***Text in blue is for instruction only and should be deleted.***

***Text in black should be included if appropriate for the trial.***

**SOP Ref No *Insert trial title*\_SOP00**

**SOP title Data Entry**

**Version *Insert number* 0.0**

**Date issued *Insert date* DDMMMYYYY**

**Valid until *Insert date* DDMMMYYYY**

**Author(s) Name:**

**Signature:**

**Date:**

**Approved by Name:**

**Signature**

**Date**

**Modification history**

|  |  |  |  |
| --- | --- | --- | --- |
| **Version No** | **Date** | **Author(s)** | **Date reissued to previous recipients** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Standard Operating Procedure**

1. **Purpose**

The purpose of this standard operating procedure (SOP) is to ensure that data are accurately recorded on the ***insert trial title*** electronic Case Report Forms (eCRFs) and managed according to the ***insert trial title*** protocol, European Union data protection laws, ICH GCP and FDA 21 CRF Part 11.

1. **Scope**

This SOP describes the procedures for ***insert trial title*** data entry and checking. Information on dealing with data queries is given in ***insert trial title SOP00 Data Query V0.0 DDMMYYYYY.***

1. **Responsibility**

Trial staff will be responsible for ensuring the required data are collected from source documents and accurately recorded and checked on the ***insert data capture system e.g. MACRO*** database. Trial staff are responsible for ensuring that data are handled and processed in alignment with data protection regulations.

1. **Personal Identifiable Information**
	1. All personal identifiable information collected on ***insert trial title*** trial subjects will be treated as confidential information, and should be handled in accordance with the terms of the European Union data protection laws.
	2. Anyone processing personal data must comply with the seven principles (Rouse, 2008):
* Notice: Subjects should be given notice when their data are being collected.
* Purpose: data collected should be used only for stated purpose(s) and not for any other purposes.
* Consent: personal data should not be disclosed without consent from its subject(s).
* Security: the collected, personal data should be kept safe and secure from potential abuse, theft, or loss.
* Disclosure: subjects should be informed of the party or parties collecting their data.
* Access: subjects should be allowed to access their personal data and allowed to correct any inaccuracies.
* Accountability: subjects should be able to hold data collectors accountable for not following the seven principles.
1. **Patient Identification Number (PIN)**
	1. Each centre has a unique number:

Site ***insert number 000*** = ***Betty Rubble Community Clinic***

* 1. All patients (both those that are eligible to take part in the trial and screen-failures) will be allocated a unique patient identification number (PIN) by ***insert data capture system e.g. MACRO database.*** The identification number will consist of ***insert number*** of digits; the first ***insert number*** of digits correspond to the site number and the last ***insert number of*** digits are the sequential patient number ***e.g. 201-001 is for the first patient at site 201.***
	2. The PIN will be in the same format for enrolled patients regardless of their cohort.
	3. For non-enrolled (ineligible) patients, the PIN will be prefixed by ***insert "X" (to denote "Screening ID"), e.g. S202-001.***
	4. The PIN should be recorded on the Screening and Enrolment Log and used in all correspondence; names should not be used in any data transmissions or correspondence.
1. **Data entry, checking and uploading using *add data capture system e.g. MACRO* database**
	1. ***Insert data capture system e.g. MACRO*** database set up
		1. With the exception of the ***insert eCRF***, all data for the ***insert trial title*** trial are to be entered onto the ***insert data capture system e.g. MACRO*** database.
		2. Only users assigned a data entry role can enter and change data values in the ***insert data capture system e.g. MACRO*** database.
		3. The electronic Clinical Record From (eCRF) for each patient consists of a number of visits (columns) for which the relevant eCRF forms are available (as rows across the columns). Some visits (***e.g. Insert Study Day X/Visit***) will only appear when the required forms for the previous visit (***e.g. Insert Study Day X/Visit***) have been started. In some cases multiple forms are available in a row for a visit. In this version of ***insert data capture system e.g. MACRO***, where there are multiple forms, the next form will automatically appear and the user will have to tick that it is not required.
	2. **Accessing *add data capture system e.g MACRO* Database**
		1. User profile permissions must be granted by the ***insert data capture system e.g. MACRO*** database programmers to be able to gain access to the ***insert data capture system e.g. MACRO*** database***.*** Each user will have a unique username and password to enter the database. All passwords must be stored in a secure place and never shared with anyone else. Should you forget your password or enter it incorrectly and lock yourself out of the database, please email – ***insert email address*** to reset your password.
	3. **Creating new subjects on the *add data capture system e.g. MACRO*** **database**
		1. All new patients must be entered on the **insert data capture system e.g. MACRO** database. To do this:
2. Login to ***insert data capture system e.g. MACRO*** using Data Entry Role.
3. Select the task list tab from the database menu.
4. Select create new subject.
5. Select the site.
6. Click on Ok.
	* 1. Appendix 1 lists the function keys and status symbols used by ***insert data capture system e.g. MACRO.***

