



USER TRAINING GUIDE FOR USE WITH NWORTH MACRO V4 STUDY DATABASES



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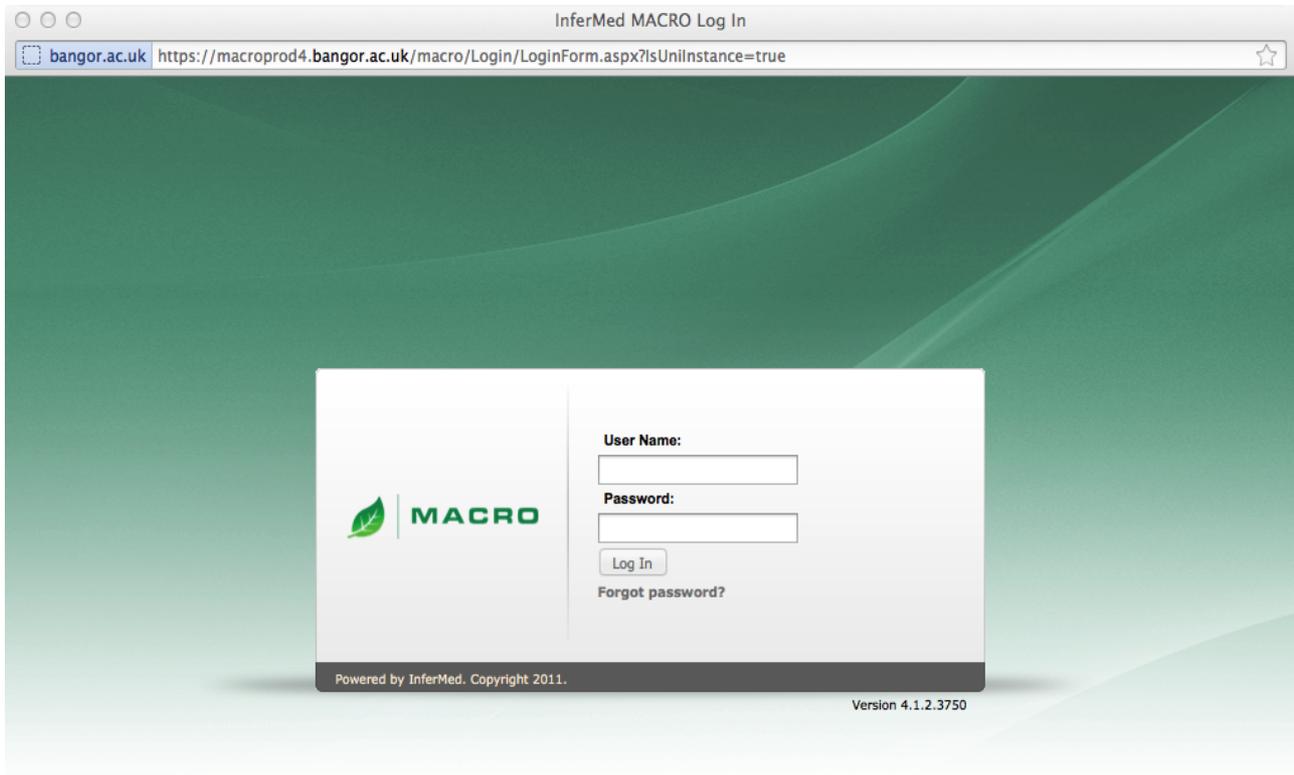
1. Before you start

Your username and password will have been provided to you by the N Worth IT team.

If you have not been issued with a username and password please contact **INSERT CONTACT DETAILS HERE** from your trial team.

2. Logging In

Enter the URL <https://macroprod4.bangor.ac.uk/macro/> into the address bar in either Internet Explorer or Firefox¹. You should see a page that looks like the one shown below:



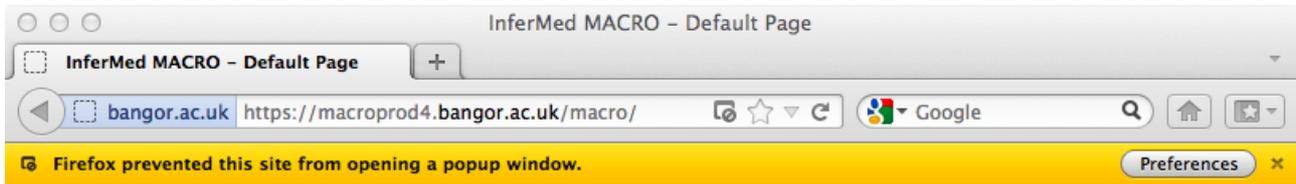
Login using the username and password provided.

¹ N.WORTH recommend using the latest version of Firefox EXTENDED SUPPORT RELEASE from <http://www.mozilla.org/en-US/firefox/organizations/all.html>

2.1 Popup blockers

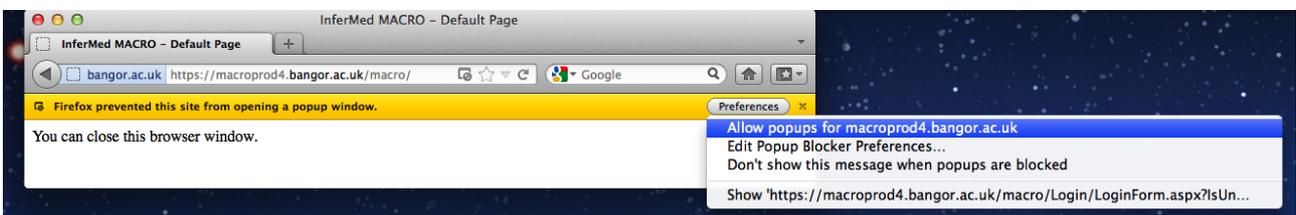
2.1.1 Firefox

If you are using firefox you might see an error message that says:



You can close this browser window.

If you do see this message, click the preferences next to the address bar to allow popups.



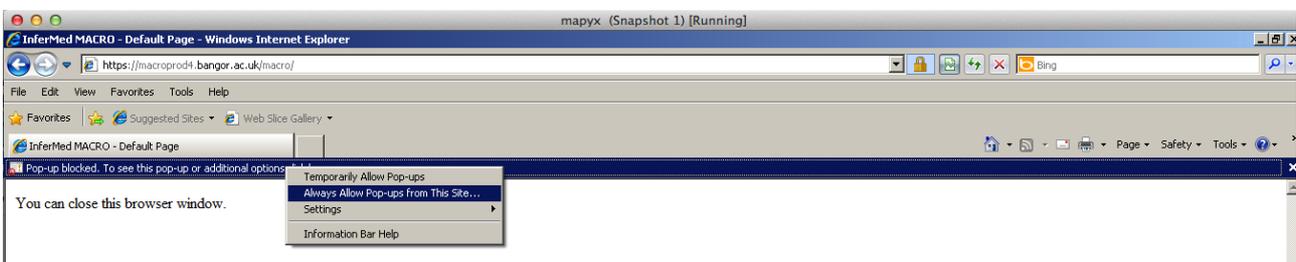
You will then need to re load the page and you should see the screen on the previous page.

