



Statins for Improving orGaN outcome in Transplantation

MACRO – User Guide



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?

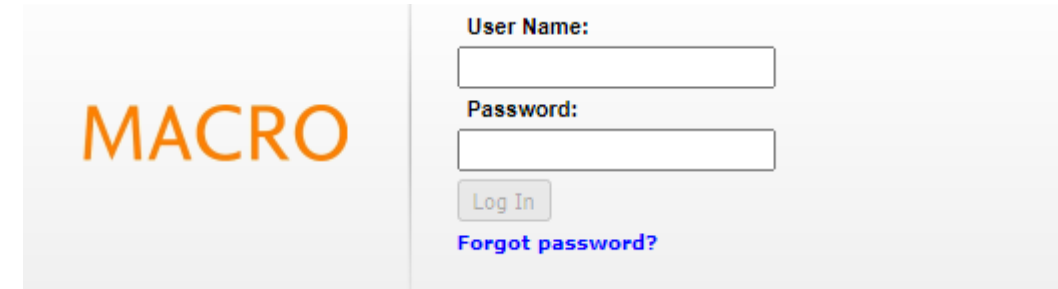
- MACRO is a database system used mostly within the not-for-profit sector for the management of clinical research data
- It supports online data entry (Electronic Data Capture)
- It has been developed so that it is compliant with Clinical Trials regulations and guidance
- MACRO's easy-to-use system allows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

LOGGING ON TO MACRO

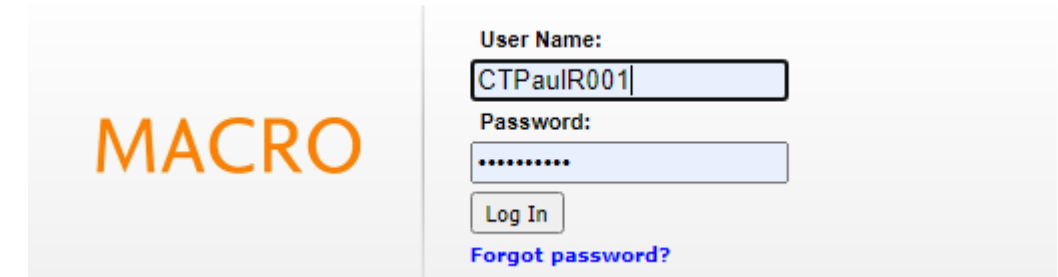
MACRO can be accessed by the below link:

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

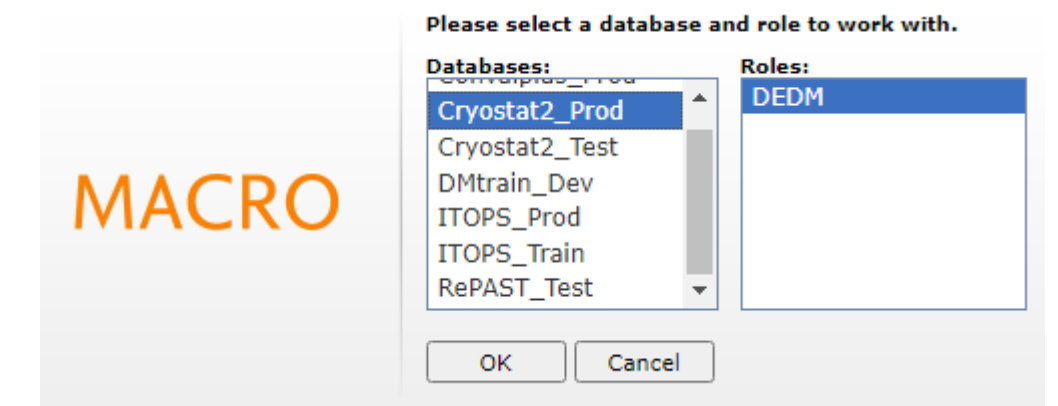
- You will receive a username and password from the Data Management Team
- You will be asked to change the password when you login for the first time, remember your chosen password
- User name is not case sensitive but Passwords are
- The NHSBT studies you have access to in MACRO will be displayed in 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.



The login screen features the 'MACRO' logo on the left. On the right, there are two input fields: 'User Name:' and 'Password:'. Below the password field is a 'Log In' button and a blue link for 'Forgot password?'.



This screen shows the login form with the username 'CTPaulR001' entered in the 'User Name:' field. The 'Password:' field contains masked characters (dots). The 'Log In' button and 'Forgot password?' link are still visible.



