NHS
Blood and Transplant

SIGNET

***S**tatins for **I**mproving or**G**a**N** outcom**E** in **T**ransplantation*

MACRO – User Guide

WHAT'S INSIDE

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This training covers the following in general :

- ✓ Macro introduction
- ✓ Logging on to MACRO
- ✓ Creating new Subjects
- ✓ Visit schedule
- ✓ Subject registration
- ✓ Data entry
- ✓ Saving the Data
- ✓ Missing data
- ✓ Data warnings
- ✓ Data queries
- ✓ Data search
- ✓ Audit history
- ✓ Macro timeout
- ✓ Points to remember
- ✓ What's next ?

What is MACRO?

NHS Blood and Transplant

- MACRO is a database system used mostly within the not-for-profit sector for the management of clinical research data
- It supports online data entry (Electronic Data Capture)
- It has been developed so that it is compliant with Clinical Trials regulations and guidance
- MACRO's easy-to-use system allows users to quickly input, monitor and run reports on subject data to collect accurate and reliable data for analysis

LOGGING ON TO MACRO

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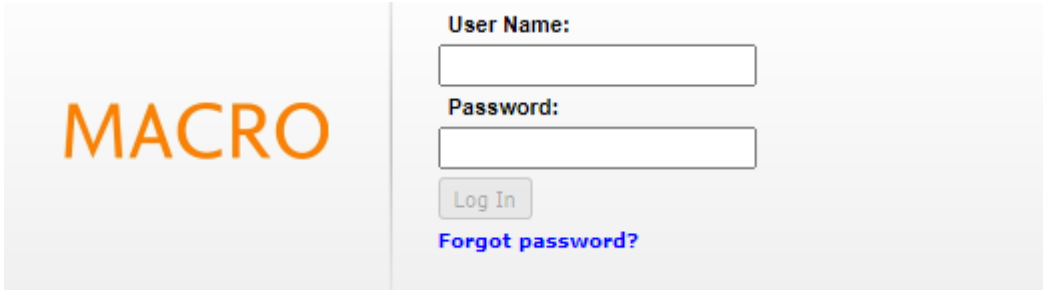
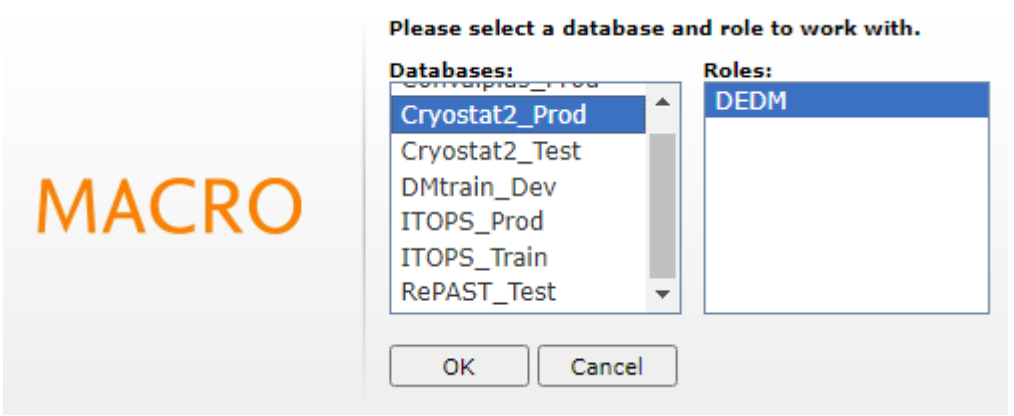
MACRO can be accessed by the below link:

https://www.ctu.nhsbt.nhs.uk/macro/

- You will receive a username and password from the Data Management Team
- You will be asked to change the password when you login for the first time, remember your chosen password
- User name is not case sensitive but Passwords are
- The NHSBT studies you have access to in MACRO will be displayed in the window on the left
- The role you have been assigned for the study you select will be shown in the window on the right.
- Click OK and the MACRO home page will open.





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MACRO HOME PAGE

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- Menu and short-cut icons:

- Standard Reports:

MACRO

Data Reports

DCR Details
DCR Summary
Missing Data - eForm Summary
Missing Data Site Summary
Missing Data - Subject Summary
Subject Data

MENU OPTIONS & SHORT-CUT ICONS

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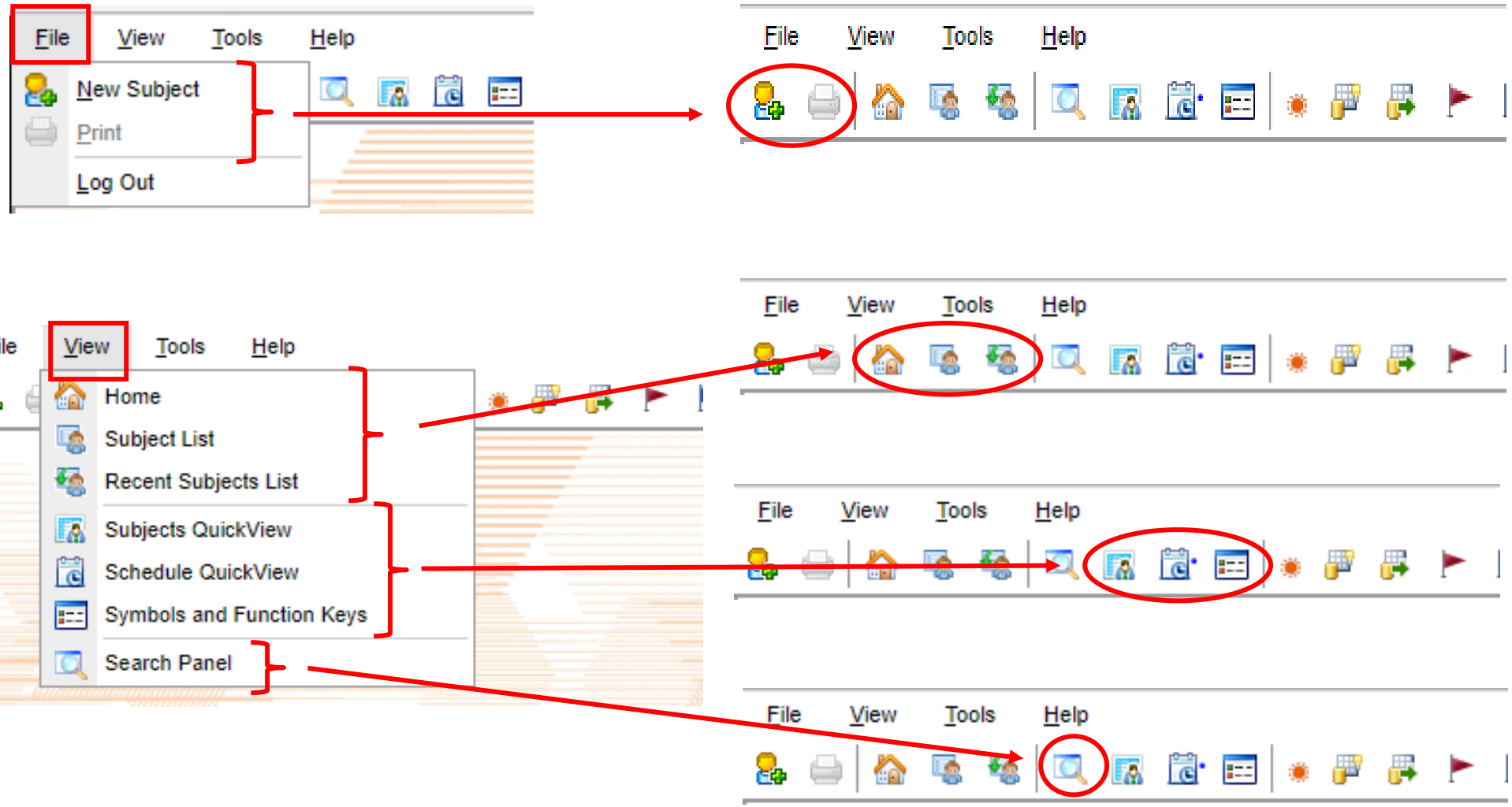

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MENU OPTION: TOOLS

To stop question tooltips box appearing during data entry as they can mask other data (Perform this step once only)