2.1.2 Internet Explorer

If you are using internet explorer you might see an error message that says:



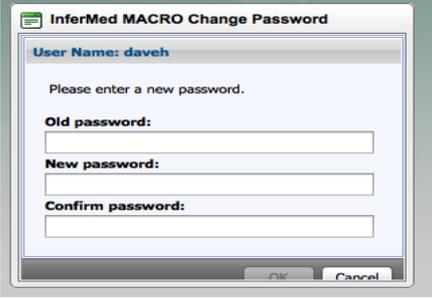
Click on the yellow bar and select always allow popups from this site.



Say yes to the prompt and you should be taken to the screen on the previous page.

2.2 Logging in for the first time.

The first time you log in to the MACRO system it will automatically ask you to change your password.



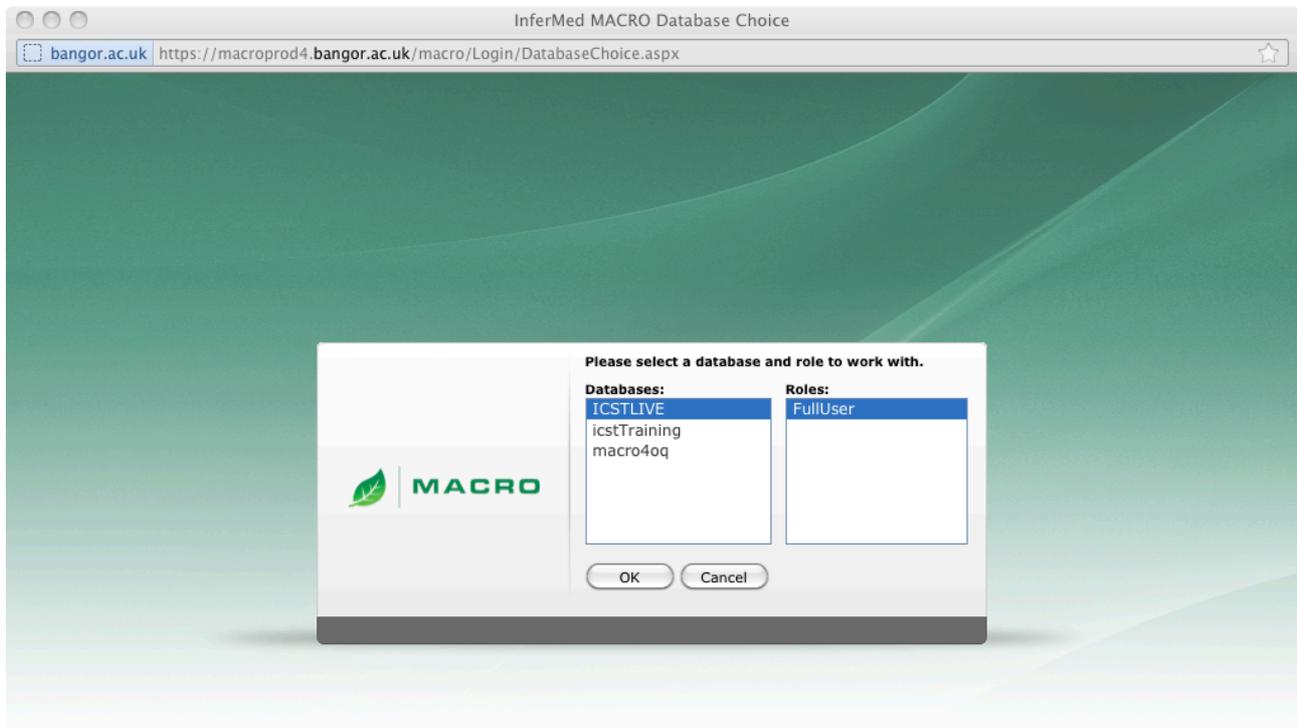
The screenshot shows a dialog box titled "InferMed MACRO Change Password". Inside the dialog, the "User Name" is displayed as "daveh". Below this, there is a prompt: "Please enter a new password." followed by three input fields labeled "Old password:", "New password:", and "Confirm password:". At the bottom of the dialog, there are "OK" and "Cancel" buttons.

When selecting your new password it must be longer than 6 characters, contain both numbers and upper and lower case characters. It must also not be based on any of your previous passwords as the system will not allow this.

Do not share your password with anyone. If you think your password might have been compromised then change it as soon as possible and also inform NWORTH IT immediately so that we can check to see if your account has been used inappropriately. If you lose or forget your password please contact NWORTH IT who will be able to create a new one.

2.3 Selecting a Database

After logging in you will be asked to select a database:



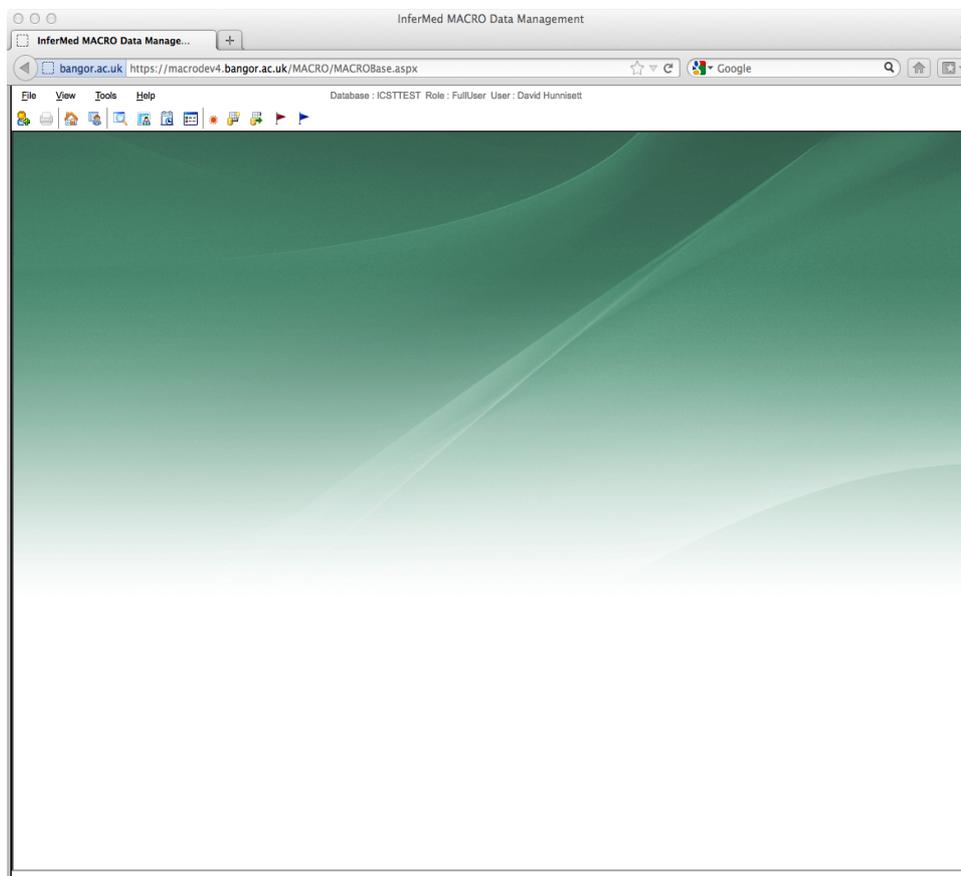
You will have a choice between \$DATABASE and \$DATABASETRAINING.

