Childhood Acute Illness & Nutrition Network

KEMRI | Wellcome Trust Clinical Trials

Pancreatic Enzymes and Bile Acids: A Non-Antibiotic approach to Treat Intestinal Dysbiosis in Acutely Ill Severely Malnourished Children

Study Specific Procedure	**SSP No:** DM03 **Version No:** 1.0 **Supersedes:** None **Effective Date:** 21st October 2021

Title: Data Query Resolution

	NAME	**SIGNATURE**	**DATE**
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Q.A. AUTHORITY	Aisha Bwika		**16th October 2021**
APPROVING AUTHORITY	Robert Bandsma		**20th October2021**

1.0 PURPOSE / INTRODUCTION:

The purpose of this standard operating procedure (SSP) is to ensure that queries in the data environment are well communicated and resolved effectively.

2.0 SCOPE / RESPONSIBILITY:

This SSP describes the process for managing quality issues with the data collected in the PB-SAM data collection systems. Issues regarding the collection instruments and changes on the environment itself are out of scope of this SSP. Please check the PB-SAM Change Management SSP for those issues. This SSP does not cover error checking and discrepancy resolution during data entry. Please check the Data Entry SSP for those procedures.

The following is the responsibility matrix for this SSP.

Role	Responsibility	Scope
Site Staff (field, data entry, lab or clinical)	Receive data queries from site data manager or from the central quality control dashboard and verifies entries with paper CRF. Resolves any anomalies identified.	Site
Site Data Manager	Runs daily & weekly data quality checks on site. Identifies anomalies and raises issues with the staff that handled the data entry. Works with central co-ordination data manager to resolve queries identified through the dashboard. Monitors tasks for resolution on the task management system.	Site
Network Data Manager	Updates dashboard Work with site data manager to resolve issues Work with KEMRI IT department for manual data operations.	Network
Network Co-ordinators (Clinical, Lab, Communication, etc.)	Monitor dashboard regularly in their subject matter area. Discuss with PIs, and site co-ordinators on data quality issues.	Network

3.0 DEFINITIONS /ABBREVIATIONS:

3.1 **Data query, or simply query:** An anomaly identified on a data element that requires resolution.

3.2 **Dashboard or Central Reports Dashboard:** A collection of useful reports about the data

collected in the system.

3.3 **Task management system, or orangescrum:** The issues or task system used to provide collaboration on pending tasks and monitoring to conclusion. Works hand in hand with the dashboard.

4.0 MATERIALS

5.0 METHODOLOGY:

5.1 Query resolution process at Site

5.1.1 During data entry, a site staff member checks completed data CRFs on the system before marking them as completed. This could be a peer data entry staff or data manager or site coordinator. (Please refer to data entry SSP and site-specific procedure on data entry). Anomalies identified at this stage are confirmed with paper CRF and fixed.

5.1.2 Site data manager runs a daily or weekly quality control script to check for missing, incomplete, incorrect values. Enters found queries on the site-specific task management project on Orangescrum.

5.1.3 Site data manager follows up with staff who have been assigned tasks from the system and those tasks are still pending to ensure they are resolved on time.

5.1.4 Site data manager deals with late tasks and discusses the same with site coordinator and PI.

5.2 Query resolution process at Co-ordination Centre

The central data manager does the following:-

5.2.1 Monitors the dashboard and the query generation process. Ensures data on dashboard is updated periodically.

5.2.2 Ensures that dashboard automatically creates new tasks for new queries. Tasks are by default assigned to the site data manager. If this is not working automatically due to implementation hurdles, then data coordinator sends these queries via email or informs site data manager to check on the dashboard for new queries.

5.2.3 Ensures sites can adequately edit own data and or delete records where appropriate. Otherwise fulfils this role on behalf of the sites and feedbacks actions.

5.2.4 Work with data manager and KEMRI IT to resolve complex database operations.

5.2.5 Subject matter coordinators (clinical, Lab etc..), monitor dashboard and orangescrum to

ensure issues are getting addressed on time.

5.2.6 Subject matter coordinators downloads reports from the dashboard and do critical analysis to identify any hidden quality issues and general process improvements to quality data.

5.3 Resolve a data query in ALEA (for staff resolving queries)

5.3.1 A staff member (with ALEA data entry role) will need to resolve each query by completing one of the following:

5.3.1.1 Amend to the correct value or information.

5.3.1.2 Add new or additional information, logged as query response.

5.3.1.3 Provide additional clarification. For example, when it is deemed necessary to overrule a database warning, this should be done, and the reason should be stated.

5.3.1.4 Confirm data are missing/unobtainable. The associated missing eCRF and/or fields should be indicated as such on the database and amended to 'incomplete'.

5.3.2 It is important to remember that overriding warnings and setting data to missing or unobtainable may result in a protocol deviation. Please check the protocol and if necessary, report findings to the trial coordinator.

5.3.3 Finally, for missing, unobtainable and overridden values, please fill in the central note to file CRF appropriately giving reasons as necessary.

5.3.4 **To view and resolve missing and irregularity data queries on orangescrum**

5.3.4.1 Any user with access to queries for the site can respond to an open query (even if it is assigned to a specific user). The responder may select a response type (i.e. In progress, resolved …) and provide a descriptive comment with the ability to also attach a file (optional). Once a query has been responded to, the user who raised the query should verify the status and correctness of the information given, then close the query.

5.3.5 **Process for viewing and resolving range check data queries on ALEA**

5.3.5.1 If the previously entered data is out of the accepted validation range but has been confirmed from the source document as the true recorded value, then responder may enter a response title **(i.e. Verified- Confirmed correct (no error)** on the query and provide a descriptive comment. Once a query has been responded to, a

user with 'close' privileges may close the query, after which it will be considered resolved.

5.4 To Resolve a data query in KIDMS (for staff resolving queries)

5.4.1 Any user with edit privileges on the KIDMS studies management system may edit/delete records on the system as appropriate.

5.4.1.1 Login to the Editing system on KIDMS (Studies Management System).

5.4.1.2 Access the record by searching on the table views.

5.4.1.3 Click on edit.

5.4.1.4 Navigate to the appropriate "event" section. And click on edit.

5.4.1.5 Make your changes as necessary.

5.4.1.6 Save.

5.5 Finally, for missing, unobtainable and overridden values, please fill in the central note to file CRF appropriately giving reasons as necessary.

5.6 Remember to access the task on orangescrum and update its status to resolved. Please contact your data manager for assistance at any point.

6.0 APPENDICES:

None

7.0 REFERENCES:

PB SAM Data Entry SSP V 1.0

8.0 DOCUMENT CHANGE HISTORY

Version Table:

Version 1.0: Title: **Data Query Resolution**	Dated: **21st October 2021**	SSP No.: **DM03**	No. Pages: **6**
Version 2.0: Title:	Dated:	SSP No.:	No. Pages:
Version 3.0: Title:	Dated:	SSP No.:	No. Pages:
This document is effective from the date of training/last approval signature and will be reviewed in two years.			

SSP Review and Updating Logs

DATE	NAME OF REVIEWER	SIGNATURE	REASON FOR REVIEW AND CHANGES MADE

SSP AWARENESS LOG

I, the undersigned below, hereby confirm that I am aware that the accompanying SSP is in existence from the date stated herein and that I shall keep abreast with the current and subsequent SSP versions in fulfillment of Good Clinical Practice (GCP).

Number	Name	Signature	Date (dd/mmm/yyyy)
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