MACRO DATABASE USER GUIDE

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https://ctu.iop.kcl.ac.uk/app/index.asp
CONTENTS

LOGIN...........................................................................................................Page 2

1. TASK LIST....................................................................................................4
   1.1 Create a new subject................................................................................5
   1.2 View subject list.....................................................................................10
   1.3 View raised discrepancies.......................................................................11
   1.4 View responded discrepancies..............................................................12
   1.5 View planned SDV marks.........................................................................12
   1.6 View changes since last session.............................................................13
   1.7 Database Lock administration...............................................................13

2. SUBJECTS....................................................................................................14

3. SEARCH.......................................................................................................15

4. ERRORS.......................................................................................................16

5. AUDIT TRAIL...............................................................................................18

6. DATABASE LOCK........................................................................................18
LOGIN

- You will be given a link to the website and allocated a unique username and password.
- It is important NEVER to share your password with anyone else as an audit trail is left by all using the database.

- Once you have logged in you will see the following page.
• Click on OPTIONS on left hand side and ensure that VIEW FUNCTION KEYS and VIEW SYMBOLS are ticked. These will then show all the different symbols you might see as you work your way through the database, and what they mean.

• The main buttons you will need are those listed on the left hand side:

  TASK LIST
  SUBJECTS
  SEARCH
1 TASK LIST

- If you click on the TASK LIST button you will see a list of options which you will need to start entering subjects on the database. These are:

CREATE NEW SUBJECT
VIEW SUBJECT LIST
VIEW RAISED DISCREPANCIES
VIEW RESPONDED DISCREPANCIES
VIEW PLANNED SDV MARKS
VIEW CHANGES SINCE LAST SESSION
DATABASE LOCK ADMINISTRATION
CHANGE PASSWORD
1.1 Create New Subject

- To start entering subject on database click on CREATE NEW SUBJECT

- You will then need to select the correct study and site and click on OK

- This will take you to a list of pages to be completed for each subject.

- The list may vary according to each study but the same principles apply.

- The list where possible, will follow the order of the CRF

- Symbols of pages next to each item show that data entry has not started on those sections.
To begin data entry you need to click on the paper symbol at the side.

You must begin with the registration form for each subject before going on to any of the other sections.

The subject number and date must be entered.
• Ticks will appear at the side of entry as the correct sort of data is entered.

• Drop down menus show range of answers as in CRF plus other codes.

• Where possible missing data codes 777/888/999 should be avoided.

• If you do enter 777/888/999 for a field where data is required as part of inclusion/exclusion criteria and exclamation mark will appear at the side of the data alerting you that isn’t right.
If other is entered and nothing is entered in the next box then a symbol of a pencil will appear to show there is missing data.

When you get to the bottom of the page and click the arrow to move to the next section a message will appear to remind you that there is some missing data.
• If you enter a value outside of the specified range an error warning will appear

• You should then click on the red cross to close the box and re enter the correct value
• There may be some instances when you might need to keep the data you have entered.
• In this case click on the overrule and type in a reason
• Forms will automatically be saved as you move from one page to the next.
• Once you want to finish data entry for that participant then click on the save symbol.

• If you start entering a section and realise you have gone wrong then click on the trash symbol. The whole form won’t be deleted it will just clear that section for you start again.

1.2 View Subject List
• Clicking on this will bring up a list of all participants entered on the database.
• Symbols to left of each subject show if there are missing data etc
• Some symbols show if the data has been monitored (SDV) visit is planned
• Clicking on a particular row will open the form for that subject

1.3 View Raised discrepancies
• Clicking on this will show a list of subjects with discrepancies queried by the monitor

• You can respond to a query by right clicking on the discrepancy
1.4 View responded discrepancies

- Clicking on this will bring up the list of discrepancies that have been answered
1.5 Source Data Verification

The Trial Manager and Data Manager will organise a visual check for a predetermined proportion of forms of each type and compare the data against a database listing. This procedure is documented for each trial. Any discrepancies will be corrected on the database. The TMG will be informed of the results of the verification and decide on action necessary if there are a large proportion of errors.