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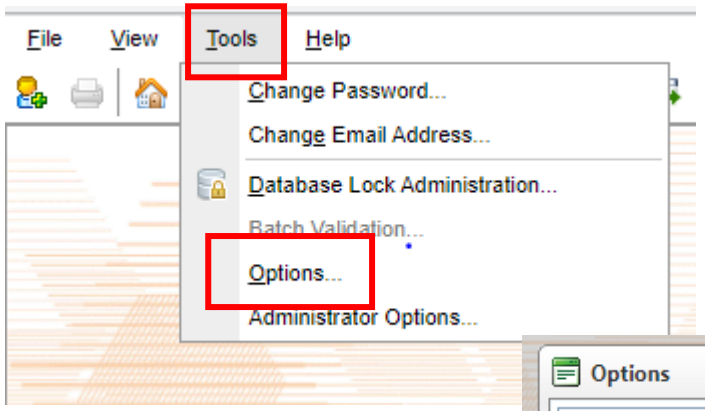

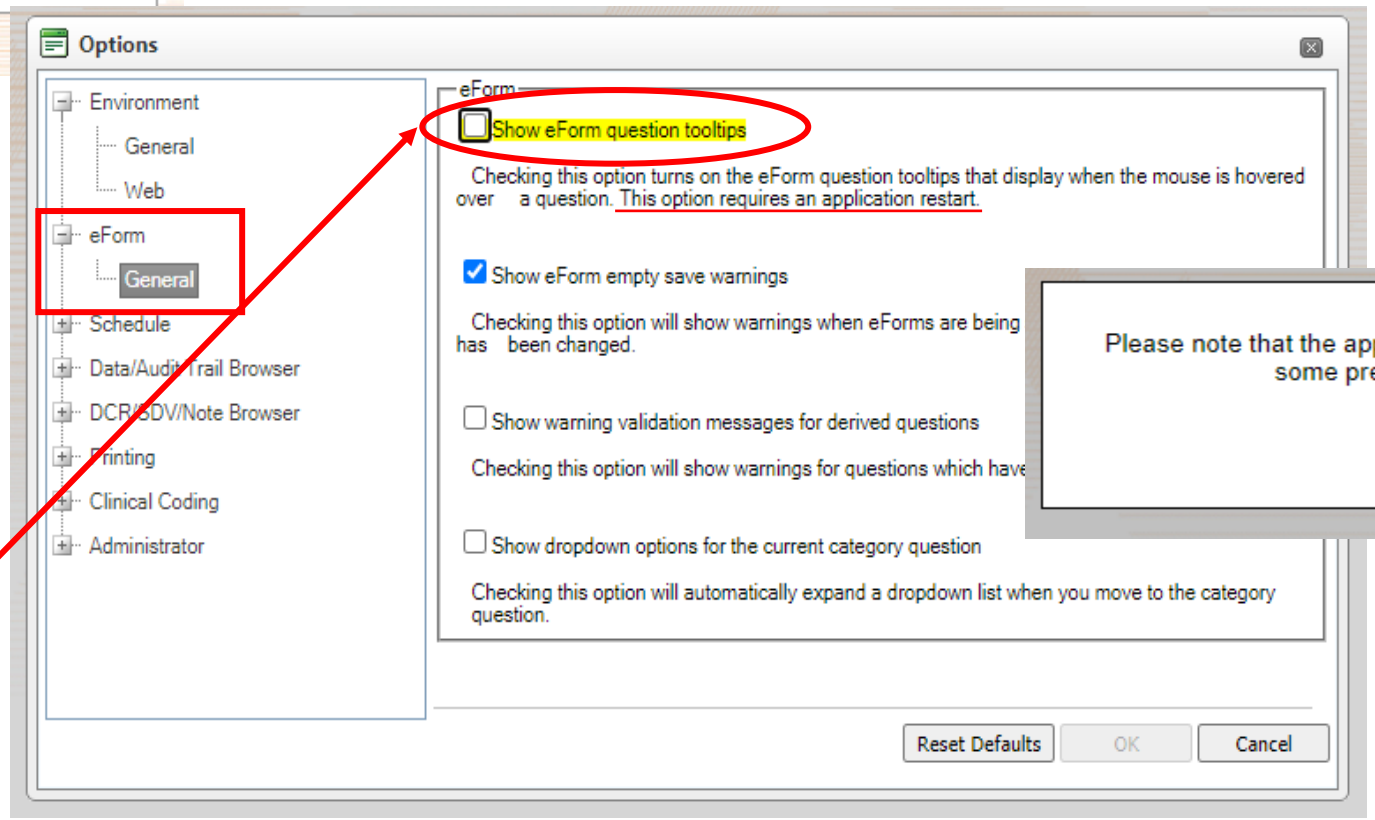

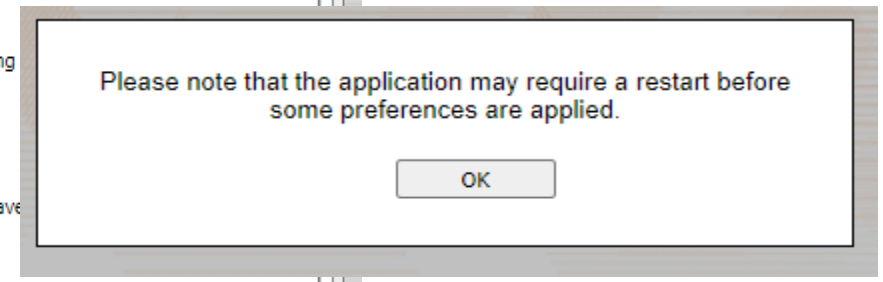

Useful Tip:

Uncheck this box!

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SEARCHING FOR SUBJECTS 1

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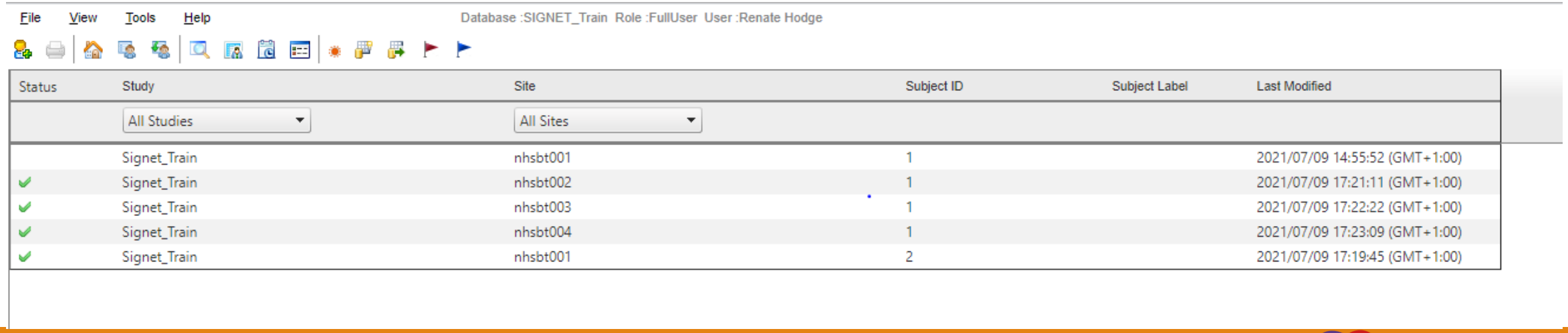
- Click the ‘Open the subject list page’ icon on the shortcuts toolbar

- The subject list page opens, click a patient in the list to continue entering their database record or resolve queries



