ICONIC electronic Case Report Form (eCRF) manual for sites.

CONTENTS

1.0 INTRODUCTION: ACCESS TO THE DATABASE

This eCRF manual is a guide on how to navigate and use the online ICONIC MACRO 4 database. It explains how to access the database, how to navigate visits and forms for a patient, how to manage data entry, what the symbols and warnings mean and how to troubleshoot any issues.

If you have problems accessing or using the ICONIC databases, please call 020 7679 9878 or email ctc.ICONIC@ucl.ac.uk

1.1 Accessing the ICONIC eRegistration Form

- Please indicate on the Site Contacts Form if a team member requires access to the ICONIC database.

- After site activation, please email the Trial Coordinator at ctc.ICONIC@ucl.ac.uk with details of each staff member who will need access to the database. **NB** The PI will also be given access as they are responsible for the data entered from their site.

- UCL CTC will email each staff member with their username and ask them to call UCL CTC for their password.

- When you log onto the database the first time you will be prompted to change your password.

- Unique log in details will be provided to each staff member. These should be kept private and **must not be shared with other members of staff.** This is to guarantee an accurate audit trail of the data entered.

- Staff with access to the ICONIC eCRFs must have the data management tasks (**J:** Forwarding PROMs to patients and GPs and entering onto database, **M:** eCRF completion & resolving data queries) listed on their site staff delegation log.

- More than one person per site must have access to the eCRF database to cover for absence.

- Sites must notify the UCL CTC if a staff member with access to the eCRFs is no longer working on the ICONIC trial, so that their access can be deactivated. Updated delegation logs and contacts forms must be sent to UCL CTC promptly.

- Occasionally the ICONIC database may need planned maintenance work. UCL CTC will email sites in advance with details of times when the ICONIC database will not be accessible.

2. General Instructions for Completing THE ICONIC eRegistration Case Report Form (eCRF)

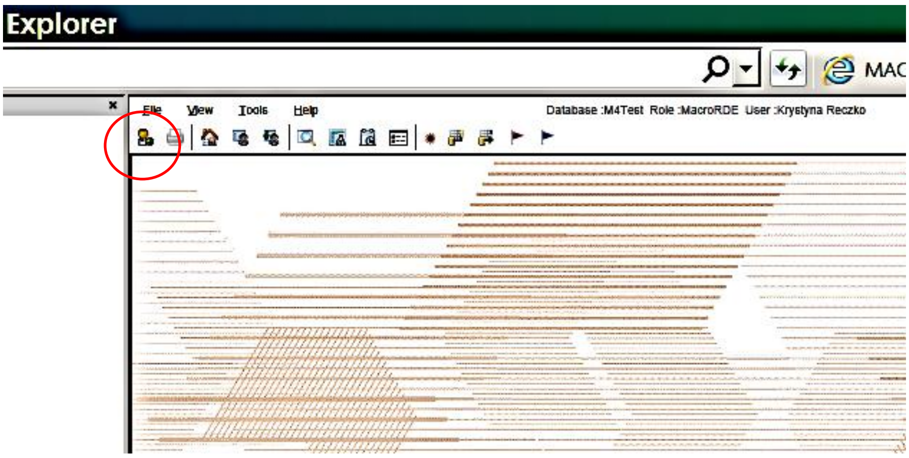
2.1 Introduction

The instructions in this section are intended to be used along with the protocol and the eCRF manual.

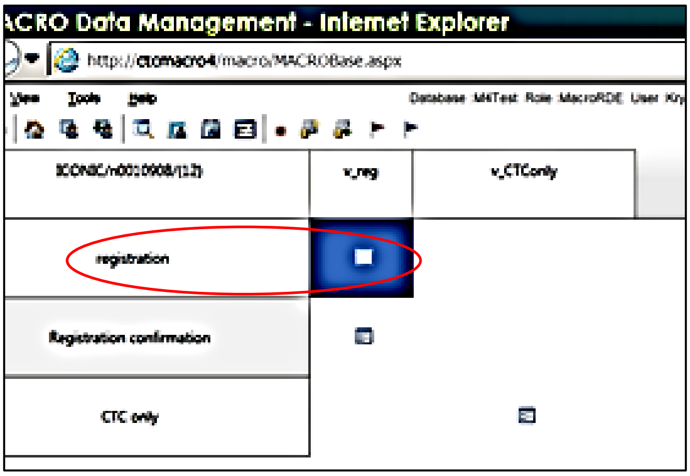
- The registration eCRF you submit must be confirmed by the ICONIC team at UCL CTC.
    - **For this reason we will only accept registrations between 09.00 and 17.00.**
- It is recommended that you complete the Registration Source Data Form before completing the registration eCRF online to ensure all answers are available before data entry.
- Any queries should be sent to the ICONIC Trial Coordinator before submitting the registration form for confirmation.
- See Section 3 below for instructions on data entry in Macro.
- If you are not able to access the MACRO database, please phone the ICONIC trial coordinator ASAP (020 7679 9878) for advice.