The TRAINING database is for training/testing. This can be used to experiment and learn how to use the MACRO database. \$DATABASE should only be used for adding live subject data.

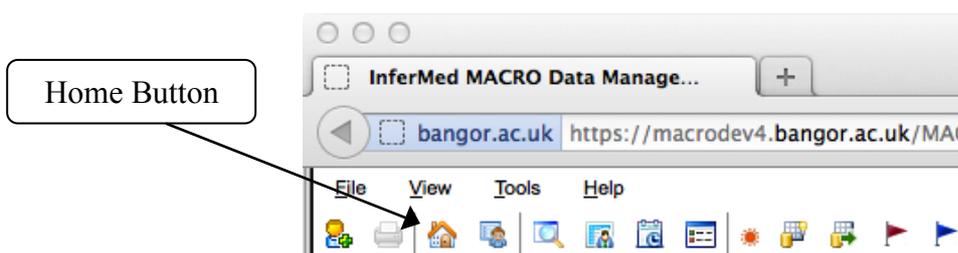
Live data should never be entered to the TRAINING database. Mock/Dummy data should never be entered to the live database.

2.4 After logging in

Once you have logged in and if needed changed your password, you will see a screen that looks like this:



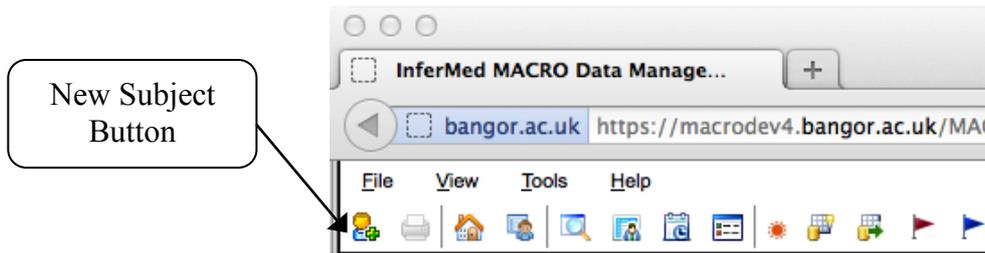
Note: Some of the options displayed above may not be present depending on the role(s) you have been assigned in the study. Most functions can be quickly accessed using the toolbar.



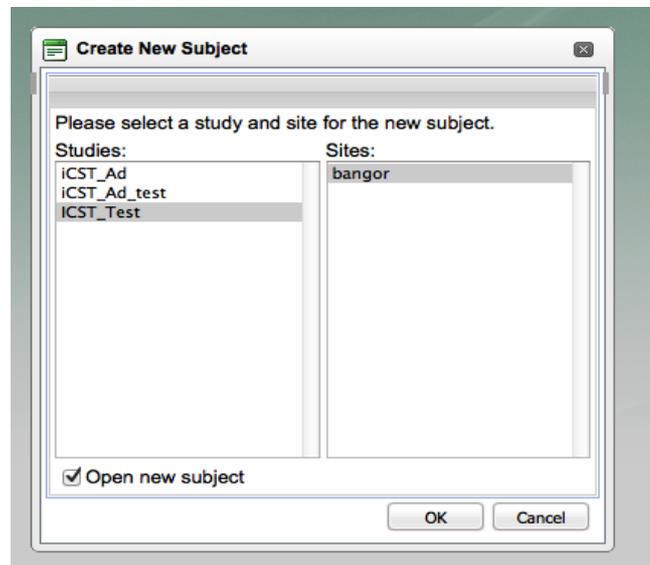
- It is possible to get back to this screen at any time by clicking the home link.

3. Adding a new subject

From the home screen click the new subject icon on the toolbar.



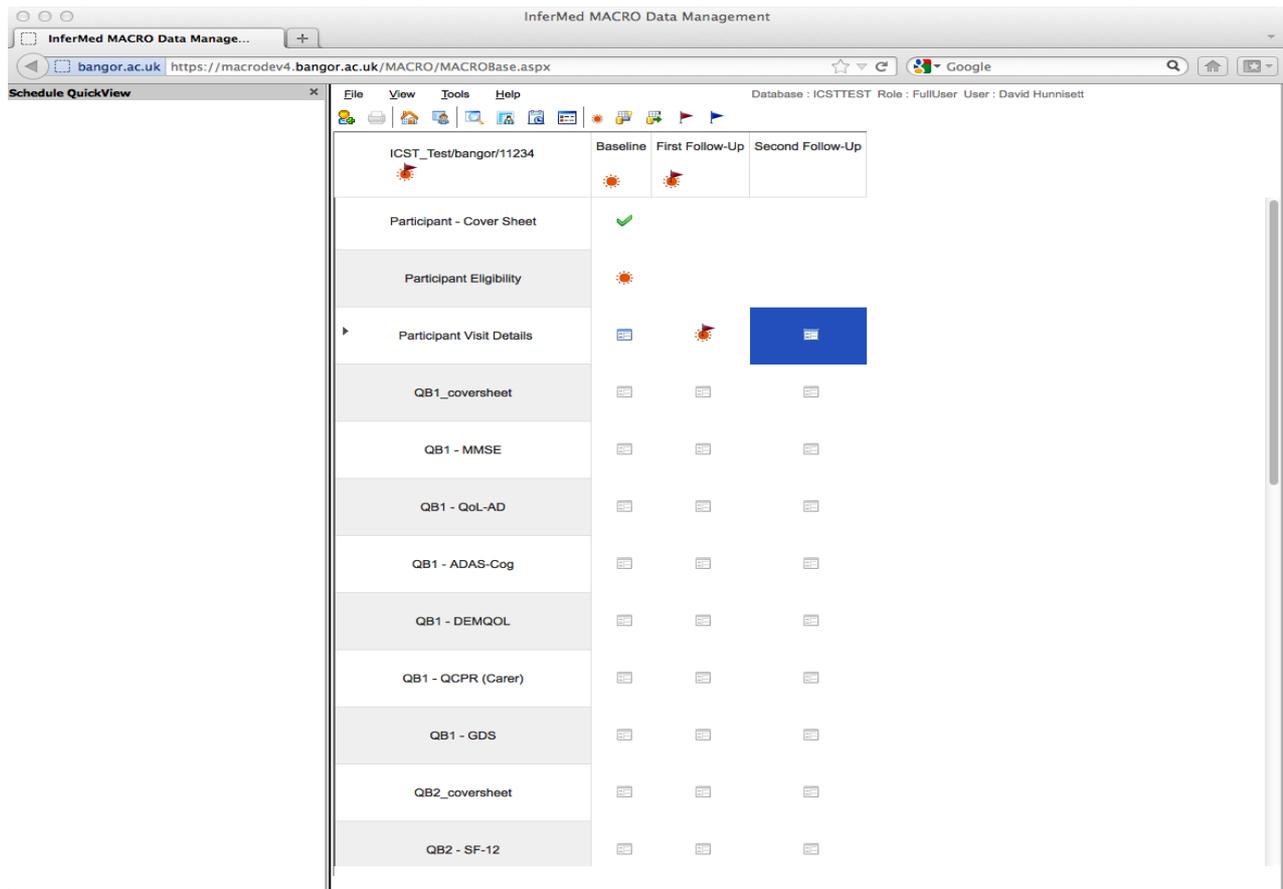
You will then be shown a screen like the one below:



In this example there is only one site where data is entered. However if, as a result of your role you can enter data at multiple sites then ensure that the correct site is selected from the menu. This database also contains more than one study. Check that both the site and study are correct and click ok.

3.1 Using the Visit Schedule

After creating a new subject the visit schedule is shown. The visit schedule will be specific for your study. In the example shown below the visit is shown as a column and the Case Report Form (hereafter referred to as a CRF) name is a row.



An active CRF can be visited by clicking on the CRF icon.

The  icon indicates that this CRF is available and data can be inputted.

The  icon indicates that this CRF is currently disabled due to the study rules. This will become available as the data from other CRFs are filled in. In the example these will become available when the CVR (CVR in this trial is an abbreviation for cover) sheet has been filled in.

The  icon shows that the form has been fully completed.

The  icon shows that the form has been started but not completed.

The  icon shows that the form has a discrepancy in raised against one or more of the questions. These are discussed in more detail in section 5 (Dealing with Discrepancies).

4. Interacting with an CRF

After selecting a CRF from the visit schedule you will be presented with a screen like the one shown below:

The screenshot shows a web browser window titled 'InferMed MACRO Data Management'. The address bar shows 'bangor.ac.uk https://macrodev4.bangor.ac.uk/MACRO/MACROBase.aspx'. The browser window contains a 'Schedule QuickView' sidebar on the left with a tree view of CRFs. The main content area displays a form for 'iCST: Individual Cognitive Stimulation Therapy for People with Dementia'. The form includes fields for 'Visit' (Baseline), 'eForm' (QB1_coversheet), 'Visit Date', 'eForm Date', and 'Laboratory' (None selected). Below this, the title 'iCST: Individual Cognitive Stimulation Therapy for People with Dementia' is displayed, followed by 'QB1 - Participant Questionnaire'. The form contains several fields: 'Participant Identity Number' (0000011234), 'Pack number' (535), 'Centre' (Bangor), 'Completed by' (empty), 'Signed?' (Yes), and 'Interview date' (empty). At the bottom, there is a question 'Move to Questionnaire 1 of QB1?' with radio buttons for 'No' and 'Yes'.

The save button saves the current state of the CRF. After saving the CRF you will be returned to the visit schedule.

BOTH SETS OF NAVIGATION BUTTONS SAVE THE FORM BEFORE MOVING TO THE NEXT CRF.

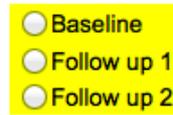
- The abort button will close the CRF without saving any changes and return to the visit schedule.

Within a CRF it is possible to fill the CRF quickly by using the tab key to jump between questions. Shift and tab will reverse the direction.

4.1 Question Types

4.1.1 Radio Questions

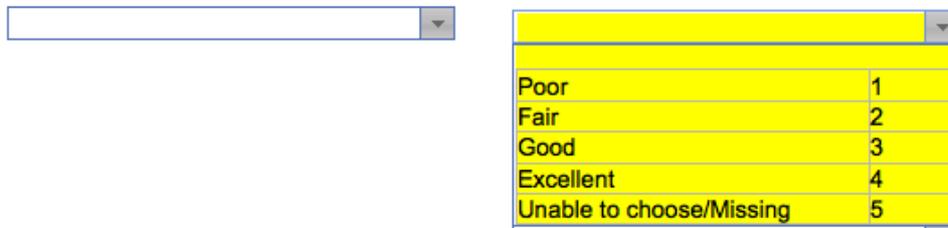
These are questions where you can choose from a small number (typically less than 3) options. They are commonly used for yes / no questions such as the example below. They can be set using the keyboard by using the up and down keys to choose the option and space to select it.



Baseline
 Follow up 1
 Follow up 2

4.1.2 Selection Boxes

These contain a larger number of choices than a radio box. You can select the desired option by using the mouse or by using the up and down arrows on your keyboard. You can also use the first letter of an option to jump to that option or use the number corresponding to the option.



Poor	1
Fair	2
Good	3
Excellent	4
Unable to choose/Missing	5

4.1.3 Text / Number / Date Questions

These questions allow entry by a keyboard. Under some circumstances (depending on the rules set for the study) moving to another question will trigger a check. If the entered value does not meet the required format (causes the rule to fail) then a message will be displayed and the system will prevent any further entry until the problem has been rectified.

4.2 Icons

There are 2 sets of icons that MACRO displays next to a question, major and minor marks.

4.2.1 Major



This question is yet to be answered.



This question has been completed.



This question is disabled (skipped) usually due to other answers.



This question has been marked as unobtainable.

4.2.2 Flag Icons

Flag Icons are shown over the main icon they are used to indicate notes,



A note has been attached to this question.



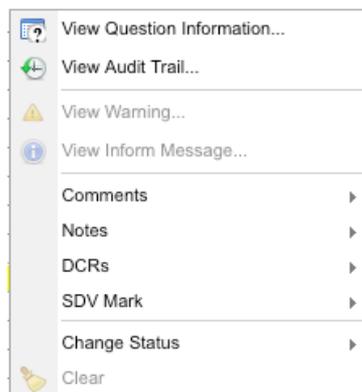
This question has been changed from its original value.



This question has a discrepancy raised. The flag will be shown over the major icon (see above). In this case the data has been entered and then a discrepancy has been raised. Once the discrepancy has been closed the flag will no longer be shown on the tick.

4.3 Question Menu

A menu can be accessed by right clicking on a question icon or by pressing the F10 key when the question has focus.



4.3.1 Clearing an answer

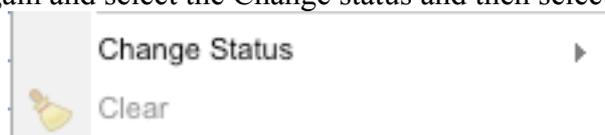
It may be necessary to clear an answer if a selection is answered by mistake so that a question can be marked as unavailable. To clear an answer select clear from the menu.

4.3.2 Marking a question as unavailable

Sometimes the answer to a question may not be available. There are often answers that cover this eventuality, if there are, then these should be used.