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SEARCHING FOR SUBJECTS 2

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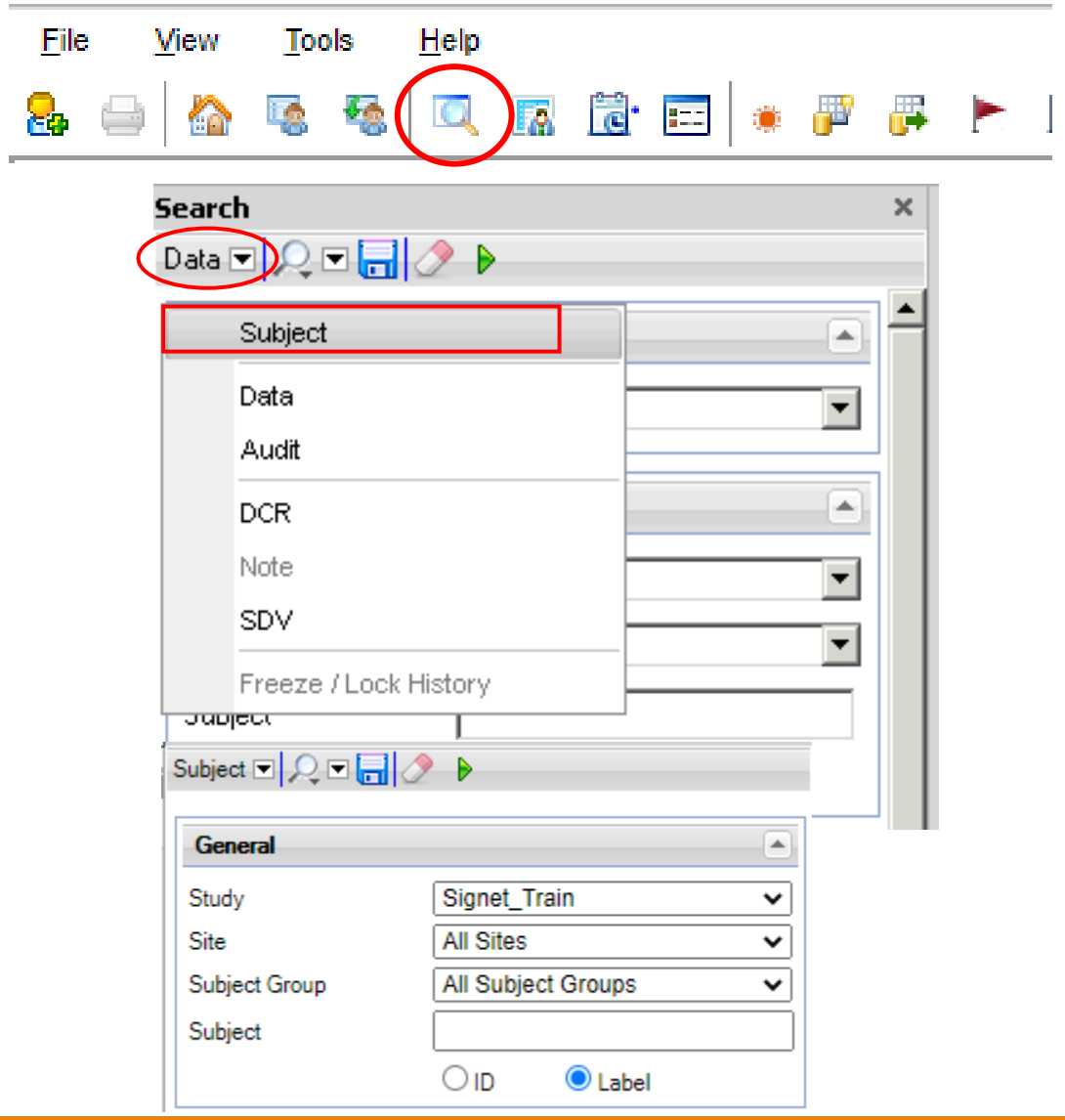
- Click the ‘Open the Search panel’ icon on the shortcuts toolbar
- A ‘Search’ panel will open on the left of the screen
- Change the ‘Data’ default selection to ‘Subject’
- Check the ‘Label’ radio button and enter the subject number in the ‘Subject’ box
- If you want to see all patients at a site, leave the Subject box blank
- Click the ‘Execute Search’ icon at the top of the panel



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CREATING NEW SUBJECTS

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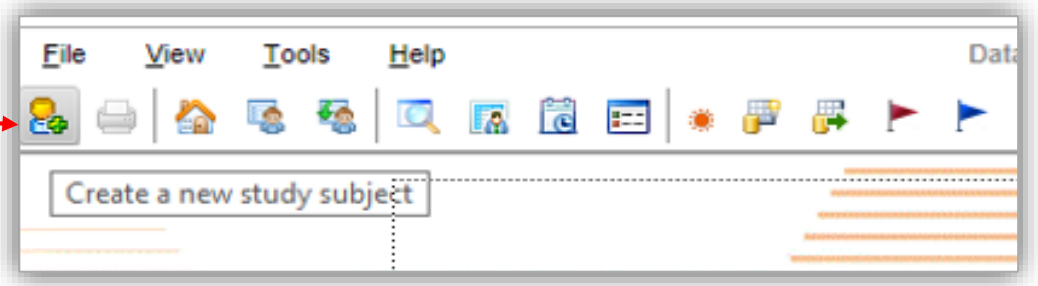
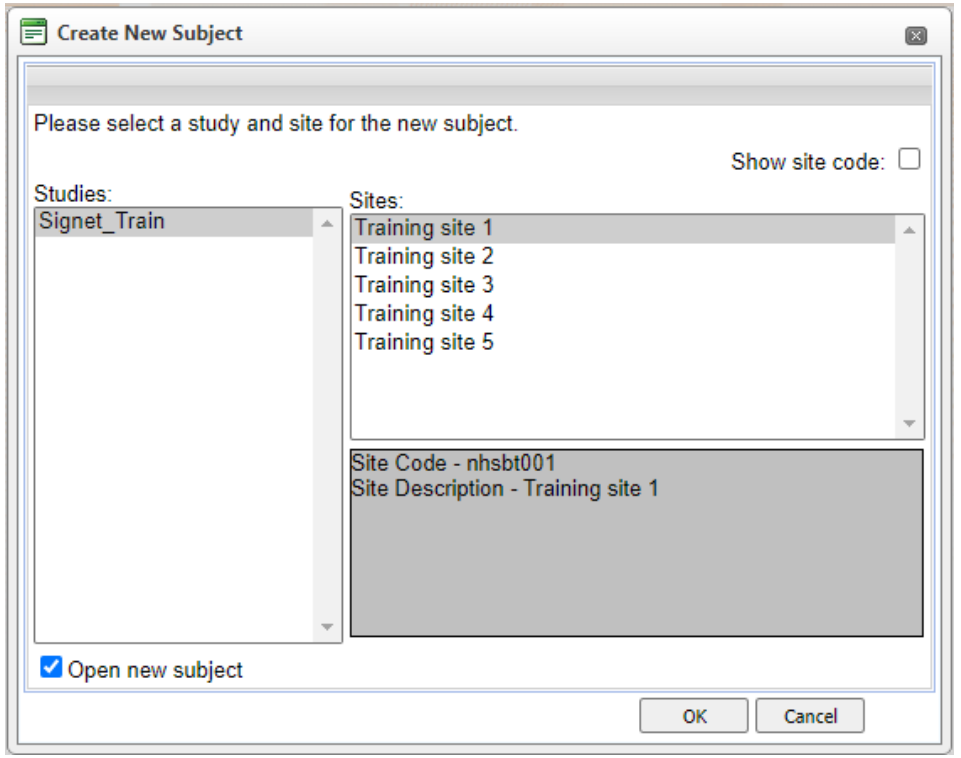
- To create a new subject, click the 'Create a New Study Subject' icon in the shortcuts toolbar



- New subject screen opens. Select your site from the list that appears and click 'OK' N.B. You should only have access to your own site

- Before creating a new subject, as a matter of good practice, you should search to ensure that the subject has not already been entered

- **New subjects created in error cannot be deleted from the system**, but they can be moved to a dummy site (or the correct site if the wrong site was selected), please contact the trial Data Manager if this is needed