2.2 Completing the Registration eCRF

1. On opening the Registration database, create a new subject by pressing the 'create a new study subject' button:

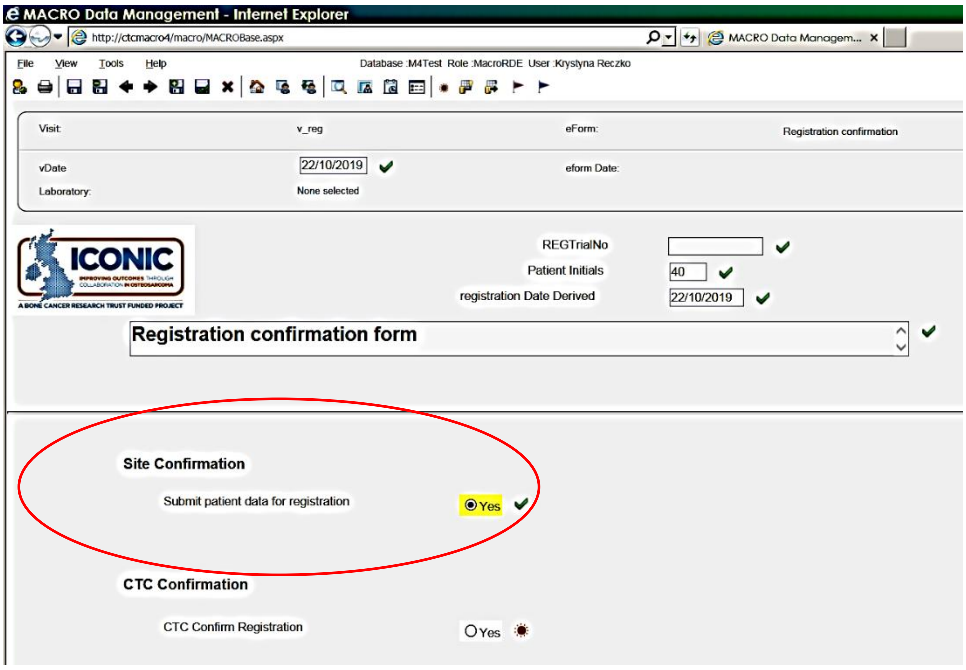


2. This will open a new registration form, click on this to open it:



3. You will need to complete the form, and save it using the button on the toolbar (see below for specific instructions on the form completion).

4. You should then open the 'registration confirmation' form, tick 'yes' for submit patient data for registration, and save as above.



5. When you save the form MACRO will generate an email for the ICONIC team at UCL CTC notifying them of the request for a registration.

6. If there are any discrepancies, the ICONIC team will ask for correction and clarification before proceeding with registration of the patient.
7. Following registration you will receive a confirmation email from UCL CTC.
8. Please note the patient Study number: **ICO-XXX** on the patient registration SDV if completed or in the patient notes.
9. Print out and file a copy of the registration confirmation email in the patient notes with the patient consent form.

2.3 When completing the form:

1. Ensure all fields are complete.
2. Do not override warnings, this will result in Data Clarification Requests/ queries (DCRs) from UCL CTC and will delay registration.

3. Some fields will automatically be blocked out in response to data that you have entered in other fields – e.g. incorrect patient information sheet details will not be accessible.