A dialog box titled 'Please select a database and role to work with.' is shown. It has two panes: 'Databases:' on the left and 'Roles:' on the right. The 'Databases:' pane lists several options, with 'Cryostat2_Prod' selected. The 'Roles:' pane shows 'DEDM' selected. At the bottom are 'OK' and 'Cancel' buttons.

- Menu and short-cut icons:

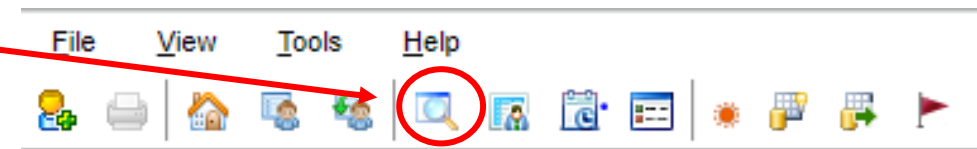
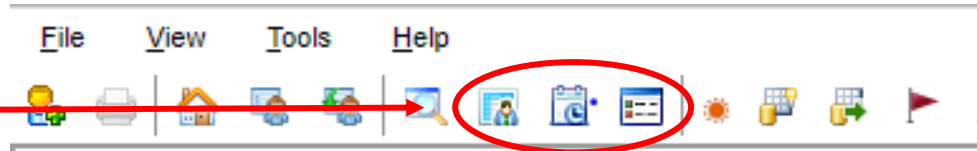
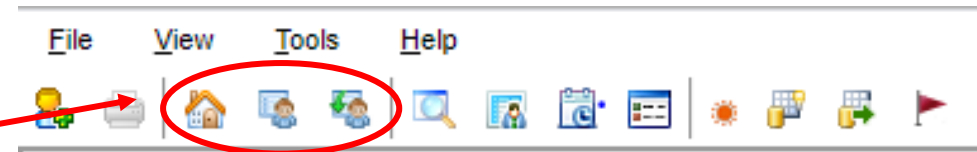
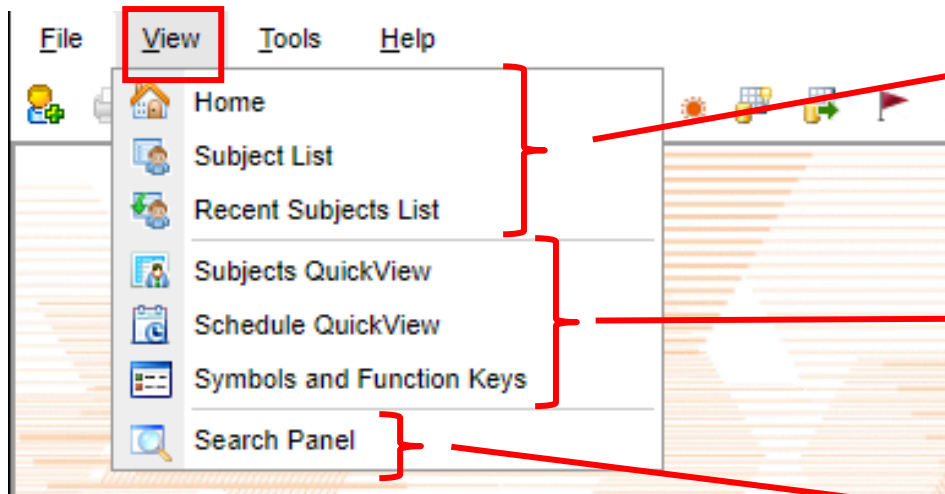
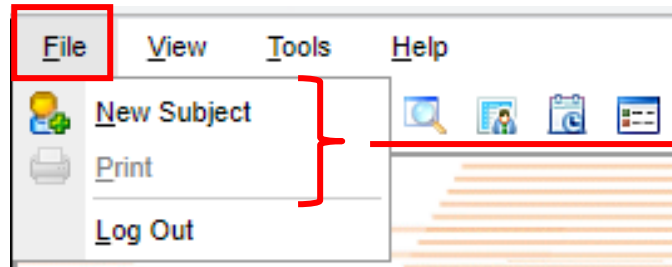


- Standard Reports:

MACRO

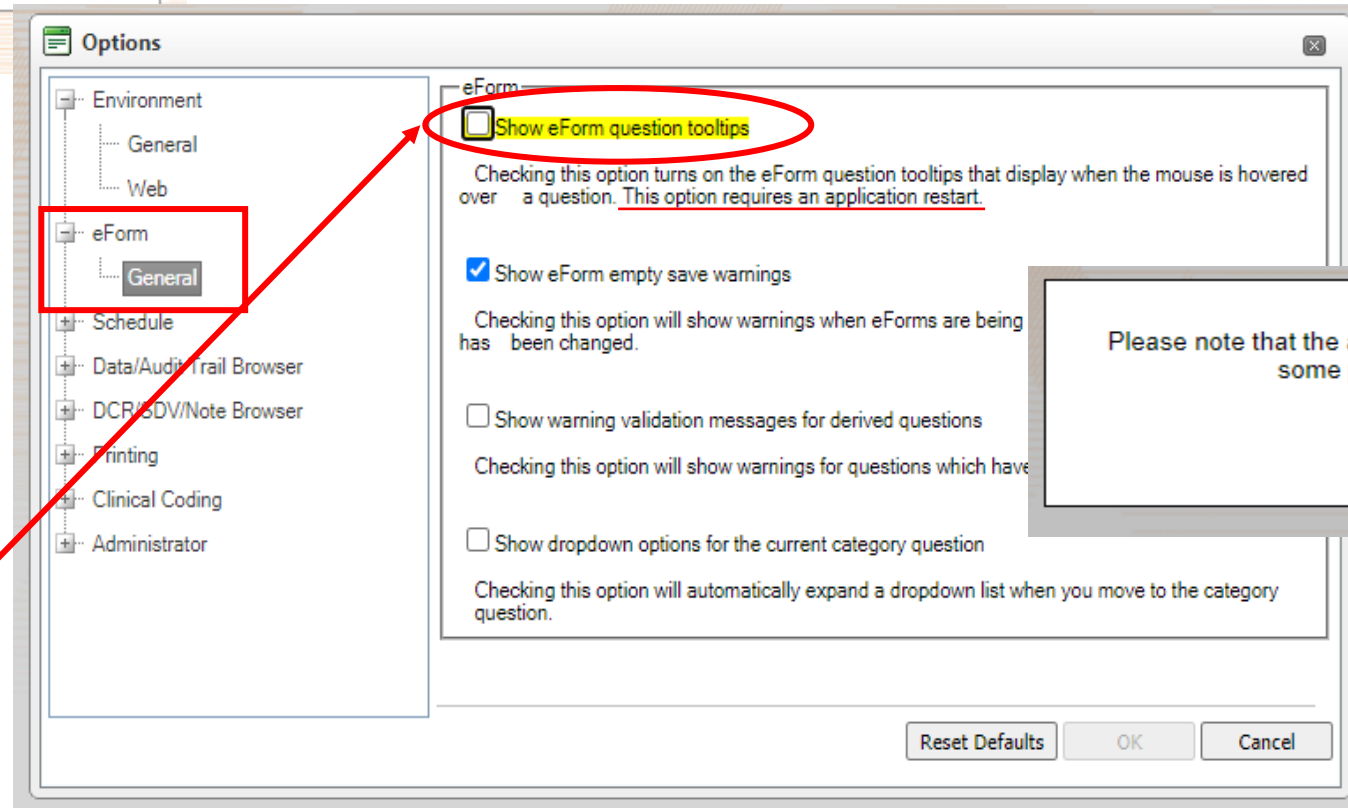
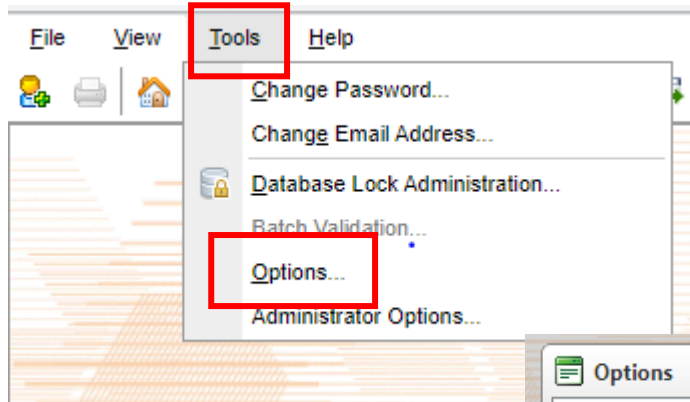


MENU OPTIONS & SHORT-CUT ICONS

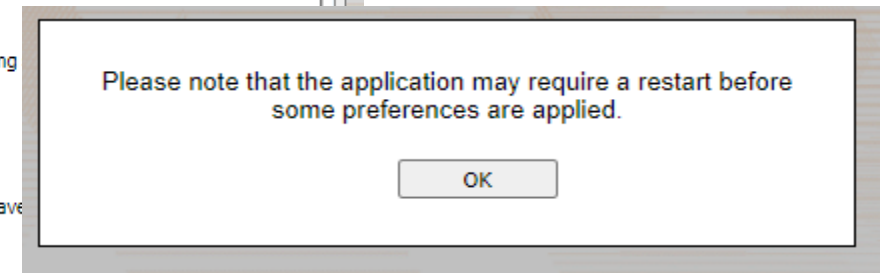


MENU OPTION: TOOLS

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



Useful Tip:
Uncheck this
box!



