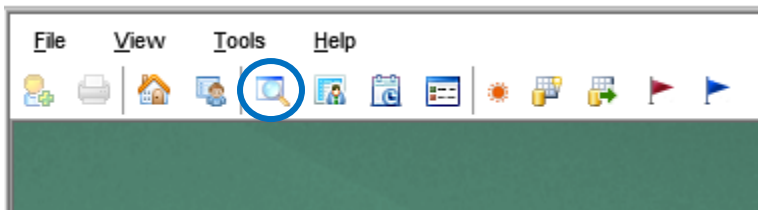
Was this infant delivered via caesarean section?  

Please repeat the process until the flag is green.

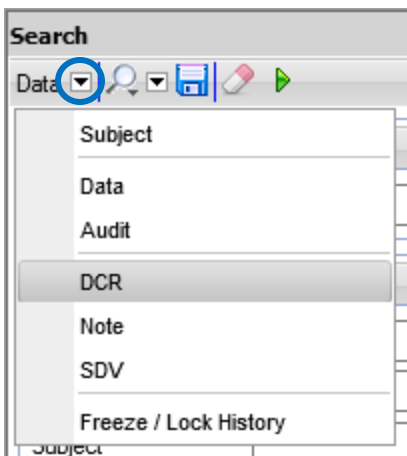
## SEARCHING FOR DCRS

To search for DCRs, it is a similar process to searching for a participant.

Once logged into MACRO, click on the search icon at the top of the screen.



Click on the arrow next to Data and select DCR.



Select your site, and tick the red flag option.

DCR | | | |

**General**

Study: FEED1

Site: s99

Subject:

ID  Label

**Study Level**

Visit:

eForm:

Question:

**User**

User:

**Date Range**

Search: None

From: 09/09/2019

To: 09/09/2019

**DCR**

Select/Clear All

Received

Batch Print:

Uni DCR Id:

DCR.Code:

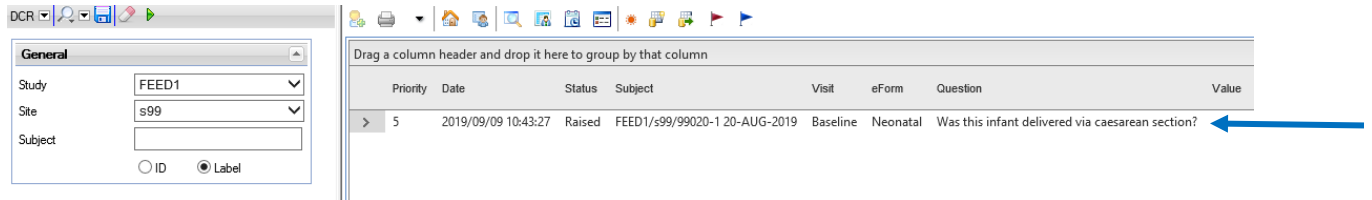
Print Code:

Resp Code:

Click enter or the green triangle to search.



All raised queries for your site will be listed here. Double click on the result line to open the form where the query has been raised.



From here you will be directed to the eForm with the raised DCR, and you can respond to the query.






















## BASIC MACRO FUNCTIONS

### KEYBOARD SHORTCUTS









The following is a list of all functions that can be performed using keys on your keyboard:

| Keys                               | Function                                    |
|------------------------------------|---|
| F1                                 | Opens the Macro help system                 |
| <b><i>In the schedule/menu</i></b> |   |
| Arrow keys                         | Move around the schedule                    |
| Enter                              | Open an eForm from the schedule             |
| <b><i>In an eForm</i></b>          |   |
| Tab                                | Move to the next question                   |
| Shift + Tab                        | Move to the previous question               |
| Arrow keys                         | Move between options in a category question |
| Space bar                          | Select an option in a category question     |
| F3                                 | Saves data and moves to the previous eForm  |
| F4                                 | Saves data and moves to the next eForm      |
| F5                                 | Prints current eForm                        |
| F6                                 | Saves data and closes current eForm         |
| F7                                 | Saves data and remains on the current eForm |
| F8                                 | Closes the current eForm                    |
| F9                                 | Clears Question Value                       |
| F10                                | Displays the Question menu                  |
| F11                                | Adds a comment                              |
| F12                                | Removes all comments from a question        |

## ICONS USED IN MACRO

| Description   |                                  |
|---|----------------------------------|
| <b>Question status</b>  |                                  |
|    | OK                               |
|    | OK Warning                       |
|    | Warning                          |
|    | Invalid                          |
|    | Not Applicable                   |
|    | Missing                          |
|    | Not Available                    |
|    | Inform                           |
|   |                                  |
|    | Frozen                           |
|    | Locked                           |
| <b>DCRs</b>   |                                  |
|   | Raised DCR                       |
|  | Responded DCR                    |
|  | Closed DCR                       |
|   |                                  |
| <b>Changes to response data</b>   |                                  |
|  | One change                       |
|  | Two changes                      |
|  | Three or more changes            |
|   |                                  |
| <b>Normal Ranges</b>  |                                  |
|  | High - above the normal range    |
|  | Normal - within the normal range |
|  | Low - below the normal range     |
|   |                                  |
| <b>eForm icons seen on the schedule</b>   |                                  |
|  | Disabled/Inactive eForm          |
|  | Blank/Active eForm               |