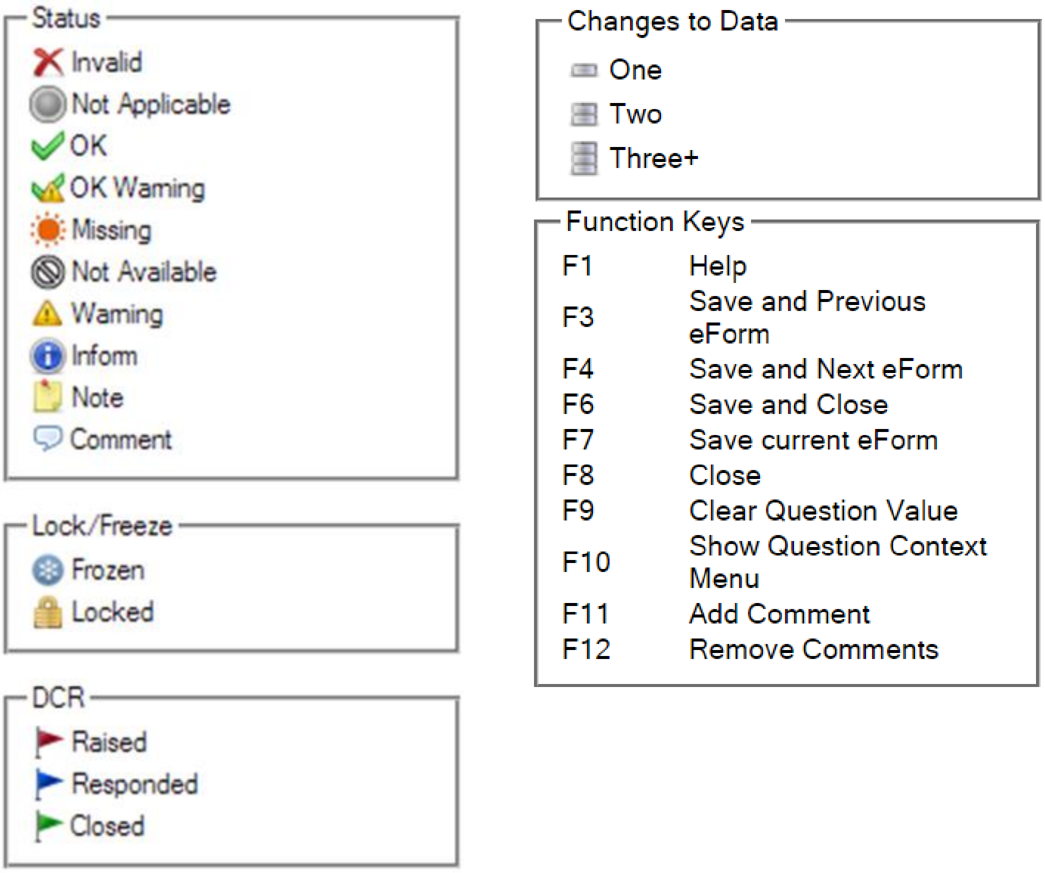
4. For the question: Name of Sarcoma MDT where patient discussed give the name of the Osteosarcoma Specialist Centre reviewing the patient and performing the resection surgery if applicable.

5. If for any reason the patient is not being reviewed at an Osteosarcoma Specialist Centre, please supply the Host institution name for the MDT meeting at 'OTHER: non Sarcoma Services MDT Site'.

6. If you have any queries or need any clarification on completing an eCRF, please contact the ICONIC Trial Team on 020 7679 9878 or email ctc.ICONIC@ucl.ac.uk.