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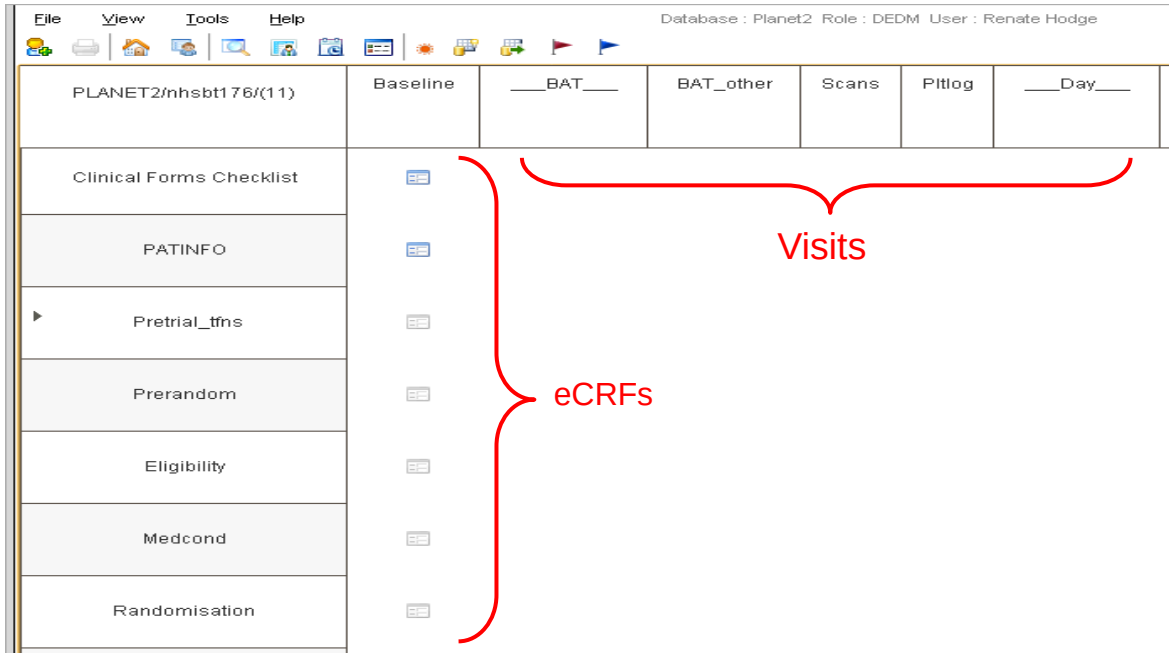
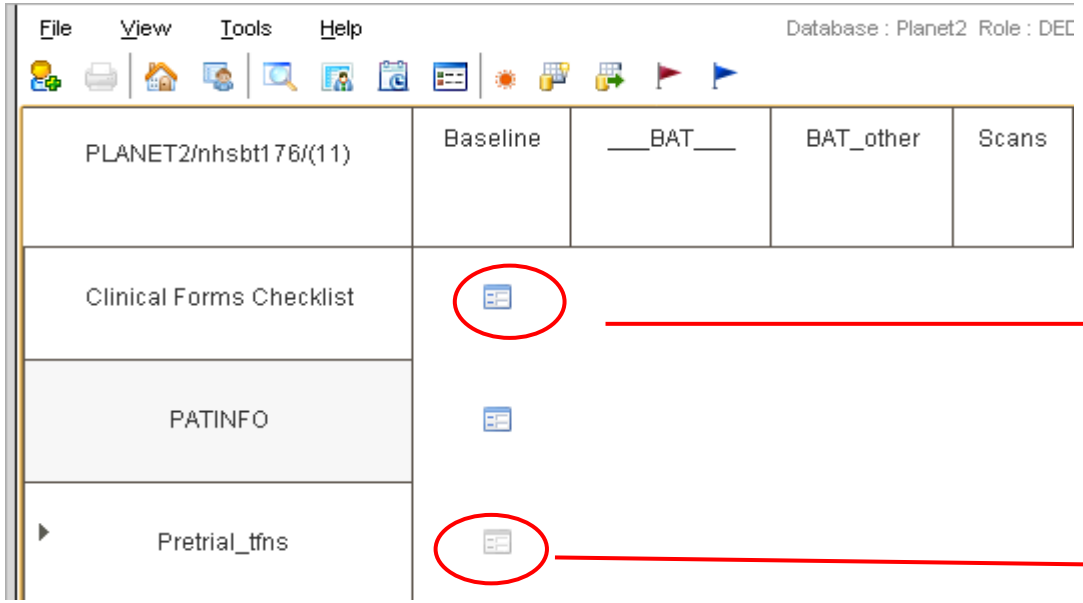
VISIT SCHEDULE

- Once a new subject has been created or an existing subject opened, the visit schedule opens
- Visit schedule displays all of the eCRFs (known in MACRO as eForms) and visits for the study
- The collection of questions, eForms and visits is known as the Study Definition





Usually there will be one or two eForms that are blue and darker which can be opened e.g. Donor Information Form

When a new subject is created, a number of the eForm symbols will be grey and faded. This means they cannot be opened at this time

SUBJECT REGISTRATION

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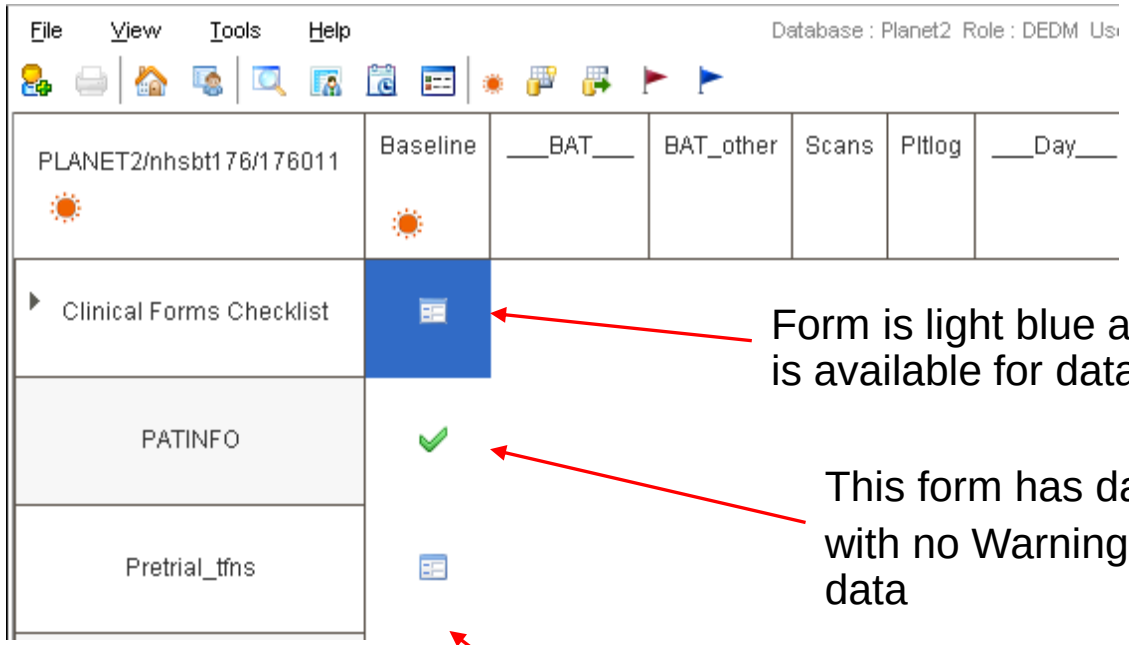
- Once certain questions are entered e.g. Site ID, Site name, Randomisation number and confirmed by MACRO as unique, the participant will become registered on the database
- Once the Participant is registered, this will inform MACRO which other eForm(s) are expected and appropriate eForm(s) will then be available for data entry
- eForms that are not available for data entry will remain light grey and cannot be opened



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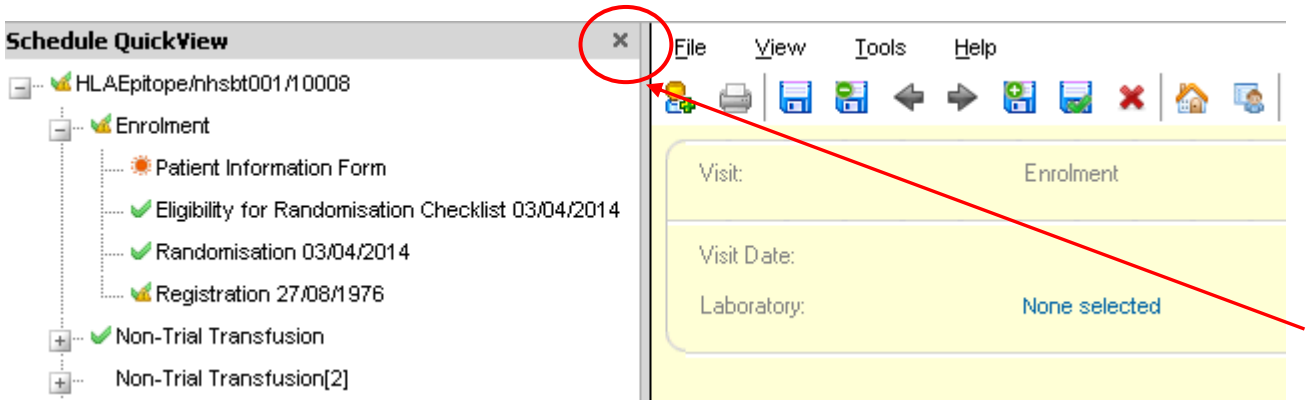
DATA ENTRY



- When you open an eForm, the Schedule Quickview panel will appear automatically at the left of the form.
- However, it may be easier to view the whole screen and enter data without this panel showing
- To hide this panel, click on the X shown here