SEARCHING FOR SUBJECTS 1

- Click the 'Open the subject list page' icon on the shortcuts toolbar

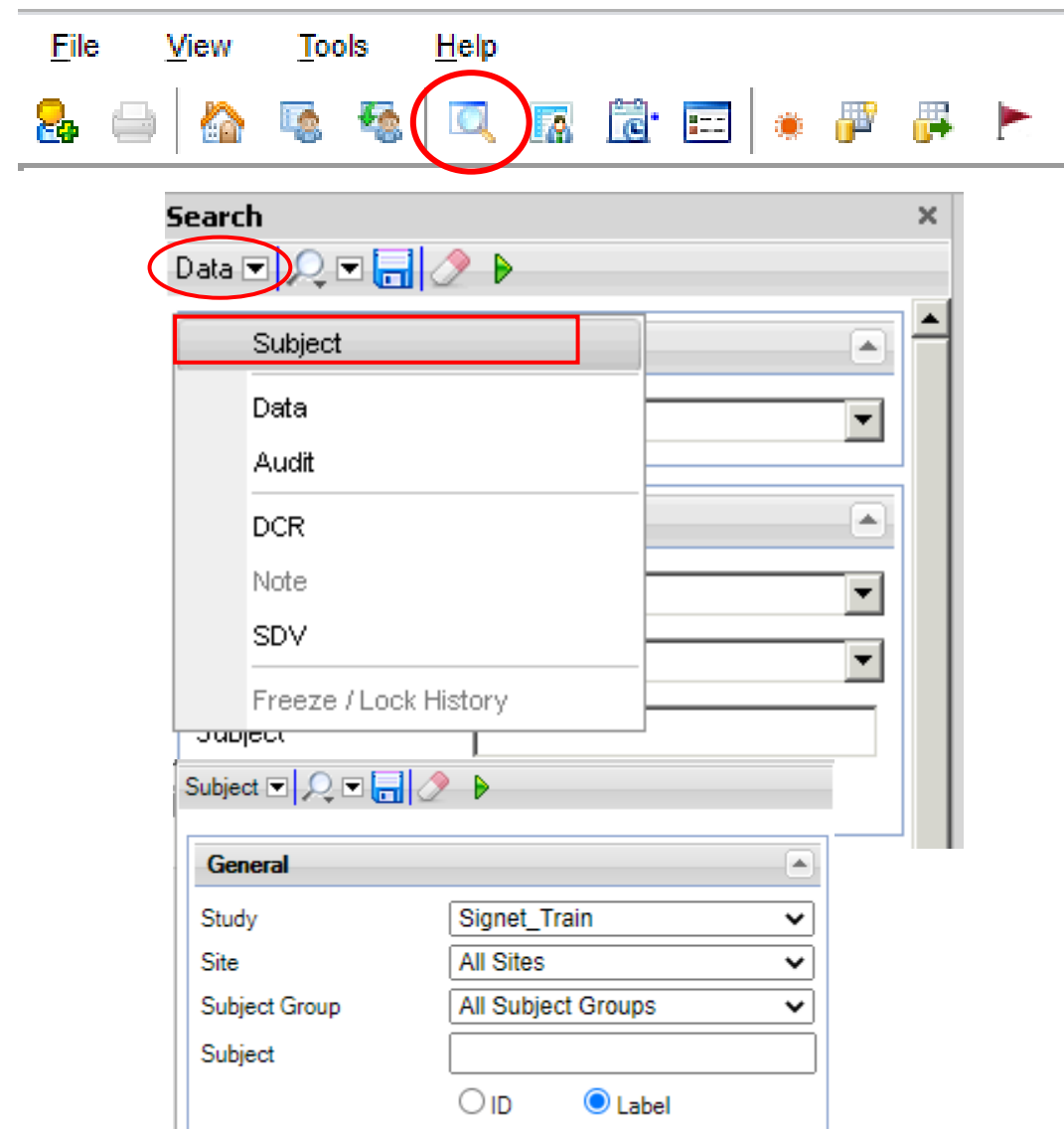


- The subject list page opens, click a patient in the list to continue entering their database record or resolve queries