***Insert screenshot***

* 1. **Entering data on eCRFs**
		1. All data entry must be done using the ***insert data capture system e.g. MACRO*** database. To do this:
1. Login to ***insert data capture system e.g. MACRO*** using Data Entry Role.
2. Select the subject tab from the database menu.
3. Select the PIN (subject number).
4. Click on the relevant form type within the ***insert data capture system e.g. MACRO*** database.
5. Enter data as per original source document using the stylus or keyboard.
6. Save the form.
	1. **Checking data entry**

There are two familiar methods of preventing and identifying data entry errors:

 Single data entry: the data entry person enters the data once. Afterwards the same person visually compares the entries with the original source document. The data entry person will then correct the errors. Single data entry should be considered when there extensive range checking built into the database and further checks are run after data entry.

* Double data entry: data is entered twice and the computer compares entries to identify mismatches along with values outside of the allowable range. The data entry person will then correct the errors. This is the most common method used in data management.
	+ 1. **Procedure for single data entry**
		- Enter the CRF onto the ***insert trial title and data capture system name e.g. MACRO.***
		- Visually audit the on-screen data, referring to the original source document.
		- If data are inaccurate, amend the data.
		- Save the eCRF(s).
		- Verification of data should done on each incoming case or sample by sample cases
		1. **Raising manual data queries**

***Insert bullet pointed steps and screenshot***

Figure 1. Identifying records for data review

***Insert screenshot***

* + 1. **Procedure for double data entry**
* Data Entry validation and range checks are set and required fields indicated, etc, where appropriate.
* Data is entered by two data entry clerks, each working independently of the other, compared by a third person, who identifies and reconciles discrepancies.
	+ 1. **Resolving data entry discrepancies**

***Insert bullet pointed steps and screenshot***

***Insert screenshot***

Figure 1. Identifying data entry discrepancies

Figure 2. Resolving data entry discrepancies

***Insert screenshot***

* 1. **Timely Data Entry**
		1. Timely data entry of data is required to ensure:
1. Site data are always backed up.
2. New study definitions, new reports, updated users/passwords/roles, new discrepancies and any new system updates are available to users.
3. New or modified patient data and new or modified discrepancies are available to online users so that central monitoring activities can be completed.
	1. **Data Entry Rules and Instructions**

The following rules must be adhered to when entering data:

* + 1. **Abbreviated text or summaries**

No abbreviations or summaries of text data will be permitted, and any ambiguous abbreviations/wording provided by site will be queried.

* + 1. **Entering ‘Other doses’ including unplanned**

**Dosage field**

The dosage field should report the actual dose administered and not the intended dose. To enter dosages other than 0.3 mg/tablets etc:

* Select ‘Other dosage’.
* Calculate and enter the actual dose that was given onto the insert data capture system e.g. MACRO database.
* Specify the reason – ‘Doctors request’ or ‘Other’.
* If ‘Other’ specify reason in free text box.

* + 1. **Entering lab values**

Laboratory values given as < on laboratory results printout forms will be entered as insert number e.g. ***0*** on the database.

* + 1. **If a patient has mistakenly been entered twice**

It is not possible to delete a patient from ***insert data capture system e.g. MACRO database***, the best option if the patient has been entered twice is to "re-use" the duplicate patient record by overwriting the fields with new data (recording ‘data entry error’ as the reason for change).

When this is not possible the add trial title data manager and/or programmer should be informed. They will discuss and document the procedures to be followed to allow for these changes.

* + 1. **Unlocking patient records**

If all fields are disabled it's possible there may be a "database lock" on the data.