The proportion of forms to be visually checked will depend on the nature and size of study, the trial risk assessment and the data monitoring. This should be agreed upon prior to the start of the trial based on the complexity of the trial and nature of the data being collected and should form part of the data and monitoring plans for the trial.

The verification should first be conducted after an agreed number of patients have been entered and every 3/6 months thereafter. This can be more frequent depending on the quality of data arriving from the investigator.

The individual carrying out the checks will have a monitor role.

Source Data Verification In Macro

SDVs can be set at the subject, visit, eForm level – studies should decide on which level is most appropriate for their checks.

Source Data Verification (SDV) is a process carried out by a data monitor and consists of cross-checking the data collected for subjects with the original information source. This is a way of checking that the data being input into MACRO is genuine and accurate. The process is sometimes known as Source Document Verification.

SDV Statuses

An SDV can have one of four statuses:

- **Planned**  SDV is yet to be done
- **Done**  Source data has been verified satisfactorily
- **Queried**  There is some problem with the data verification
- **Cancelled**  The SDV mark is no longer required

The SDV status of an object (subject, visit, eForm) will only be Done if the object itself has a Done SDV and not if it only contains other objects with Done SDVs.

For example, an eForm may contain questions which each have Done SDVs. Unless the eForm itself also has a Done SDV, the Done icon will not be displayed on the visit schedule and in the browser for the eForm.
Changed Data

If data changes after an SDV mark has been set to Done, the SDV mark will be automatically reset to Planned, to allow re-verification of the data.

Viewing all SDVs or a subset via the data browser

1. Click Search on the left menu panel.
2. Click to select SDV.
3. Complete the filter screen to reflect your needs and press Refresh.
4. The SDV listing window will be displayed. Click on a record in the list and the SDV details will appear on the section beneath. Details of the question to which the SDV is attached will be displayed to the left of the SDV details.

Changing the status of multiple question SDVs

You can change the status of all question SDVs on a single eForm from Planned to Done in one go.

1. Open the visit schedule.
2. Right click on the eForm containing the SDVs you wish to change.
3. Select Change all Planned question SDVs to Done.

1.6 View changes since last session

- A list of changes since your last session can be viewed by clicking on this

1.7 Database Lock Administration

- The database will be timed out if not used for about 5 mins
- This can also occur if log out by clicking on the red cross in the top right hand corner rather than clicking on the LOG OUT button at the top of the screen
- You may be just asked to re-enter username and password, but the database may lock
- To remove the lock click on Database lock administration and click on the lock and delete
2. Subjects
   - Clicking on SUBJECTS on left of page will bring up a list of subjects entered
If you scroll down and click on the participant you want it will open that particular record.

3. Search
   • Clicking on SEARCH on the left of the page shows 6 boxes for the types of search you can do: DISC/SDV/NOTES/SUBJECT/DATA/AUDIT
These are alternative ways to view discrepancies and data discussed in section 1 Task list.

It may be easier to search for a particular participant by clicking on SUBJECT then adding the site and subject number.

Then click REFRESH and the record will appear in the window.

4. Errors

If you need to change data that has been entered and saved a pop up window will appear asking why data has been changed.
• You will need to say whether it was a ‘transcription error’, ‘wrong patient data entered’ or ‘new information’.
• Then click OK to continue

• If you find an error but don’t know how to deal with it try clicking on the HELP button which contains detailed information about the database
If you still think there is an error that needs reporting this should be sent to the Trial Coordinator of the study in question, they will be responsible for coordinating Issue Logs to the Clinical Trials Unit.

Info needed will be the question no., the problem, and what you were doing at the time of error.

Question no. can be found by right clicking on the question then clicking View Question Details'. The question no. on this example is RAIN_S01.
5. Audit Trail

- An audit trail is left for everything done on the database

6. Database lock

- Once the monitor is sure data is correct in each section, and any queries/discrepancies resolved then sections can be locked
- Once a section is locked then no further data entry can take place
- A symbol of a lock will appear next to sections that are locked.
- Only the monitor can close discrepancies and lock the database.