3.0 ICONIC eCRFS: USING THE MACRO 4 DATABASE SYSTEM

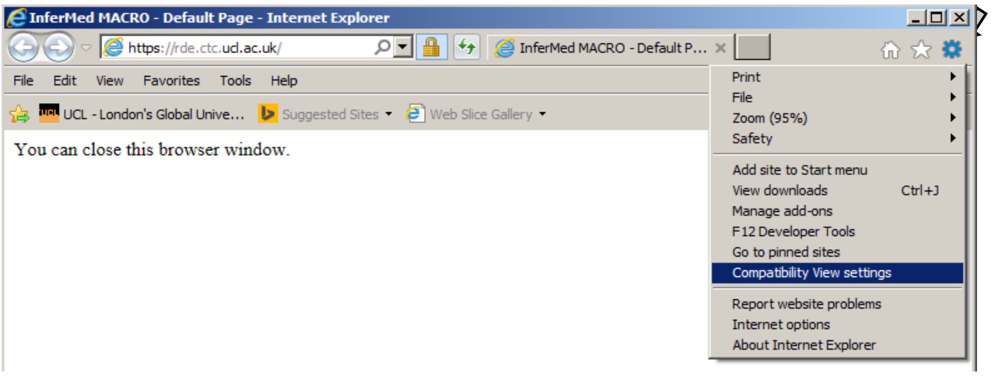
3.1 Symbols and Function Keys



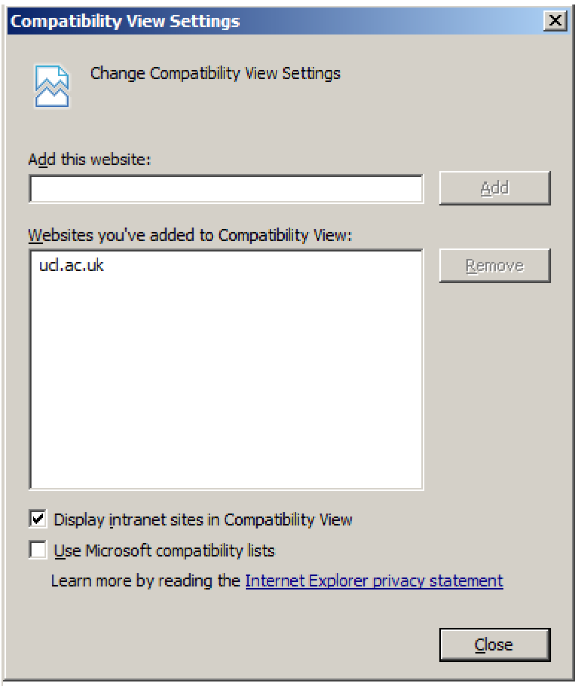
3.2 Logging In and Out

- Open a web browser. Use only:
  - **Internet explorer** (IE) version 9 or above,
  - **Google Chrome** or
  - **Microsoft EDGE**,
  - *do not use Firefox or any other browsers.*
- Go to the following link: https://rde.ctc.ucl.ac.uk/
  - Ensure pop up windows are not blocked as MACRO 4 opens in a new window.
  - If you are using Internet Explorer (IE) version 9 or 10, Macro will not work unless you add ucl.ac.uk to the Compatibility View Settings (for IE version 11, don't use compatibility mode). To do this, go to the main IE screen

(not the pop up). In the top right, choose Settings > Compatibility View Settings as in the screen shot below:



- Then click Add to add ucl.ac.uk to the list of sites:



- Once you have done this you can then log in. If you are using Google Chrome or IEv11 or above, you do not need to do this.
- Enter your username and password and click 'OK'. If this is the first time you are logging in, you will be prompted to change your password. If you need to change your password at any other time, go to 'Tools' – 'Change password'.
- Passwords must be between 8-15 characters in length and have at least one number and a mix of upper and lower case letters.

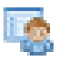
- You must change your password every 150 days.
- If you forget your password, click on the *Forgot password* link on the Macro Login Screen to reset it. An email will be sent to you with a temporary password. This can take up to 20 minutes to be delivered.
- If there has been no activity for 20 minutes, MACRO 4 will log you out. Therefore, **please ensure forms are saved regularly.**
    - for patient confidentiality reasons do not leave a computer unattended while you are logged in.
- Please ensure you log out at the end of each session before closing the window. To log out, go to 'File' – 'Log Out'.
    - This is important as failure to log out properly may result in forms becoming inaccessible.

3.3 Home Page

When you successfully log in to the ICONIC database the Home Page opens and the task bar (below) appears in the top left of the web browser.

3.3.1 Task Bar

You can hover the mouse pointer over the icons to see their function and they are also listed below. The same functions are available in the file/view/tools option menus as well.

	Create a New Study Subject (Patient)
	Open the Home Page (from the patient data entry screens)
	Open Subject (Patient) List
	Open Search Panel
	Open Subject Quick View (shows patient list in left window pane while doing data entry)

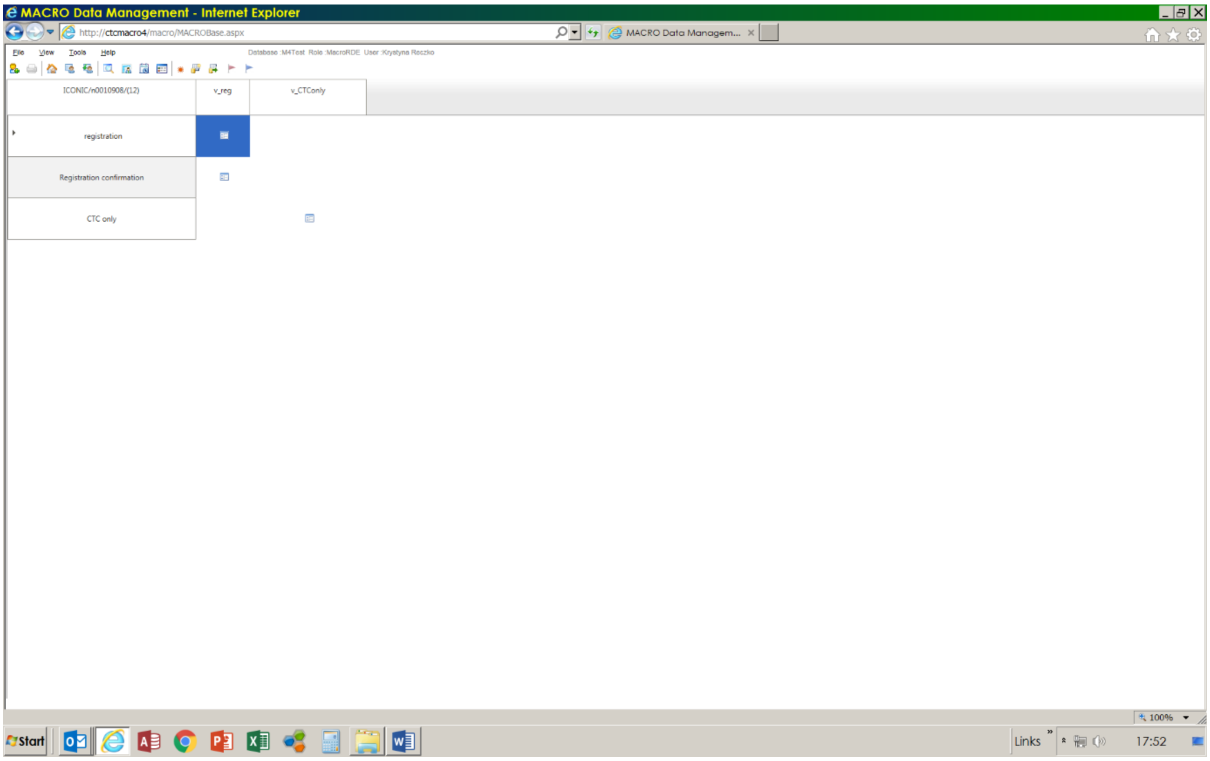
	Open Schedule Quick View (shows patient schedule in left window pane while doing data entry)
	Open Symbols and Function Keys panel