Sometimes (if a suitable option is not present) however it may be required to mark a question as unavailable:

1. If needed clear the answer to the question using the process above.
2. Show the menu again and select the Change status and then select the unobtainable option:



If the change to unobtainable option is not available make sure that the question has been cleared first. If the question is optional then there will be no option to mark it is unobtainable.

4.3.3 Notes comments, DCRs and Source Data Verification

To raise a discrepancy (Referred to as a DCR in the menu) select raise discrepancy. This is dealt with in more detail in section 5. Notes and comments are very similar. All Comments are public but it is possible to mark a note as private. The policy for notes, Source Data Verification (SDV) marks, discrepancies and comments will be unique to your trial. Please see your trial pack or contact your trial macro contact for details.

5. Dealing with Discrepancies

It may be necessary to raise a discrepancy. For example, the paper version was unreadable or macro was not allowing the correct value to be inputted.

5.1 Raising a new discrepancy

Discrepancies are raised against a question. To raise a discrepancy first display the question menu either by pressing F10 or right clicking on the symbol for the question. Select DCRs and then add.

YOU WILL THEN SEE A DIALOG LIKE THE ONE SHOWN BELOW:

The priority will depend on the nature of the discrepancy. Your trial should have guidelines for this. The OC Discrepancy ID should always be left blank.

Leave the OC
DCR id blank

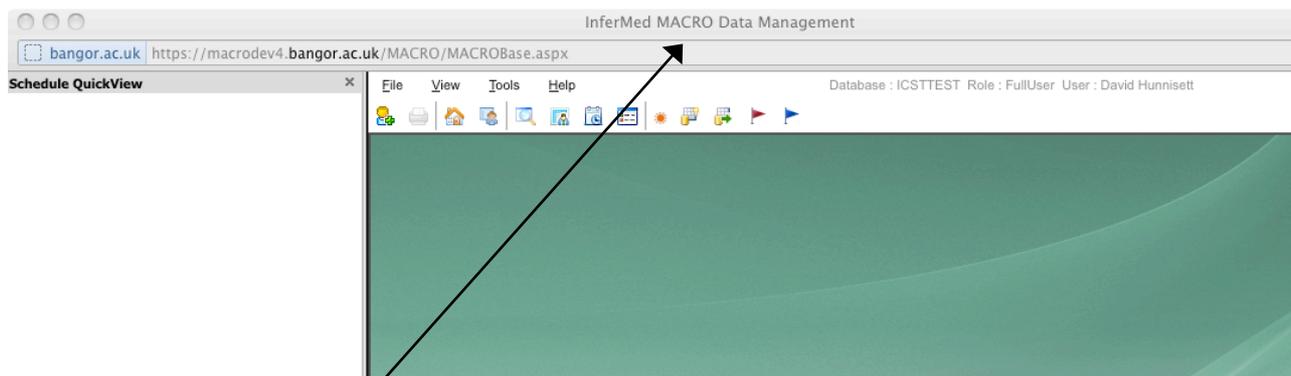
The screenshot shows a dialog box titled "New DCR - ICST_Test". It contains the following fields and controls:

- Name: PwD_QoL_AD6
- Value: [Empty text box]
- Enter DCR text: [Large text area]
- Additional Details:
 - OC DCR Id: [Empty text box]
 - Priority: 5 (with up/down arrows)
- Buttons: OK, Cancel

If the discrepancy is related to a problem with macro then please contact the NWORDH via email as well as raising a discrepancy.

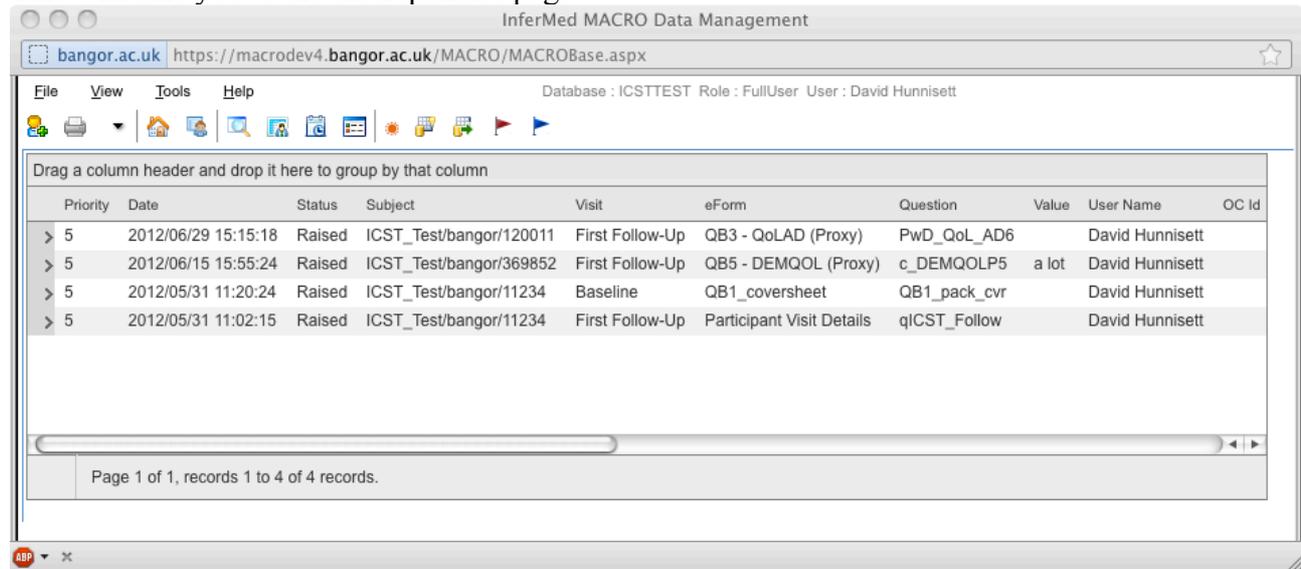
5.2 Viewing Raised discrepancies

From the home page there is a button that will take you to the list of open discrepancies.

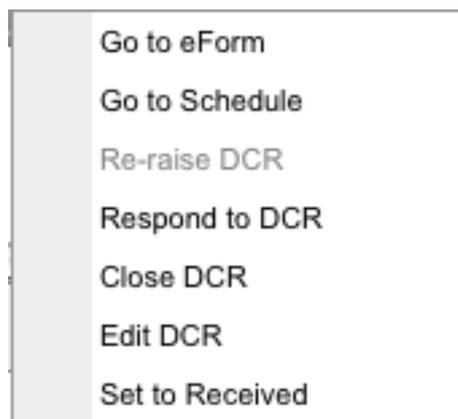


Button to show

This will take you to the discrepancies page:



Double clicking on a discrepancy will take you the question with the discrepancy.
Right clicking will bring up the menu below:



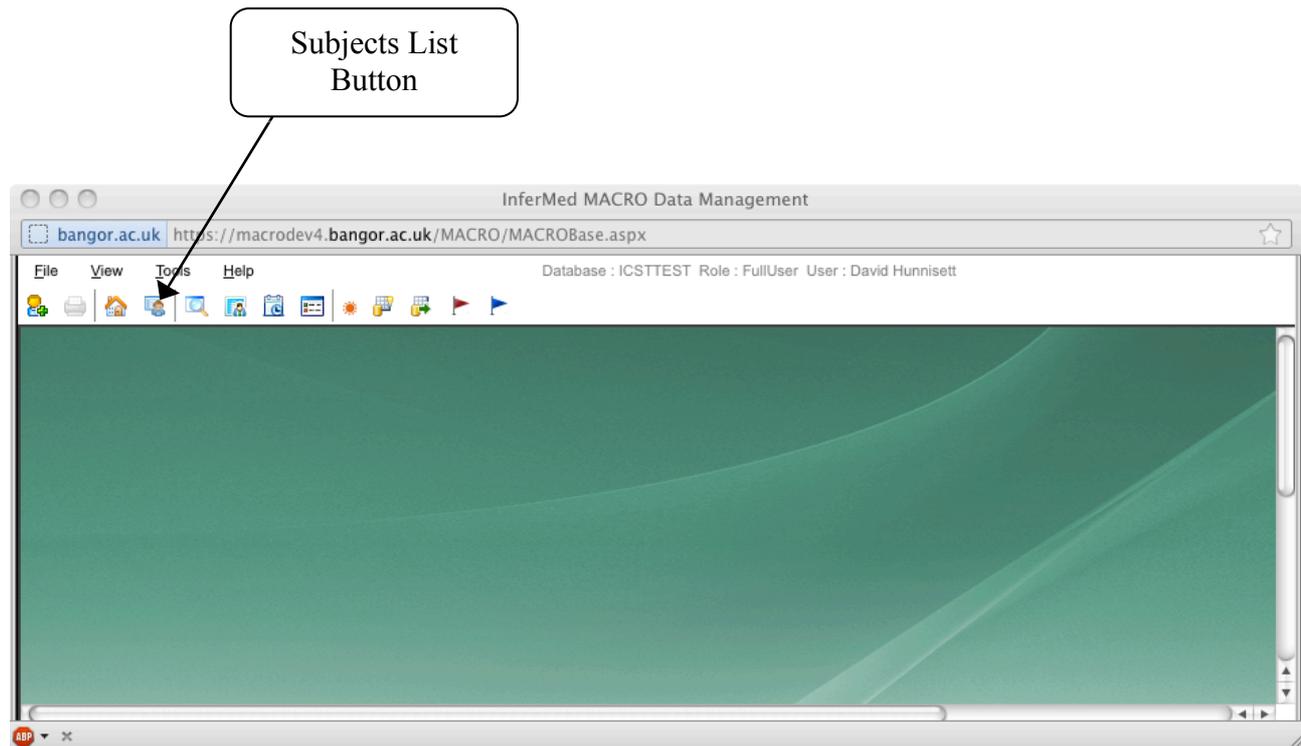
Using this menu you can respond to a discrepancy. Responding adds information to the history but does not close the discrepancy. Closing the discrepancy should be used when the discrepancy has been completely dealt with.

6. Editing an existing subject

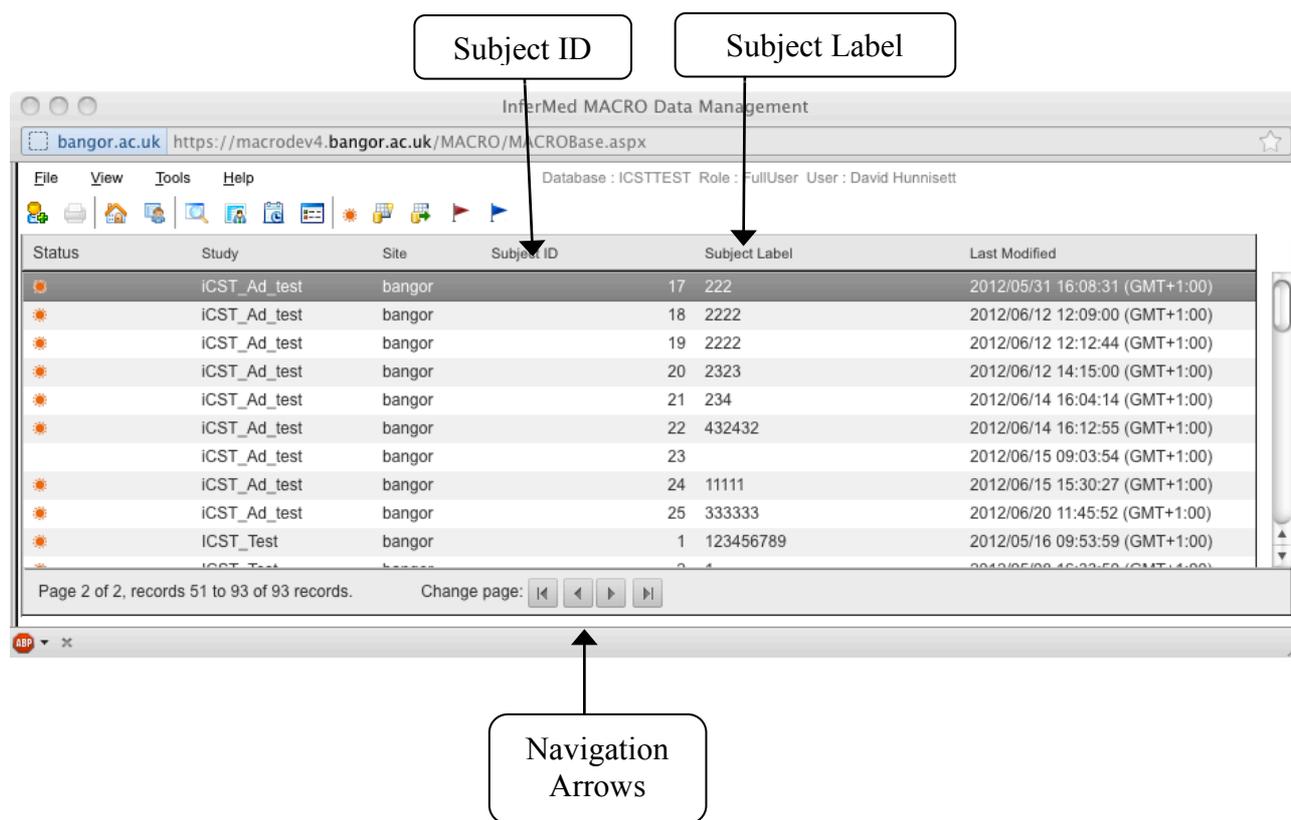
There are three ways to edit an existing subject. They can be found either by using the subject list, by using the search function or by using the subjects menu.

6.1 Using the Subject List

The subject list can be accessed by clicking on the View Subject List button.



The page will show a list of subjects.