Buttons available when an eForm is open:

| Action  |   |
|---|---|
|    | Save and move to previous eForm in visit.         |
|    | Save and move to next eForm in visit              |
|    | Move to previous eForm in visit without saving    |
|    | Move to next eForm in visit without saving        |
|    | Save and keep eForm open                          |
|    | Save and close eForm and return to schedule       |
|    | Close eForm without saving and return to schedule |
|  | Print current eForm                               |

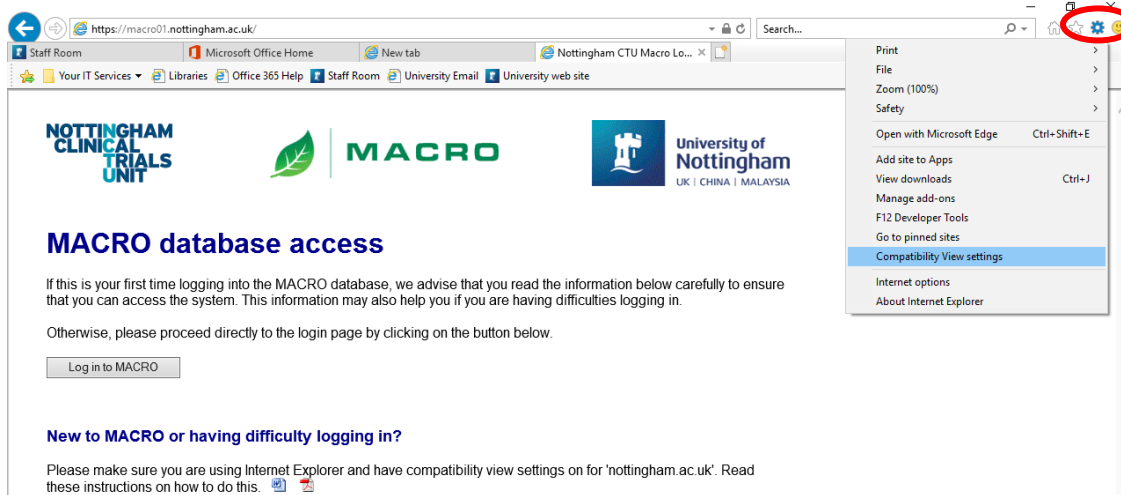
## COMMON ISSUES

### COMPATIBILITY ISSUES

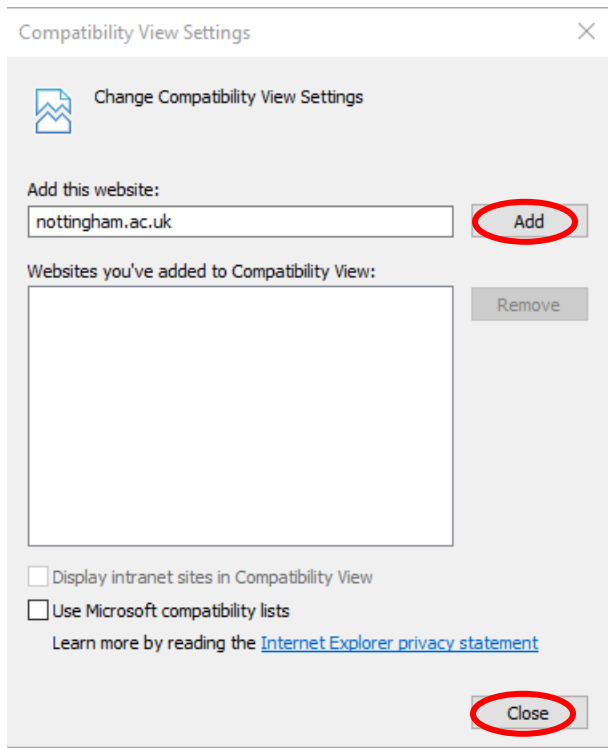
A common issue for users not being able to enter data is the compatibility settings are not set up correctly:

- Please use the Google Chrome browser or Internet Explorer to access the MACRO database
- If you are using Internet Explorer  as your browser when using MACRO, you will need to add Nottingham.ac.uk to your Compatibility View settings

To add, open Internet Explorer. Click the cog in the top right hand corner of the page. Select compatibility view settings.



Type in 'nottingham.ac.uk' into the Add this website box, and then click on the Add button.



Click on the close button. You should now be able to login and enter data in MACRO.

Any further problems please contact NCTU for further advice and guidance with regards to using the Macro database system.