3.4 Patient Visits

3.4.1 Patient's Visit Schedule

- On opening an existing patient's record, the next screen displayed is the patient's Visit Schedule.
  This is a matrix of **Visits** and **eForms** that define the patient's progress through the trial.

- The Visits are displayed across the top of the page and represent the assessment timepoints. As you go down the Visit columns, the horizontal rows of eCRFs contain different data collected at those timepoints.
- As you enter eCRFs, you will normally start at the top of the column and Macro will navigate down through the blank forms.
- When the last form is finished, you will be taken to the form at the top of the column in the next visit.



- In some browsers e.g. Chrome, don't maximise the window to fill the whole screen as the scroll bars can disappear, making it difficult to access the forms towards the bottom and right of the screen.
  - If this happens, click on '**Restore down**' at the top right of the window. The window will reduce in size but can be stretched to fill the screen, and the scroll bars will appear, especially if the scroll wheel on the mouse is used.

3.5 Data Entry

3.5.1 Dates

- Dates must be entered in the following format: dd/mm/yyyy.
  Any dates not in this format will be rejected by Macro.

- Full dates should always be given.

  - In exceptional circumstances, if you do not know the full date please use the following data processing rules:
    - Month and year known, but not date e.g. UK/01/2019, enter as 15/01/2019
    - Only year known e.g. 2019, enter as 02/07/2019
- Today's date can be entered in a date field using the shortcut: **t**

3.5.2 Saving and Closing Forms

- To save, close or move between forms, the following icons are found in the task bar at the top left of the screen or at the bottom right of the form. You can hover the mouse pointer over icons to see their function and they are also listed below:

	Save the current form. The data will be saved, and the form will remain open.
	Save and move to the previous form in the schedule. If no data has been changed this option will not be available
	Move to the previous form in the schedule **without saving** the data
	Move to the next form in the schedule **without saving** the data
	Save and move to the next form in the schedule. If no data has been changed this option will not be available
	Save and close the current form

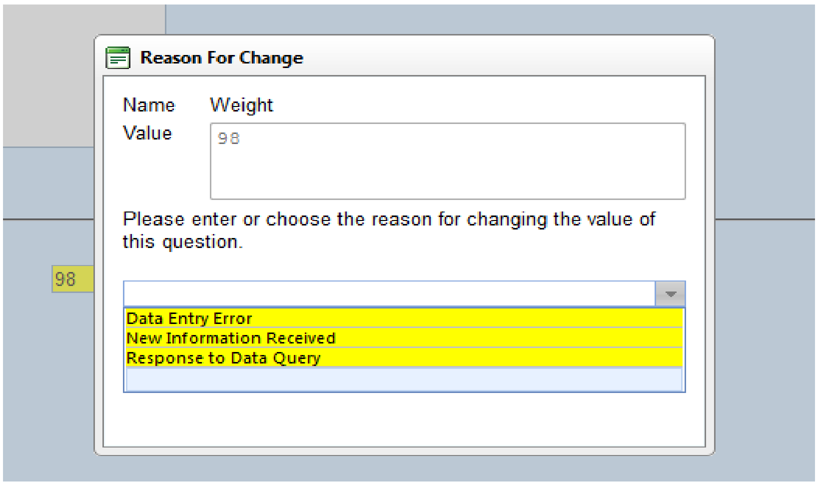
Close and clear data from current form.