File View Tools Help						Database :SIGNET_Train Role :FullUser User :Renate Hodge					
Status	Study	Site		Subject ID		Subject Label		Last Modified			
	All Studies	All Sites									
	Signet_Train	nhsbt001		1				2021/07/09 14:55:52 (GMT+1:00)			
✓	Signet_Train	nhsbt002		1				2021/07/09 17:21:11 (GMT+1:00)			
✓	Signet_Train	nhsbt003		1				2021/07/09 17:22:22 (GMT+1:00)			
✓	Signet_Train	nhsbt004		1				2021/07/09 17:23:09 (GMT+1:00)			
✓	Signet_Train	nhsbt001		2				2021/07/09 17:19:45 (GMT+1:00)			

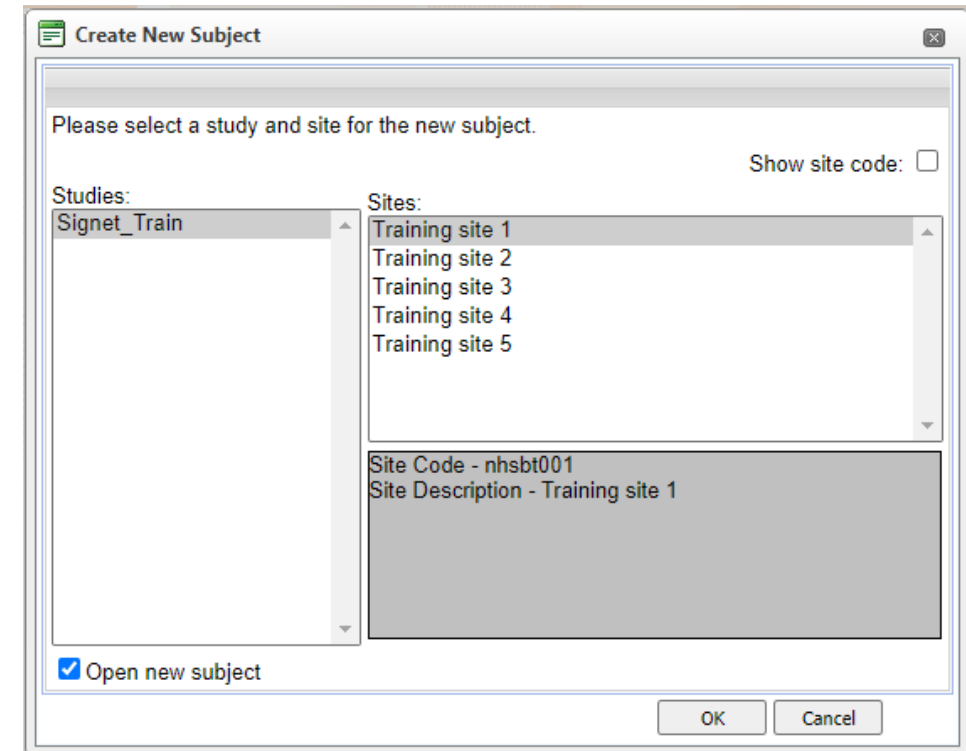
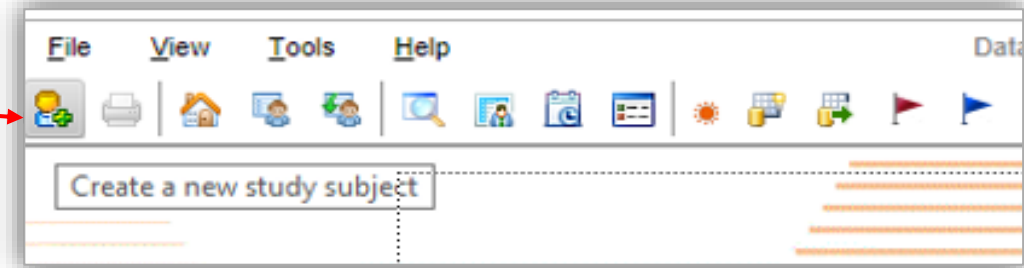
SEARCHING FOR SUBJECTS 2

- 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






CREATING NEW SUBJECTS

- 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












- 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

PLANET2/nhsbt176/(11)				
Baseline	___BAT___	BAT_other	Scans	
Clinical Forms Checklist				
PATINFO				
Pretrial_tfns				