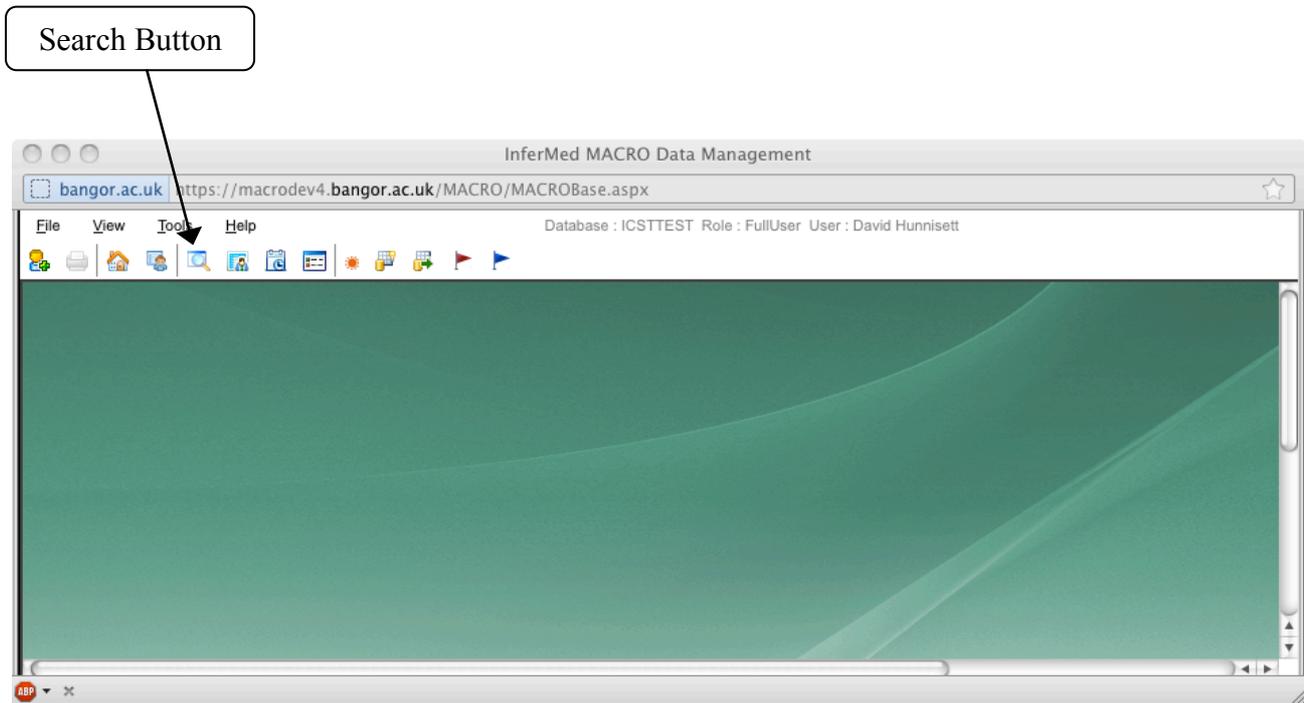
Clicking on an individual subject will take you to the subject visit page. If there are more than 50 subjects then the list will only show the first 50 subjects. To view the next 50 subjects use the navigation arrows.

CLICKING ON ONE OF THE HEADINGS WILL SORT THE LIST BY THAT HEADING E.G. CLICKING ON LAST MODIFIED WILL SORT THE LIST BY LAST MODIFIED DATE.

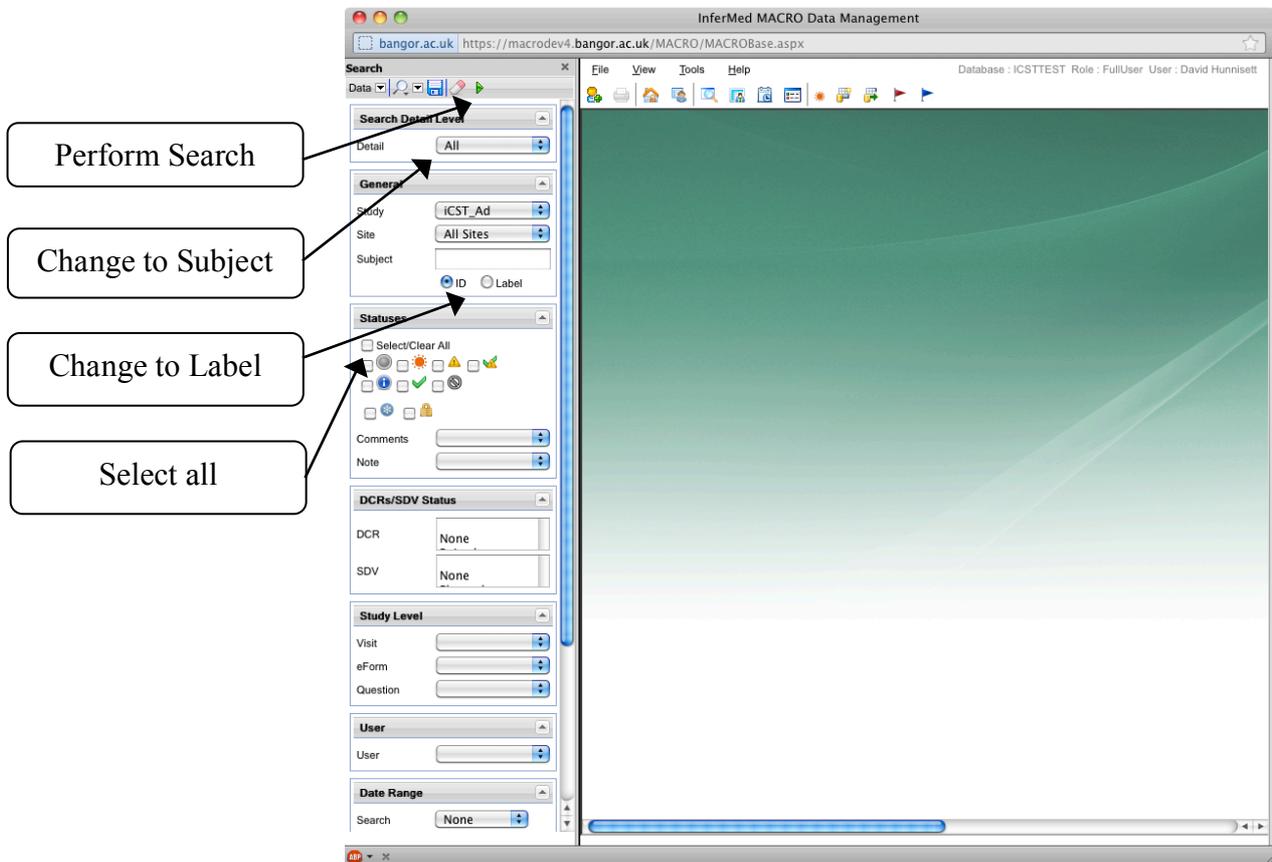
The Subject number is automatically assigned by macro and will always be unique. The subject label is the subject ID used within the trial. If there is no label it is because the questions needed to set the label have not yet been answered.

6.2 Using the Search Function

ON THE TOOLBAR THERE IS A SEARCH ICON.