- Use this if you have opened a form by mistake, or you do not wish to save changes to a form.

Please do not save empty forms

3.5.3 Editing Data

If you need to edit data which has already been entered and saved, you need to give a reason for the change. Select from the drop down menu or type as free text:



3.5.4 Statuses of Question Fields

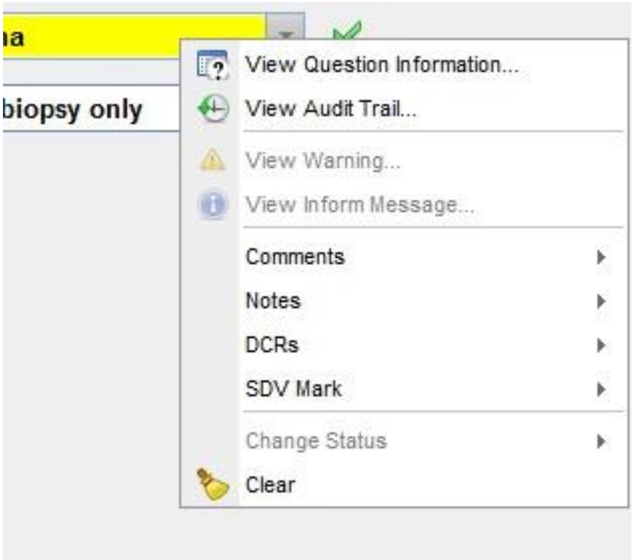
The status of a field is indicated by the symbol next to it. For further details on Warnings, Notes and Data Not Available, see the Question Menu section (3.5.5) below.

	Not applicable
	OK
	Missing
	Warning
	OK Warning (i.e. warning overruled)
	Note
	Not Available

3.5.5 Question Menu

The question menu can be opened once the cursor is in the question field.

- Either press F10 or right click.
- The options are shown below.



See also the Data Clarification Requests (DCRs) section (3.8).

3.5.5.1 Warnings

Any data that do not meet the on entry data validations will trigger a warning popup on screen. You can overrule the warning immediately, but if you do not, you can still open it at a later date.

	Warnings can be viewed and if necessary overruled from the question menu. Enter the reason why the warning should be overruled and then click on 'close'. If the form was already saved, you will be asked to provide a reason for the change.
	The status of the field will then be 'OK warning'

3.5.5.2 Notes

- Notes should be added to a field **only if necessary**.
- **Anything written in a note will not be included in data analysis.**
- Data must be entered into the data field, but a note may be added as explanation to avoid a DCR (query) being raised.

- E.g. if an unusual entry has already been discussed and agreed with UCL CTC, you may enter the data in the field and raise a note against the field to describe the issue.
- Alternatively, if the unusual data entry raises a warning, you may overrule the warning and explain the reason in the 'reason for overrule'.
- From the question menu select 'Notes' – 'Add...' Then enter the note and click 'OK'.

3.5.5.3 Data Not Available

- Use if the data requested for a field is not available, for example if a test was mistakenly omitted.
  - Open the question menu,
  - Select 'Change Status' and
  - Choose 'Not Available'.
- In these cases it is best practice to raise a note against the field to explain why the data cannot be provided.

3.6 View Patient List

This lists all existing subjects at your site.

- Select 'View' - 'Subject List' or click the Subject List icon at the top of the screen in the Task Bar.
- The Subject List opens in the main window.
- Details are provided for each subject under several column headings.
- Click on a column heading to sort the list for that column. Click again to reverse the order.
- You choose a patient in the Subject Label column beginning with **"ICO-"**.
- ***Subject ID is NOT the patient's Trial Number***. Whenever you contact the CTC about a patient or use the search function, you should ***use the*** **Subject Label which is synonymous with the Trial Number**
- Using the browser's **Ctrl + F** search can help you find the patient quickly
- Double click a subject to open their schedule