The user should select "Database lock administration" from the Task List and see if a lock is listed for that patient (this can happen if a patient record is left open and the laptop is switched off, for example). If so, the lock can be removed by the user who originally opened the patient (as listed in the Database Lock Administration window). Beware that database locks should only be removed if the subject is *definitely* not still open, otherwise data corruption could occur.

* + 1. **Entering partial dates**

Missing day will be entered as in 15 and a comment added confirming that it is estimated.

Missing month will be entered as 06 and a comment added confirming that it is estimated.

* + 1. **De selecting *radio* buttons**
1. Right click on the field or question and select clear

Place the cursor on the question or field and press F9.

***Insert screenshot***

* + 1. **Populating new eCRFs**

All eCRFs for each Study Day must be completed, or confirmed as not done/unobtainable before the eCRFs for the next Study Day will appear (Figure **2**).

Figure 2. *Insert trial title* window showing all forms for Day 03/11/2014 have been completed and hence next set of forms are available.

***Insert screenshot***

* + 1. **Mistakenly opening eCRFs which do not require data entry**

It is not possible to delete erroneous eCRFs from the insert trial title database. If you open an eCRF which does not require data entry, do not save the form select the trash can icon instead.

***Insert screenshot***

If you mistakenly select the save icon the eCRF will now appear in the missing data queries listings. To resolve this missing data query the questions: ‘Sample taken’, ‘Is data available’ or ‘non study medications given’ must be answered as no.

***Insert screenshot***

* + 1. **Missing eCRFs and data fields**

Missing eCRFs and/or field(s) are flagged with ***insert icon.*** If a CRF and/or data item are deemed missing (e.g. unable to obtain the information, the visit/test was not done or if a patient has not attended their visit) the associated eCRF and/or fields should be changed to ‘unobtainable’.

***Insert instructions: e.g. to do this, right click the mouse or select F10 and then select – ‘Change status to unobtainable’ (see Figure 3)***

Unobtainable data can be re-amended to missing data at any time by following the same steps and selecting ‘Change status to missing’.

Figure 3. Setting data to unobtainable or missing on *insert data capture system e.g. MACRO.*

***Insert screenshot***

* + 1. **Entering eCRFs for ineligible patients**

Information for ineligible, including non-consenting, patients will be entered in the database as stated in the protocol. It will only be necessary to complete the ***insert relevant form e.g. screening/ randomisation form.***

* + 1. **Overruling database warnings**

All database warnings may be over ruled if deemed necessary. To overrule any database warning click on ***‘Overrule this warning’ (Figure 4).***

Figure 4. Overruling a warning on *insert data capture system e.g. MACRO* database

***Insert screenshot***

Complete the reason for the overruling the warning ***(Figure 5)*** and click on close.

Figure 5. Entering the reason for overruling a warning on *insert data capture system e.g. MACRO database*

***Insert screenshot***

* + 1. **Protocol Deviations**

It is important to remember that overruling database warnings or setting data to unobtainable may result in a protocol deviation.

If warnings are overruled or data are unobtainable, please be sure to check the relevant SOPs, protocol and if necessary complete the Protocol Deviation and Violation log and report findings to the trial co-ordinator. This is required in addition to recording the reason for overruling the warning on ***insert data capture system e.g. MACRO*** database.

* 1. **Online access to MACRO database**

The online version of the database can be accessed using the following ***insert web link***

* 1. **Suggestions for database modifications**

Should you note that an additional database modification is required. For example, a daily medication is not listed on the drop down menu and you would like it to be added. Please notify the ***insert trial title*** Database Manager and, if appropriate, a request will be launched with the database programmer to complete the modification.

1. **References**
* Rouse, M (2008) EU Data Protection Directive (Directive 95/46/EC) [Online] Available from: <http://searchsecurity.techtarget.co.uk/definition/EU-Data-Protection-Directive> [Accessed: 23rd December 2014].
* ***Insert trial title*** SOP00 Data Query V0.0 DDMMYYYY
* ***Insert trial title*** Data and Safety Monitoring Plan V0.0 DDMMYYYY
* *Insert trial title* Database Delegation Log V0.0 DDMMYYYY
* ***Insert trial title*** Protocol Deviation log V0.0 DDMMYYY

**Appendix 1 – *Insert data capture system e.g. MACRO database function keys and status symbols***