- Users can either use the mouse, Enter key or the Tab key to move between fields on eForms. Using the keys between questions may be quicker than the mouse.
- After you have selected an answer for a category question, the cursor will automatically move to the next question without the need to tab/click on it

SAVING THE DATA

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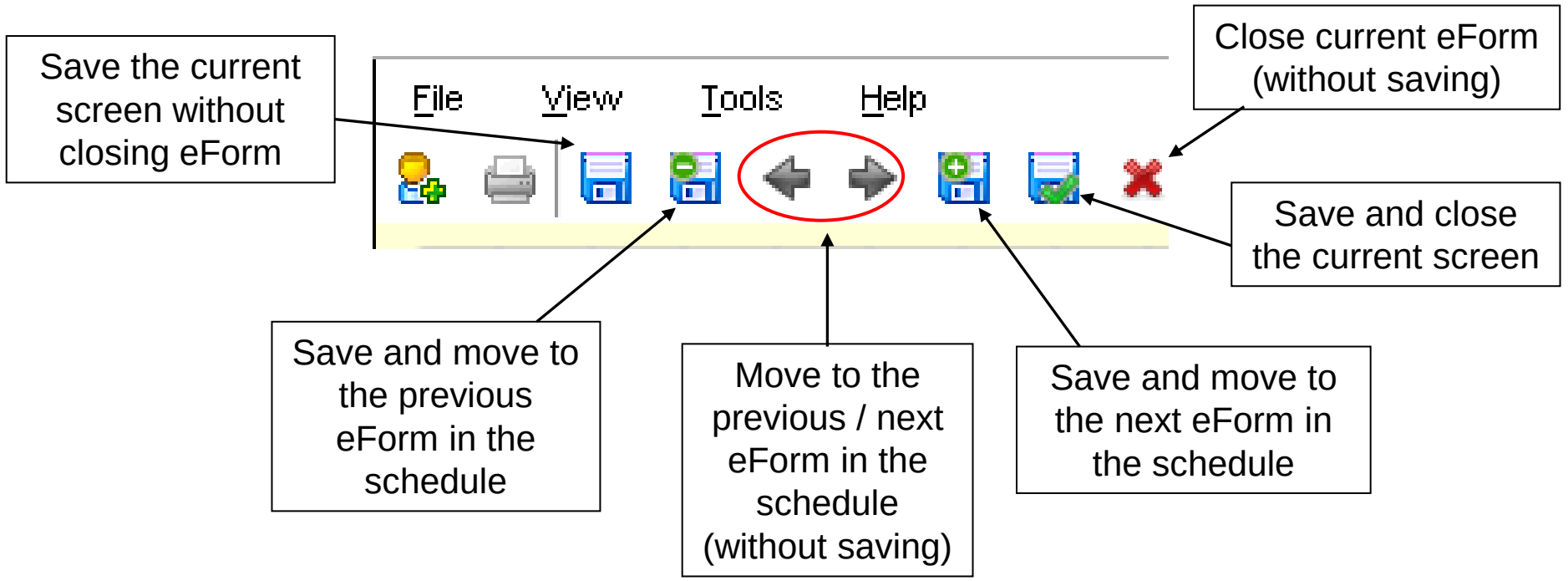
- There are several 'save' options that can be used once an eForm has been opened. These are shown in the shortcut toolbar above the open eForm
- Any data that has been entered but not yet saved will be lost
- If an eForm has been opened in error DO NOT SAVE the page otherwise a blank record will be created



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MISSING DATA

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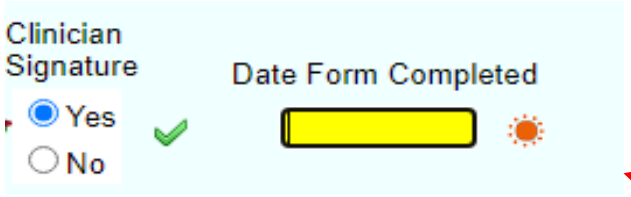
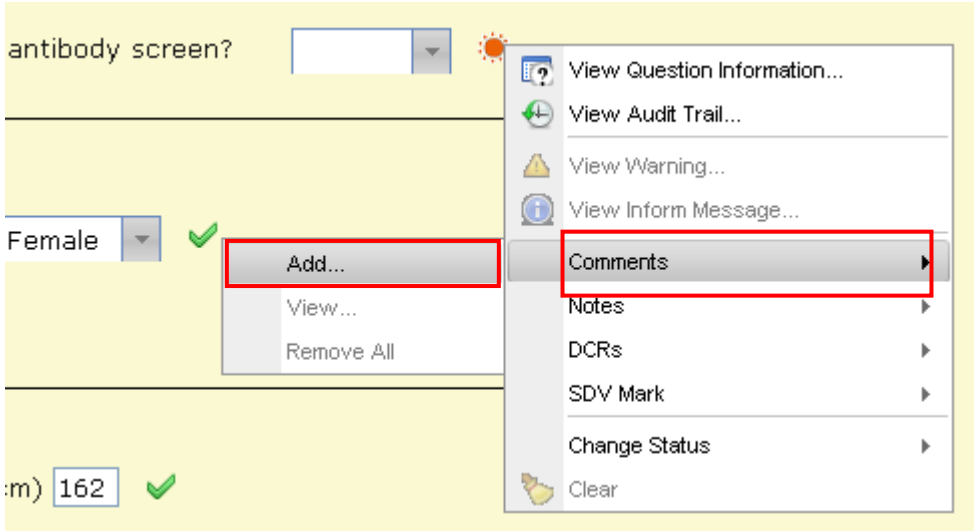
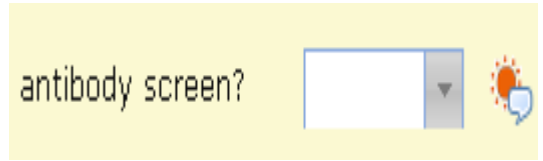


- If data is unavailable at the time of completing the form then the data field should be left blank and a Missing Data Report should be run regularly to make sure missing items are dealt with.

- The ‘Missing’ icon will appear, which looks like this





- Do not override this ‘Missing’ status. If data is genuinely unobtainable at site or not available at the time of data entry, **please add a comment to the question explaining this**

- If a comment is not added explaining why this data is missing, it will be queried by the trial team when the data is reviewed

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DATA WARNINGS

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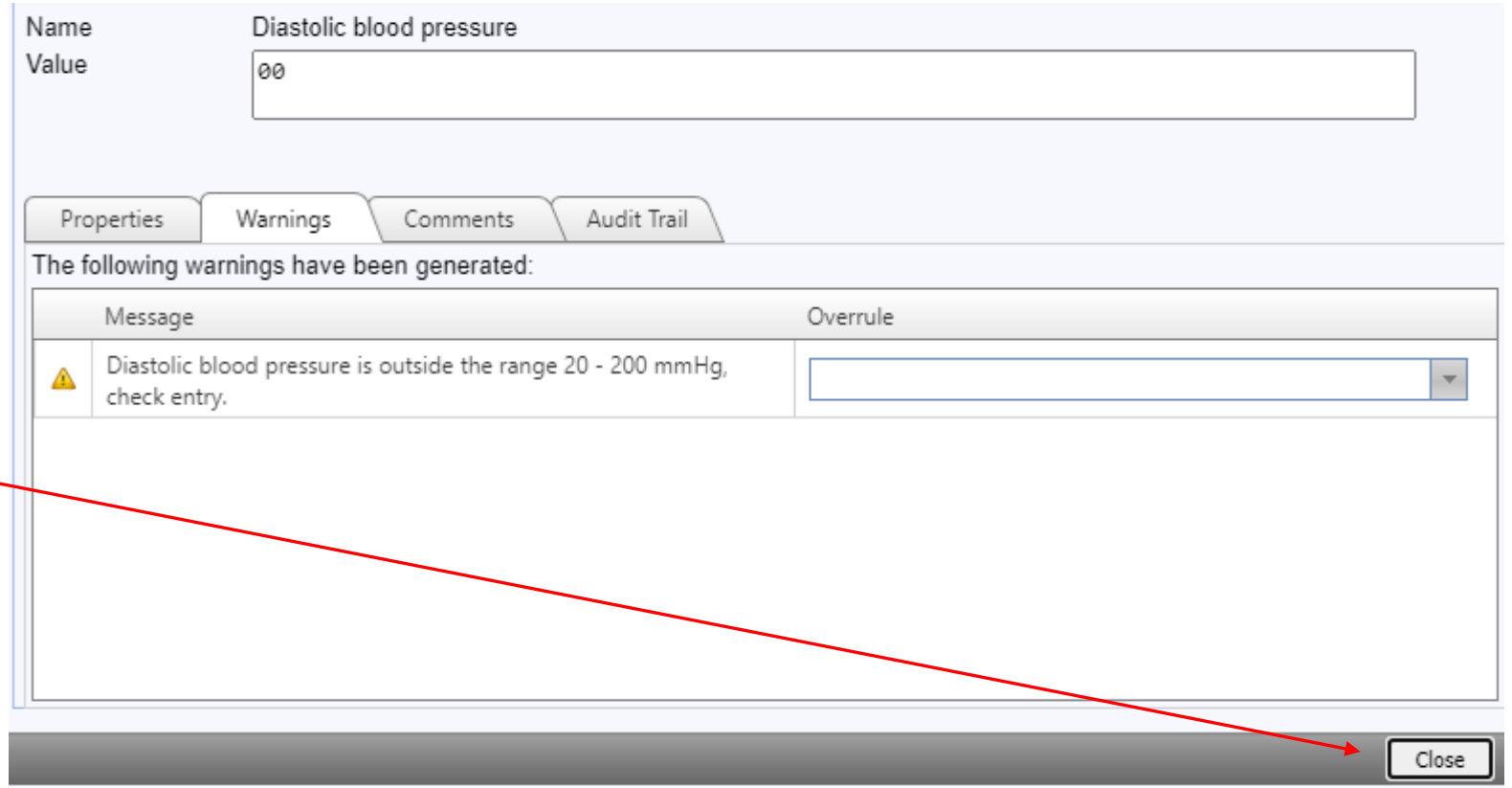
- If data entered is inconsistent with a warning condition that has been built into the study design, then a warning message is fired, and a pop up will be displayed