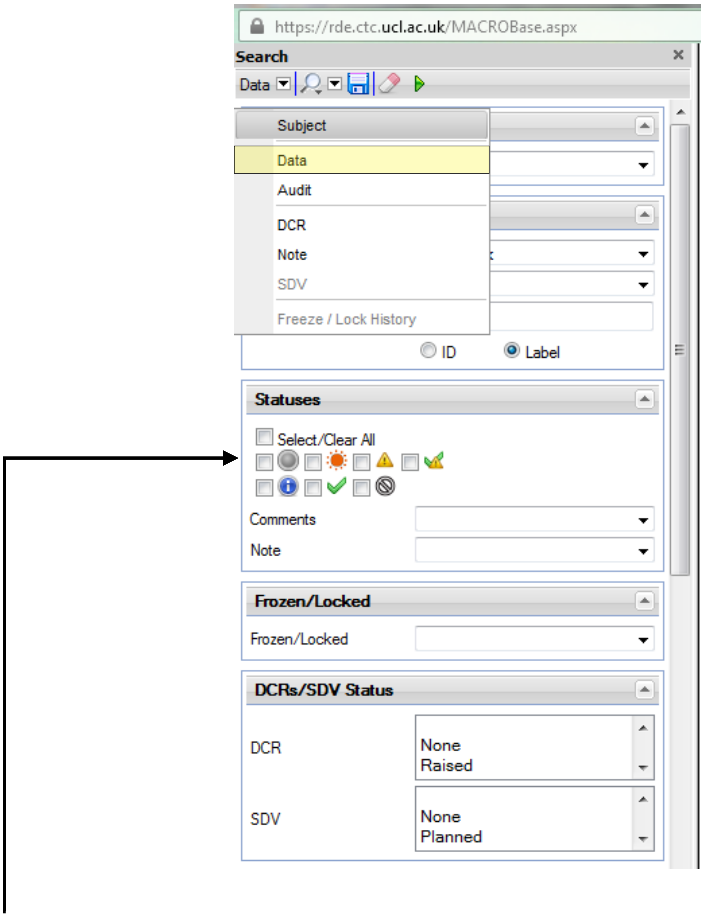
3.7 Search Panel

The search panel searches for Data clarification requests (DCRs, or queries) or question statuses including Missing data or Warnings.

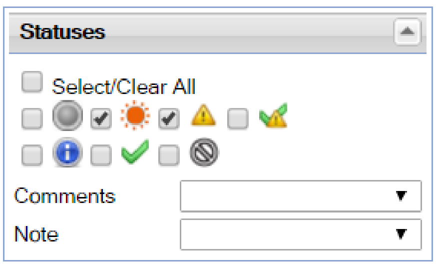
(N.B. All patients with missing data can also be listed by clicking the missing data icon in the task bar.)

3.7.1 Searching for warnings or missing data:

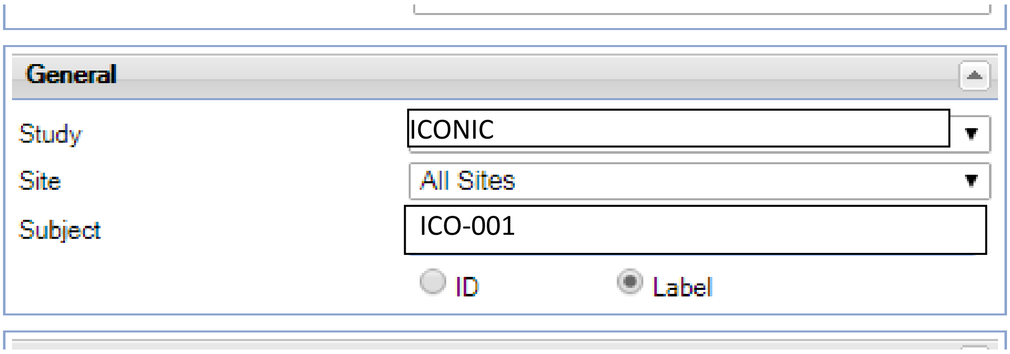
- Select 'View' – 'Search Panel' or
  - click the Open Search Panel icon .
- The search panel opens on the left side of the browser window.
- From the top left on the search panel, select Data from the drop down list.



- Depending on the type of data you are looking for you can select one or more question statuses by checking the tick boxes.
- In the example below the search would pull out missing data and data with warnings that were not overruled:



- You can narrow your results by only choosing particular patients. In the General Box, you would enter either the patient's subject ID or label. In the example below, only the records for the patient with label/trial number **ICO-001** would be displayed.



- Results can also be narrowed with the Study Level, User, and Date Range boxes.
- Click the Execute search button to view the search results in the main window. A list of results will be shown.
- Double clicking on the result takes you straight to the eform and highlighted field.
- To get back to the list of searched items you just need to press either (to save the data) or (not saving any changes) to toggle back to the search results.
- When you are finished you close the search panel using the **X** in the top right hand corner of the panel.

