



Standard Operating Procedure

1. Purpose

The purpose of this standard operating procedure (SOP) is to ensure that data are accurately recorded on the PB SAM study's electronic Case Report Forms (eCRFs) and managed according to the PB SAM study's protocol, European Union data protection laws, ICH GCP and FDA 21 CFR Part 11.

2. Scope

This SOP describes the procedures for the PB SAM study data entry and checking. Information on dealing with data queries is given in the PB SAM study **PB SAM Data Query v1.01 SOP**.

3. Responsibility

Clinical study staff will be responsible for ensuring the required data are collected from source documents and accurately recorded and checked on the Clinical database database. Clinical study staff are responsible for ensuring that data are handled and processed in alignment with data protection regulations.

4. Personal Identifiable Information

- 4.1. All personal identifiable information collected on the PB SAM study subjects will be treated as confidential information, and should be handled in accordance with the terms of the European Union data protection laws.
- 4.2. 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.

5. Patient Identification Number (PIN)

5.1. Each country has a unique number:

e.g. Country 10 = Kenya



5.2. Each centre has a unique number:

Site 001 = Kilifi County Hospital

Site 002 = Mbagathi Hospital

5.3. All patients (both those that are eligible to take part in the study and screen-failures) will be allocated a unique patient identification number (PIN) on the **Clinical database**. The identification number will consist of **8** digits; the first **2** digits correspond to the country number, the second group of **3** digits correspond to the site number and the last **3** digits are the sequential patient number **e.g. 10-002-001 is for the first patient at site 002(Mbagathi) in Kenya.**

5.4. The PIN will be in the same format for enrolled patients regardless of their cohort.

5.5. For non-enrolled (ineligible) patients, the PIN will be prefixed by **"S"** (to denote **"Screening ID"**), **e.g. S202-001.**

5.6. 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.



6. Data entry, checking and uploading using Clinical database

6.1. Clinical database set up

- 6.1.1. With the exception of the **lab eCRF** which go to KIDMS, all data for the PB SAM study are to be entered onto the **Clinical database**.
- 6.1.2. Only users assigned a data entry role can enter and change data values in the Clinical database.
- 6.1.3. The electronic Case Record Form (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. Study Day X/Visit**) will only appear when the required forms for the previous visit (**e.g. Study Day X/Visit**) have been started. In some cases multiple forms are available in a row for a visit. In this version of **Clinical database**, where there are multiple forms, the next form will automatically appear and the user will have to tick that it is not required.

6.2. Accessing Clinical database Database

- 6.2.1. User profile permissions must be granted by the Clinical database administrator/Central Data Manager to be able to gain access to the Clinical 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 – chainsupport@kemri-welcome.org to reset your password.

6.3. Creating new subjects on the Clinical database (Subject to change)

- 6.3.1. All new patients must be entered on the Clinical database. To do this:
 - a) Login to Clinical database using your username and password credentials.
 - b) Select **PB SAM Study** from the list of projects under “**My Projects**”
 - c) Select “**Add/Edit Records**” from the menu under the header “**Data Collection**”.
 - d) Select create add new record.
 - e) Select and event for which you’d like to capture the data.
- 6.3.2. Appendix 1 lists options of data collection used by Clinical database.



 My Projects or  Control Center

 Project Home

 Project Setup

Project status: **Development**

Data Collection  [Edit Instruments](#) 

 **Scheduling**

- Generate schedules for the calendar using your defined events.

 **Record Status Dashboard**

- View data collection status of all records

 **Add / Edit Records**

- Create new records or edit/view existing ones

PB SAM DATA ENTRY SOP



Appendix 1 lists options for scheduling subject data entry for events used by Clinical database.

CHAIN Network Study

Event Grid

"6" is a new Record ID. You will need to click any of the gray buttons below to create a record for this Record ID and begin entering data for it.

The grid below displays the form-by-form progress of data entered into the project for one particular Record ID for all defined events. You may click on the colored buttons to access that form for that event. If you wish, you may modify the events below by navigating to the [Define My Events](#) page.