- If the data entry is correct, click 'Close' and the Warning Status Symbol will appear next to the question, and **add a comment** explaining why the current data is valid to prevent a query

- If the data entry is incorrect, simply amend the data and if the warning condition is now resolved, the Warning will disappear



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DATA QUERIES

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A DCR (Data Clarification Request) is a query, manually raised against an individual question if:

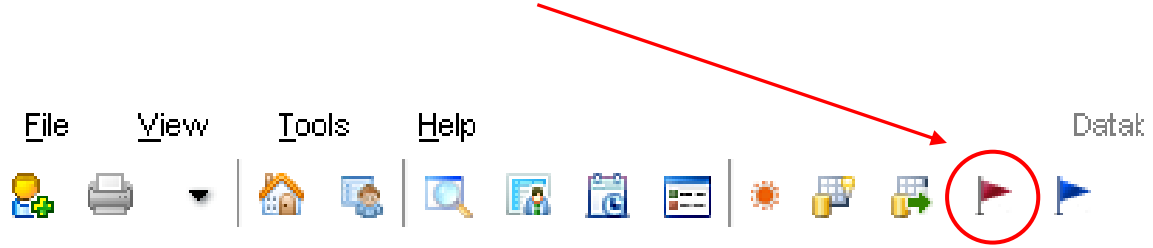
I. There is concern over **accuracy, completeness or validity of data**
II. Additional explanations are required regarding warnings or missing data flagged by the database

DCRs will be raised by the trial team / data manager reviewing the data and the staff at site should regularly review these DCRs and respond to them as appropriate

Questions can have more than one DCR

The DCR text should explain the issue fully and clearly

Click the ‘View raised DCRs’ icon on the shortcuts toolbar



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DATA QUERIES - continued

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The list of raised DCRs displays, click on a row to go to the relevant eForm containing this DCR

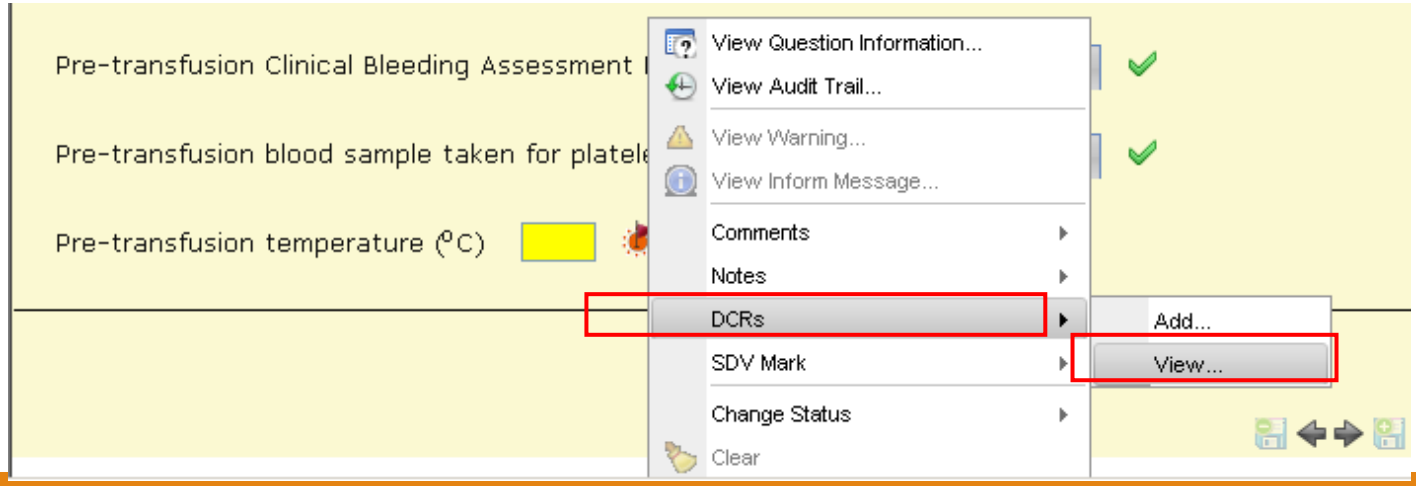
File View Tools Help Database :Cryostat2_Prod Role :DEDM User :Roshni Paul

Drag a column header and drop it here to group by that column

Priority	Date	Status	Subject	Visit	eForm	Question	Value	User Name	OC Id	Text
5	2020/10/05 12:25:12	Raised	Cryostat2/nhsbt031/R02423	Day 1	Randomisation	Tranexamic Acid bolus given to the patient in ED?		Roshni Paul		Form 3: Randomisation & Procedures In ED: Q7, If a Tranexamic Acid bolus
5	2020/10/05 12:25:12	Raised	Cryostat2/nhsbt031/R02427	End of Study	Hospital Stay	Time first admitted to level 3 care [ICU]		Roshni Paul		Form 7: Hospital Stay Form: Q1 and Q4 to Q6: These questions are blank. P
5	2020/10/05 12:25:12	Raised	Cryostat2/nhsbt031/R02427	Day 1	Pre-Hospital	Time of Arrival at ED	16:17	Roshni Paul		Form 2: Pre-Hospital Information Form: Q4, Date and time of arrival at ED i
5	2021/04/09 07:48:39	Raised	Cryostat2/nhsbt031/R22401	End of Study	Hospital Stay	Total length of hospital stay		Roshni Paul		Form 7: Hospital Stay Form: Q8, Total length of hospital stay is recorded as
1	2020/10/05 12:25:12	Raised	Cryostat2/nhsbt073/R05204	End of Study	Hospital Stay	Date re-admitted to level 3 care [ICU]	05/10/2018	Roshni Paul		Form 7: Hospital Stay Form: Q4: The patient appears to have only been adn
5	2020/10/05 12:25:12	Raised	Cryostat2/nhsbt073/R05206	End of Study	Hospital Stay	Total length of hospital stay		Roshni Paul		Form 7: Hospital Stay Form: Q8, Total length of hospital stay is recorded as
5	2020/10/05 12:25:12	Raised	Cryostat2/nhsbt073/R05206	Day 1	Pre-Hospital	Time of Arrival at ED	06:24	Roshni Paul		Form 2: Pre-Hospital Information Form: Q4, Date and time of arrival at ED i

To view an existing DCR from the eForm:

Right click on the DCR icon on the eForm, select ‘DCRs’ and ‘View...’ from the menu