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

PLANET2/nhsbt176/(11)						
Baseline	___BAT___	BAT_other	Scans	Pittlog	___Day___	
Clinical Forms Checklist						
PATINFO						
Pretrial_tfns						
Prerandom						
Eligibility						
Medcond						
Randomisation						

Visits

eCRFs

SUBJECT REGISTRATION

- 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

Database : Planet2 Role : DEDM User

Site ID	eForm Name	Status
PLANET2/nhsbt176/176011	Baseline	Available for data entry
	Clinical Forms Checklist	Available for data entry
	PATINFO	Not available for data entry
	Pretrial_tfns	Not available for data entry

Form is light blue and so is available for data entry

This form has data entered with no Warnings or Missing data

A blue eForm icon denotes that the eForm can be opened but does not contain any data

DATA ENTRY

Schedule QuickView

HLA/Epitope/nhsbt001/10008

- Enrolment
 - Patient Information Form
 - Eligibility for Randomisation Checklist 03/04/2014
 - Randomisation 03/04/2014
 - Registration 27/08/1976
- Non-Trial Transfusion
- Non-Trial Transfusion[2]

Visit: Enrolment

Visit Date:

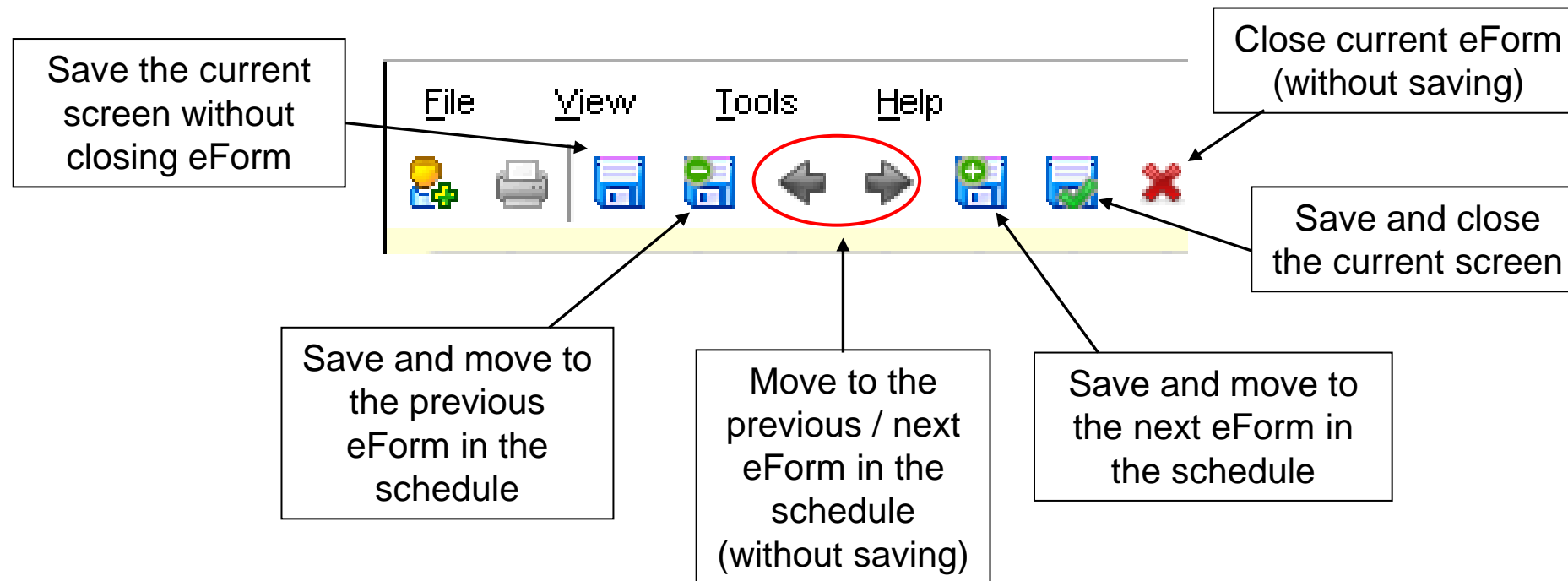
Laboratory: None selected

- 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

- 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



MISSING DATA

Clinician Signature
☒ Yes ☐ No ✓

Date Form Completed
[Yellow box] ☀

- 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

antibody screen? [] ☀

Female [] ✓

[Add... View... Remove All]

[m) 162] ✓

- View Question Information...
- View Audit Trail...
- View Warning...
- View Inform Message...
- Comments**
- Notes
- DCRs
- SDV Mark
- Change Status
- Clear



antibody screen? [] ☀

- 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

Name
Value

Diastolic blood pressure
00


Properties

Warnings

Comments

Audit Trail

The following warnings have been generated:

Message	Overrule
 Diastolic blood pressure is outside the range 20 - 200 mmHg, check entry.	<input type="text"/>

Close



DATA QUERIES

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



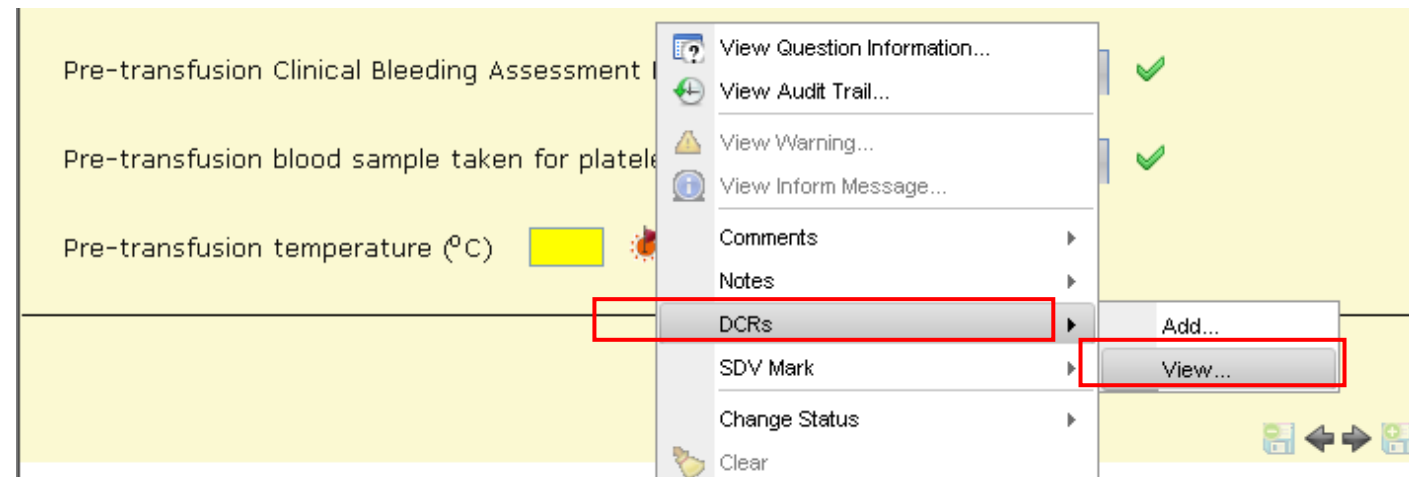
DATA QUERIES - continued

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

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



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**

The screenshot shows the 'DCR Browser' window. It contains a table with columns: Date, Status, Subject, Visit, eForm, Question, Value, User Name, OC Id, Text, Unique DCR Id, Print Batch, and Received Date/Time. A single record is visible with a status of 'Raised'. Below the table, a dialog box titled 'Set DCR to Responded' is open, showing the 'Name' as 'Temperature' and the 'Text' as 'Temperature was not taken'. The 'OK' button in the dialog is highlighted with a red box.

Date	Status	Subject	Visit	eForm	Question	Value	User Name	OC Id	Text	Unique DCR Id	Print Batch	Received Date/Time
2014/04/04 14:11:27	Raised	HLAEpitope/nhsbt101/20008	Transfusion	Pre-transfusion	Temperature		rde	2000802	Pre-transfusion checklist: Transfusion 1, 04/08/2013: Pre-transfusion	nhsbt101-15-Server	2	

Page 1 of 1, records 1 to 1 of 1 records.

Set DCR to Responded

Name: Temperature

Text: Temperature was not taken

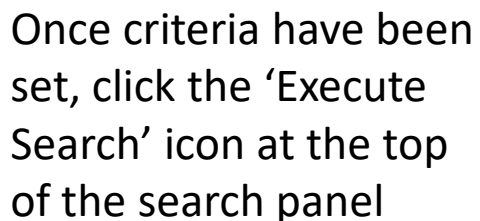
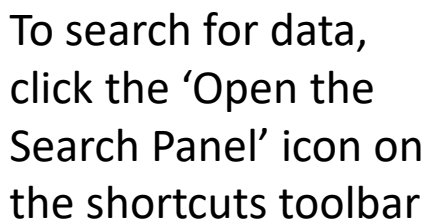
OK Cancel

Raised DCR

Date of randomisation:

31/05/2021





DATA SEARCH

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

Data

Search Detail Level

Detail
All

General

Study
Cryostat2

Site
All Sites

Subject Group
All Subject Groups

Subject
ID
Label

Statuses

☐ Select/Clear All
☐
☐
☐
☐
☐
☐

Comments

Note

Frozen/Locked

Frozen/Locked

DCRs/SDV Status

DCR
None
Raised

SDV
None
Planned

Study Level

Visit
All Visits

eForm
All Eforms

Question
All Questions

User

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

Has the patient had a thromboembolic event or serious transfusion related adverse reaction?