Legend for status icons:

- Incomplete Incomplete (no data saved) ?
- Unverified
- Complete

NEW Record ID 6

Data Collection Instrument	Enrolment	24 to 48Hr Assessment	Day 45 Follow Up	Day 90 Follow Up	Day 180 Follow Up	Study Conclusion
Admission Form	<input type="radio"/>					
Daily Review		<input type="radio"/>				
Follow Up Day 45			<input type="radio"/>			
Follow Up Day 90				<input type="radio"/>		
Follow Up Day 180					<input type="radio"/>	
Study Conclusion						<input type="radio"/>



6.4. Entering data on eCRFs

- 6.4.1. All data entry must be done using the Clinical database database. To do this:
- a) Login to Clinical database using your username and password credentials.
 - b) Select **PB SAM Network Study** from the list of projects under “**My Projects**”
 - c) Select “**Add/Edit Records**” from the menu under the header “**Data Collection**”.
 - d) If editing an existing record, select the record ID from the existing list.
 - e) Select an event for which you’d like to capture the data.
 - f) Enter data as per original source document using the stylus or keyboard.
 - g) Upon completing the data entry, select the Form Status from the question labelled “**Complete?**”.
 - h) Save the form.

6.5. 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 is 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.

6.5.1. Procedure for single data entry

- Enter the CRF onto the PB SAM Network Study project selected from the list of my projects in Clinical database.
- 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 be done on each incoming case or sample by sample cases

6.5.2. Raising manual data queries

- Next to the field data, click on the bubble icon as highlighted in the Figure below.
- From the pop-up window, select Open Query options. You can optionally select a user to assign this query.
- Add some useful comments to the query that will be helpful in its resolution.



Anthropometry and Nutrition Weight	
Measurement 1 <small>* must provide value</small>	<input type="text" value="8.50"/> <input type="text" value="Kg"/>
Measurement 2	<input type="text" value="8.52"/> <input type="text" value="Kg"/>
Final measurement	<input type="text" value="8.51"/> <input type="text" value="Kg"/>

Figure 1. Identifying records for data review

Date/Time	User	Comments and Details
31-08-2016 1:00pm	echimwezi	Data Changes Made: adm_weight1 = '8.50'
01-09-2016 7:27am	colima	<input type="radio"/> Verified data value — OR — <input checked="" type="radio"/> Open query Assign query to a user (optional): <input type="text" value="-- select user --"/>
		Comment: <input type="text"/>

Figure 2. Open query and add comments detailing why the query has been opened.

6.6. Timely Data Entry

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

6.7. Data Entry Rules and Instructions

The following rules must be adhered to when entering data:

6.7.1. 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.

6.7.2. 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 Clinical database.
- Specify the reason – 'Doctors request' or 'Other'.
- If 'Other' specify reason in free text box.

6.7.3. Entering lab values

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

6.7.4. If a patient has mistakenly been entered twice

It is not possible to delete a patient from Clinical 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 PB SAM study's Central Data Manager and/or programmer should be informed. The Central and Site Data Managers will then discuss and document the procedures to be followed to allow for these changes.

6.7.5. 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.

6.7.6. Entering partial dates

This functionality is currently not supported. Most questions that deal with dates e.g. data of birth of a participant will ask whether the data captured is the "True date" or "Estimated".



6.7.7. De-selecting radio buttons

- a) Click on the **reset** link next to the options for question.

DOB True OR Estimated True Estimated [reset](#)

6.7.8. 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. The PB SAM study event grid showing Daily Review Form has been completed. By looking at the Legend for status icons, one can quickly identify which forms have data entry started and not completed and ones with incomplete (or have no data saved) .

The grid below displays the form-by-form progress of data entered into the project for one particular Record ID for all defined events. You may click on the colored buttons to access that form for that event. If you wish, you may modify the events below by navigating to the [Define My Events](#) page.

Record ID 3-3 (CHAIN Enrolment ID 30001003)

Legend for status icons:
 Incomplete Incomplete (no data saved) Unverified Complete

Data Collection Instrument	Enrolment	24 to 48Hr Assessment	Day 45 Follow Up	Day 90 Follow Up	Day 180 Follow Up	Study Conclusion
Admission Form	<input checked="" type="radio"/>					
Daily Review		<input checked="" type="radio"/>				
Follow Up Day 45			<input type="radio"/>			
Follow Up Day 90				<input type="radio"/>		
Follow Up Day 180					<input type="radio"/>	
Study Conclusion						<input type="radio"/>

6.7.9. Mistakenly opening eCRFs which do not require data entry

It is not possible to delete erroneous eCRFs from the PB SAM study database. If you open an eCRF which does not require data entry, do not save the form select the cancel button labelled “- - cancel - -” can icon instead.

Complete? Incomplete

Lock this record for this form? Lock

Save Record
 Save and Continue
-- Cancel --
 Delete Record (All forms/events)
 Additional delete options:
 Delete data for THIS EVENT only
 Delete data for THIS FORM only



If you mistakenly select the save icon the eCRF will now appear incomplete or complete depending of the previously set/edited form status. The form can then later be reused to capture data for another study participant. Alternatively, the data previously captured for the event on the form can be reset – deleted and entered again by selecting the options, as highlighted in the Figure x below

6.7.10. Incomplete eCRFs and data fields

Incomplete eCRFs are flagged with . If a CRF item is deemed incomplete (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 ‘incomplete’.