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DATA QUERIES - continued

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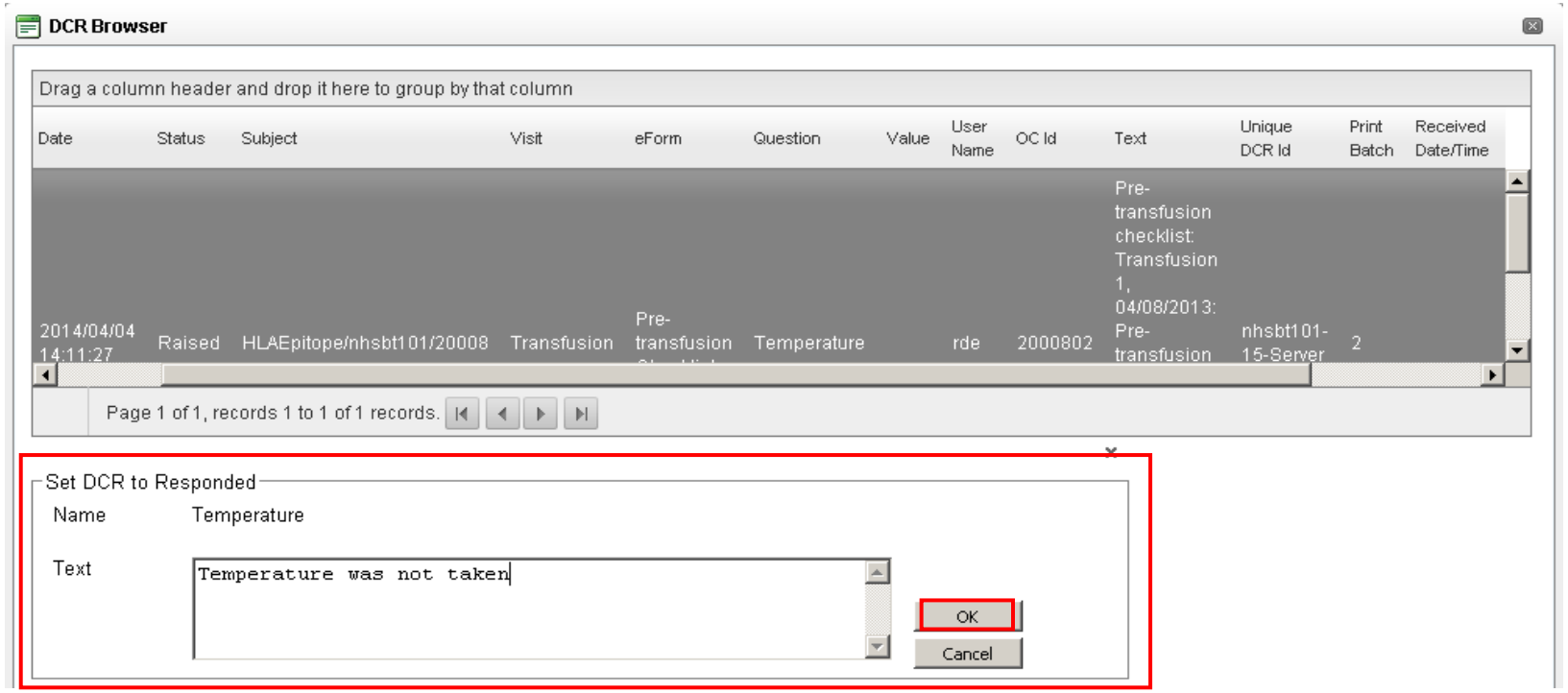
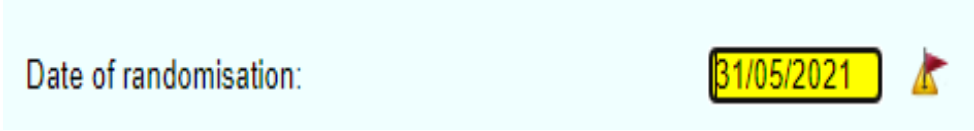
To respond to an existing DCR:

- To respond to a DCR, right-click on the DCR and select Respond to DCR
- Enter response into the box that appears entitled ‘Set DCR to responded’ and click ‘OK’
- Once you have responded to the DCR the colour of flag changes from **red** to **blue**
- The trial Data Manager will review all responses and check that the data has been amended as appropriate, if all is satisfactory, the DCR will be closed and the flag will now appear **green**

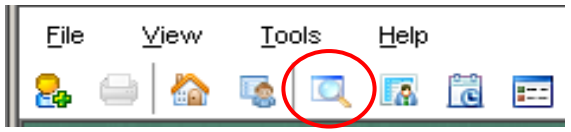


Raised DCR



DATA SEARCH

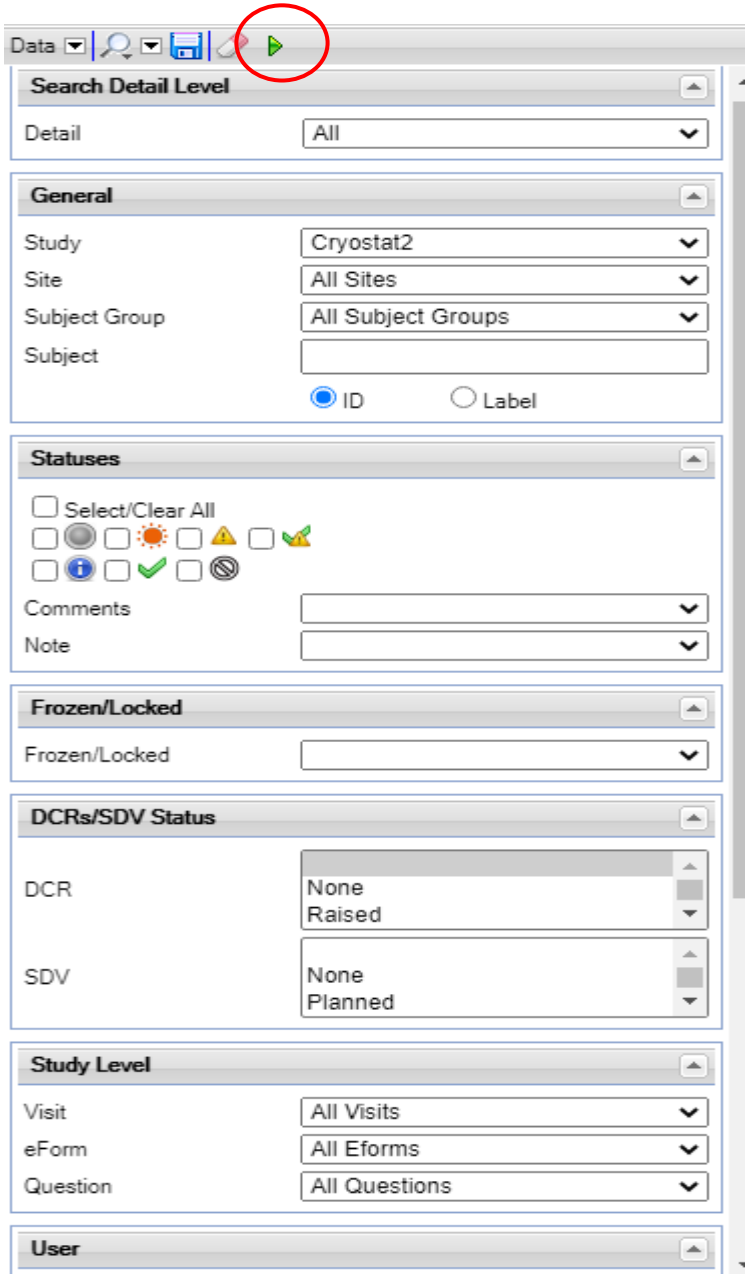
To search for data, click the ‘Open the Search Panel’ icon on the shortcuts toolbar



Once criteria have been set, click the ‘Execute Search’ icon at the top of the search panel

Using the Search Panel, you can identify data items that fit specific criteria:

- Site
- Subject
- Data with a particular current status
- Within a particular visit/eForm/question
- Entered by a particular user
- Generated before or after a particular date