☐ Yes☒ No

Has the patient died?

☒ Yes☐ No

24 Hours From Arrival In Emergency Department

Medications

?

View Question Information...

🔄

View Audit Trail...

⚠

View Warning...

i

View Inform Message...

Comments

Notes

DCRs

SDV Mark

Change Status

🔔

Clear

Current Entry

Name

Value

has patient had thromboembolic event

No

Properties

Comments

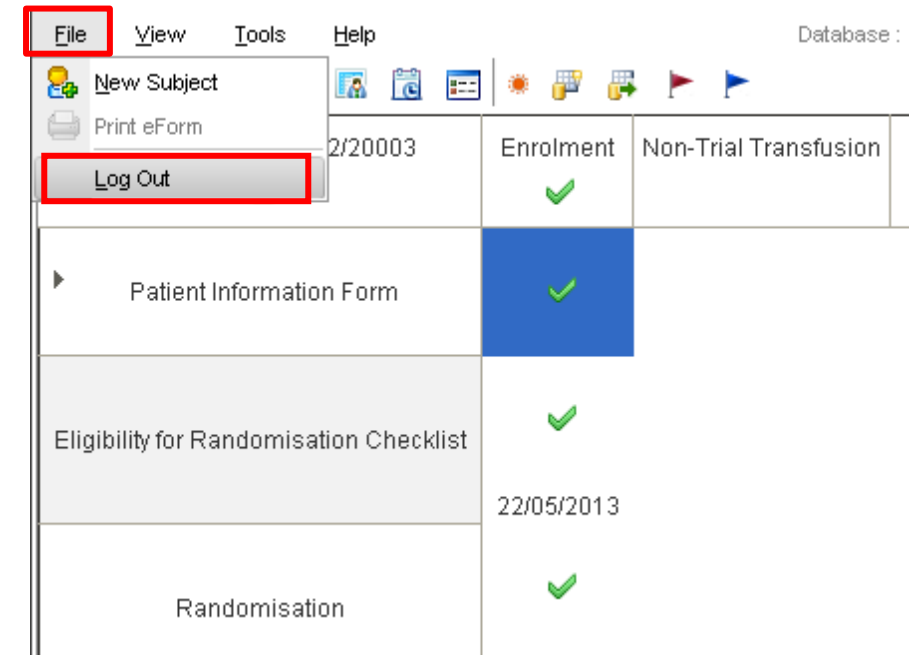
Audit Trail

Value	Value Code	Status	UserName	Time Stamp	Database Time Stamp
No	0	OK	ctsharr001	2020/08/10 15:33:28 (GMT+1:00)	2020/08/10 15:34:09 (GMT+1:00)
		Missing	CTDALLN001	2020/06/01 12:58:06 (GMT+1:00)	2020/06/01 13:00:59 (GMT+1:00)

Updated Entry

Original Entry

- 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



The screenshot shows the MACRO software interface. The 'File' menu is open, and the 'Log Out' option is highlighted with a red box. The interface includes a menu bar with 'File', 'View', 'Tools', and 'Help'. Below the menu bar, there are icons for 'New Subject', 'Print eForm', and 'Log Out'. The main area displays a table with columns for 'Database', 'Enrolment', and 'Non-Trial Transfusion'. The table contains several rows, including 'Patient Information Form', 'Eligibility for Randomisation Checklist', and 'Randomisation'. Each row has a green checkmark in the 'Enrolment' column. The date '22/05/2013' is visible in the bottom right corner of the table area.

Database	Enrolment	Non-Trial Transfusion
2/20003	✓	
Patient Information Form	✓	
Eligibility for Randomisation Checklist	✓	
Randomisation	✓	





POINTS TO REMEMBER

- 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

Status

-  Invalid
-  Not Applicable
-  OK
-  OK Warning
-  Missing
-  Not Available
-  Warning
-  Inform
-  Note
-  Comment

DCR

-  Raised
-  Responded
-  Closed

WHAT'S NEXT ?

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



Thank's a lot