- a) From the Data Collection menu, select “Add/Edit Records”
- b) Select the record you would like to edit from the dropdown list.
- c) Select the event and form to edit.
- d) Move to the bottom of the page (eCRF)
- e) Select – “Incomplete” on “Completion?” under Form status heading (see

- f) Figure 3)



Unobtainable data can be re-amended to incomplete data at any time by following the same steps and selecting 'Incomplete' from the Form status at the bottom of the eCRF.

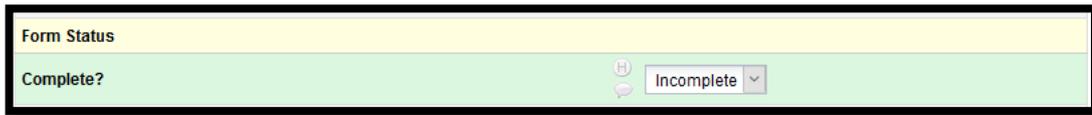


Figure 3. Setting form data to incomplete on Clinical database.

6.7.11. Entering eCRFs for ineligible patients

Information for ineligible, including non-consenting, patients **WILL NOT** be entered in the database, as stated in the protocol.

6.7.12. Overruling database warnings

Clinical database does not prevent acquisition of data that is out of range. It provides warning messages regarding out-of-range values but these can be overridden.

All database warnings may be over ruled if deemed necessary. To overrule any database warning click on 'Close' (Figure 4).

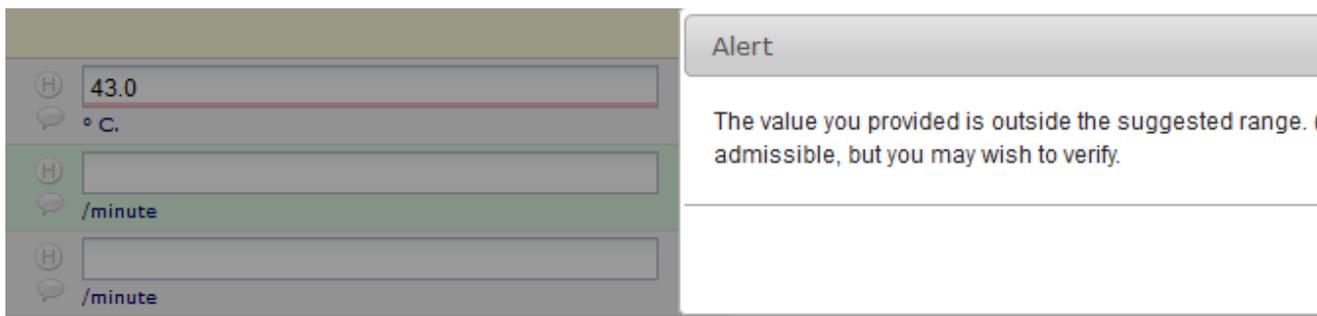


Figure 4. Overruling a warning on Clinical database database

Click in the bubble icon (Figure 5) next the field you have just overruled. Complete the reason for the overruling the warning (Figure) and click on close.



Figure 5. Click on highlighted icon to view the data resolution workflow, add comments for overruling the warning.



Event: Enrolment
Field: adm_init_temp ("Temperature")
Status:  Not Opened

Date/Time	User	Comments and Details
01-09-2016 12:39pm	colima	<p><input checked="" type="radio"/> Verified data value</p> <p>— OR —</p> <p><input type="radio"/> Open query</p> <p>Assign query to a user (optional): <input type="text" value="-- select user --"/></p> <p>Comment (optional): <input type="text" value="This is the actual value recorded in the source document"/></p>

Figure 6. Enter the reason for overruling a warning on Clinical database database.



6.7.13. 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 clinical study co-ordinator. This is required in addition to recording the reason for overruling the warning on Clinical database database.

6.8. Online access to Clinical database database

The online version of the database can be accessed using the following link
<http://production.chainnetwork.org>

6.9. 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 PB SAM Study Central Data Manager and, if appropriate, a request will be launched with the database administrator to complete the modification.



7. References

- Rouse, M (2008) EU Data Protection Directive (Directive 95/46/EC) [Online] Available from: <http://techtarget.com/definition/EU-Data-Protection-Directive> [Accessed: 31st August 2016].
- PB SAM Data Query SOP V1.0
- PB SAM Data and Safety Monitoring Plan SOP V1.0
- PB SAM Database Delegation Log V1.0