3.8 Discrepancies or Data Clarification Requests/Queries (DCRs)

The status of a DCR is shown by the following symbols:

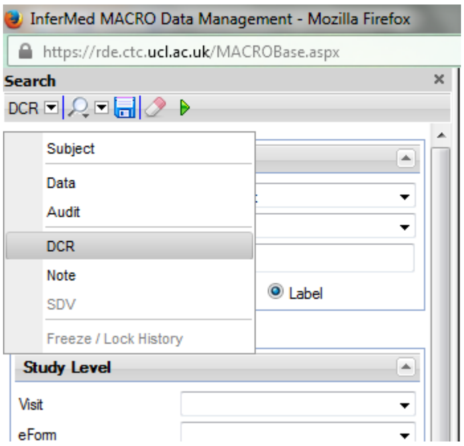
Raised DCR
Responded DCR
Closed DCR

3.8.1 Viewing DCRs

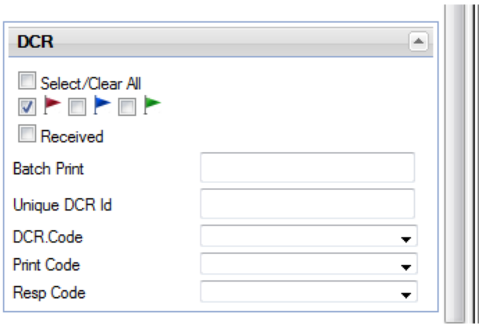
3.8.1.1 Using the search panel

- Select 'View' – 'Search Panel' or
  - click the Open Search Panel icon

  to open the search panel.
- Select **'DCR'** from the drop down list located at the top left of the search panel:

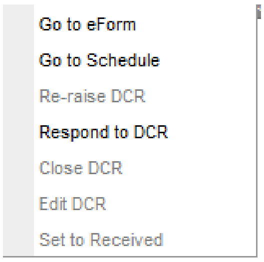


- Select your search criteria, ensuring you select the type of DCR you are searching for (usually red flag):



- Click the Execute search button (or the 'Return' key) to display the DCRs for all patients in the main window.
  - If you want to search for the DCRs for a particular patient or eform you can enter their Subject ID or full Subject Label in the Subject box and use the other boxes in the search panel to narrow down your results.

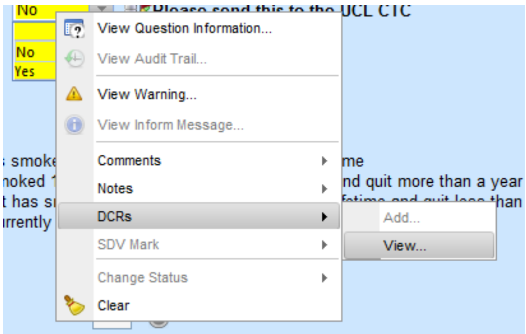
- Retrieve raised DCRs for all patients by clicking the raised DCRs icon in the task bar instead of using the search panel.
  - **Remember there is a 1000 records limit** on the number of results that can be displayed.
- Click on the grey arrow on the left of the DCR to expand the DCR history, including any previous responses.
- Right click on the top line of the DCR to get the following menu:



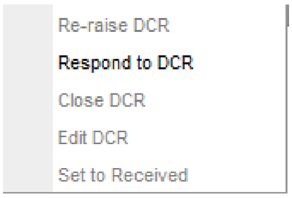
- You can choose either to go to the patient's schedule, or to the eform, or respond to the DCR from here.
  - **Please note you cannot update the data from here.**
    - If you want both to change the data and respond to the DCR you must go to the eform where the DCR is raised.
    - Alternatively, double clicking on the DCR will take you straight to the eform and highlight the field where the DCR is raised.
  - Once you have made your changes, saving the eform will toggle you straight back to the list of DCRs so that you don't have to use the search menu again.

3.8.1.2 Using the question menu within a form

- Ensure the cursor is in the question field which has the DCR on .
- Open the question menu either by pressing **F10** or right clicking.
- Select 'DCRs' – 'View...'.
  - View will not be available on questions where there are no DCRs raised.
    - ***NB: the symbol will not show up next to fields in question groups - the data tables kept in boxes on the eform.***



- DCRs/View will display that question's DCR browser.
- Click on the grey arrow to the right of the DCR to expand the DCR history including any previous responses.
- Right click on the top line of the DCR to get the following menu:



3.8.2 Responding to DCRs

- Select ‘Respond to DCR’.
    - Enter response,
    - click ‘OK’
    - close browser.
- The following symbol will then be showing: .
- If required, amend the data on the eForm and when asked for the reason for the data change please choose ***Responding to data query*** from the drop down menu.
- **Please note that you must respond to the DCR as well as amending the data.**
- Only when a DCR has been responded to: can it be closed by UCL CTC: .