AUDIT HISTORY

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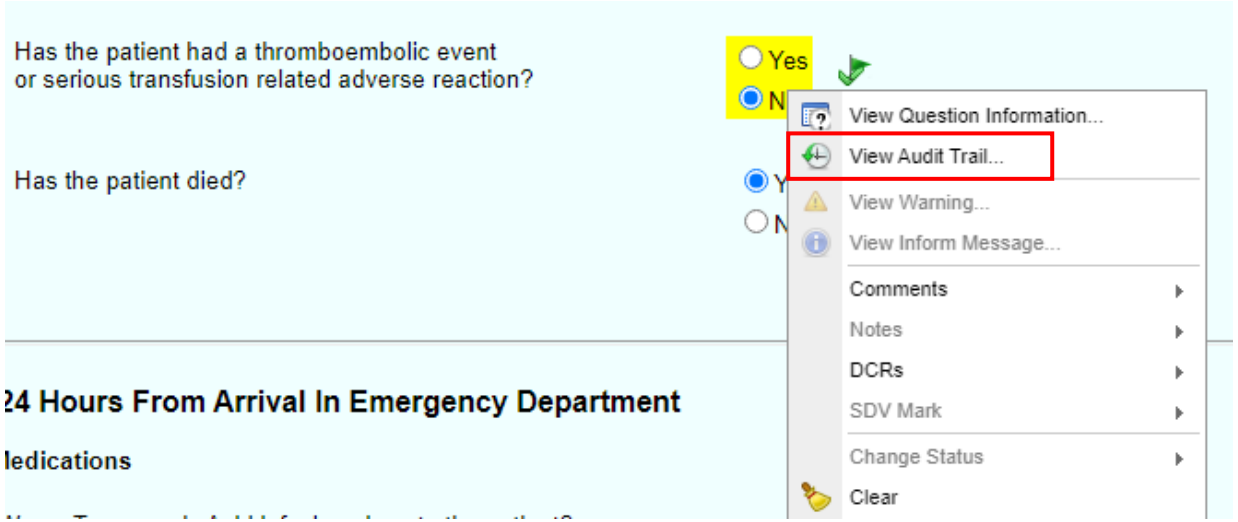
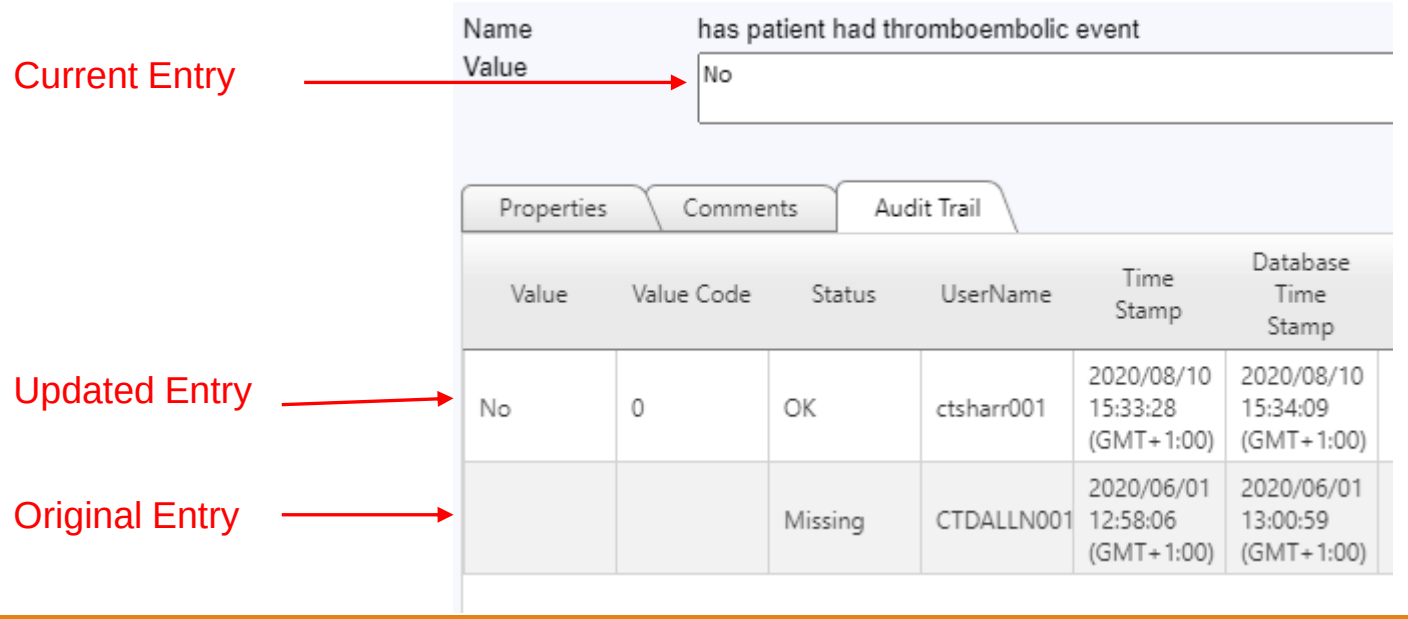
The Audit Trail is a chronological record of:

- Question status
- Response value
- Any warning messages
- Any overrule reasons
- Any reasons for change
- Any attached comments and lock status

Whenever any of these items are changed, a record is kept of the date/time of the change and the name of the user who carried it out.

An audit trail is maintained so that changes or modifications to data can be viewed; the audit trail is necessary to comply with GCP





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MACRO TIMEOUT PERIOD AND LOGGING OUT

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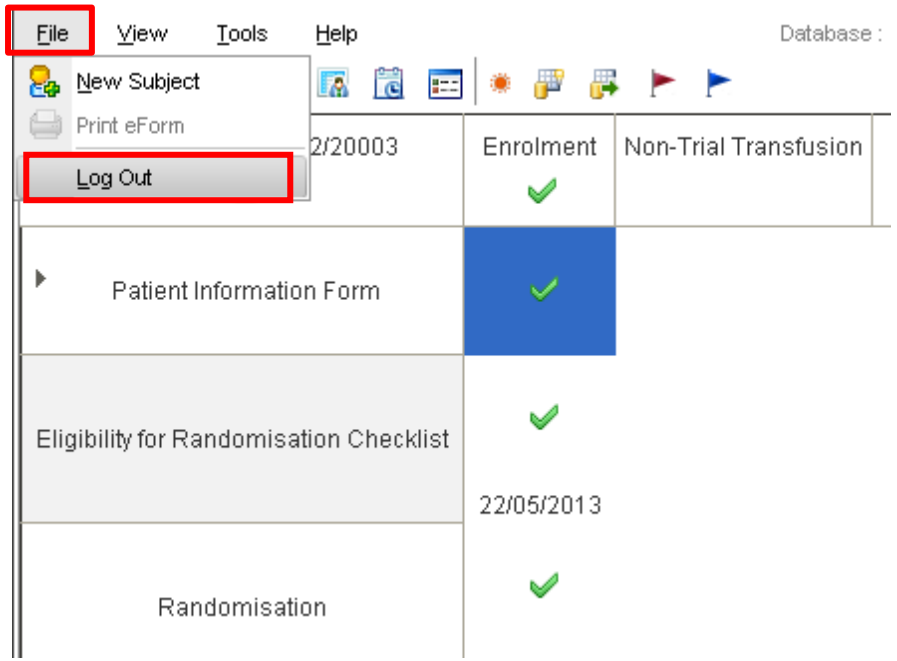
- MACRO has a system timeout period which is designed to prevent tampering by unauthorised users
- If the Data Entry module is left unused by the user for 15 minutes, any open subject records are closed and the user's password is needed to continue working
- Any data that has been entered but not yet saved will be lost
- For this reason, it is advised to make a habit of saving entered data regularly, especially when taking a pause in data entry
- As a matter of good practice, all users must also log out of MACRO if leaving PCs unattended or at the very least close the eForm and lock their screen when away from their desks
- When you have finished entering data, you should close the session using the 'Log Out' option in the 'File' menu



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POINTS TO REMEMBER

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- Please check for warnings ⚠ once you save each form.
- Some of the forms require PI sign-off (SAE forms, End of Study Form).

FORMS IN SIGNET

Form 1	Donor information
Form 2	Consent/ Authorisation
Form 3	Eligibility checklist
Form 4	Randomisation
Form 5	Intervention
Form 6	End of study
Form 7	Unblinding
Form 8	Withdrawal
Form 9A	Serious Adverse Event Form
Form 9 B	Serious Adverse Event- Narrative Form

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WHAT'S NEXT ?

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After training session

- Access granted for Training database to enter dummy patient data (for practice)
- Database training signature log needs to be signed off
- You will be given access to Live database
- Refresher training can be done using SIGNET database specific presentation before the start of the project, if required
- Any MACRO issues, please contact the Trial Data Manager:

Roshni Paul (Roshni.paul@nhsbt.nhs.uk) **Phone:** 01223 588924

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