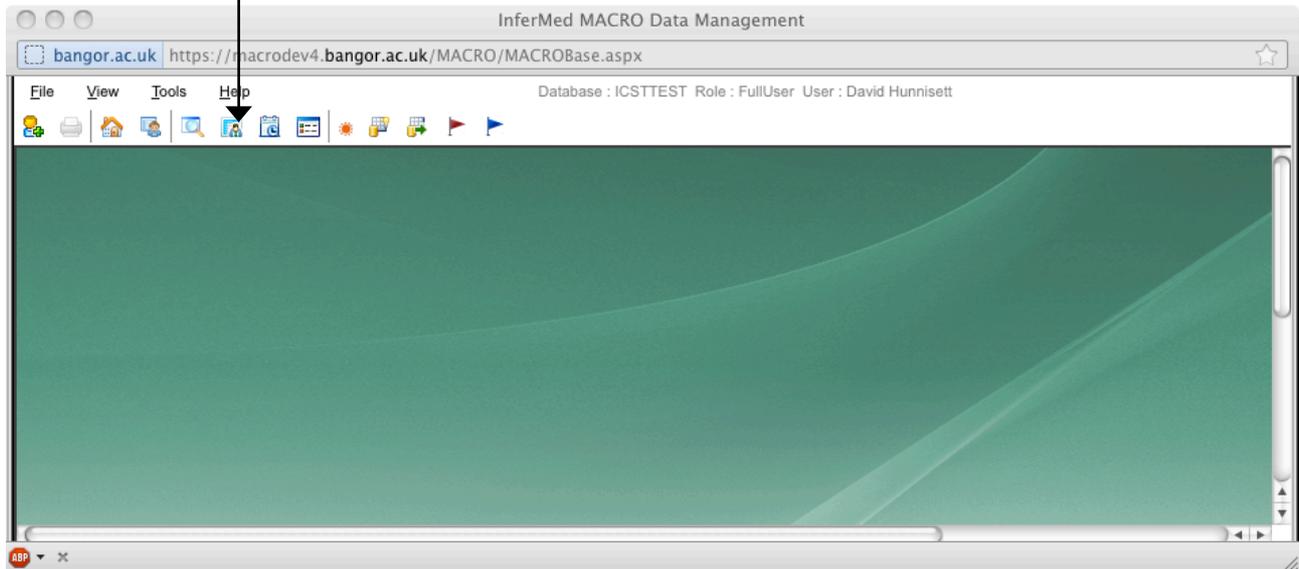


After opening the search menu select subject from the search detail level, Label from the general section.

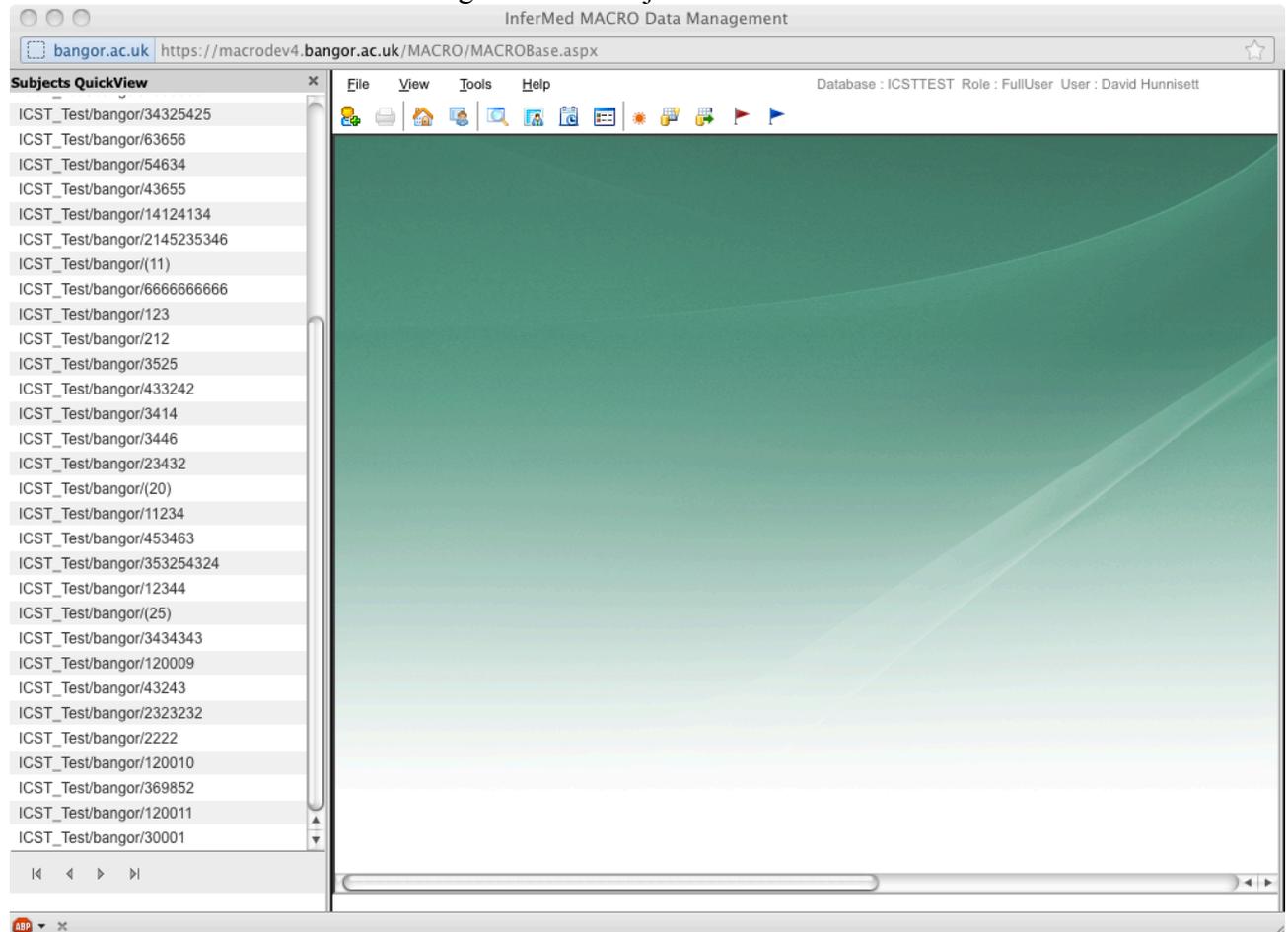


ENTER THE SUBJECT ID AND CLICK REFRESH
A LIST OF SUBJECTS THAT MATCH THAT ID WILL BE SHOWN
USING THE SUBJECTS QUICK LIST.

Quick List



You will then be able to scroll through a list of subjects.



7. Getting more help and support

The help button will display the help system. This is quite extensive and contains answers to many questions. Your trial will have a DATABASENAME_TRAINING as well as a DATABASENAME version. The DATABASENAME_TRAINING can be used for experimentation and training. Try things out in the training version to see what happens with no risk to the trial.

IF IN DOUBT ASK US!