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:** DM05 **Version No:** 1.0 **Supersedes:** None **Effective Date:** 21st October 2021
Title: Change Management			
	NAME	SIGNATURE	DATE
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APPROVING AUTHORITY	Robert Bandsma		**20th October2021**

APPROVED

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1.0 PURPOSE / INTRODUCTION:

The purpose of this standard operating procedure (SOP) is to ensure that changes in the data management environment are well documented and communicated effectively.

2.0 SCOPE / RESPONSIBILITY:

This SOP describes the process for managing changes from the point the need for change (feature request, bug, or issue) is identified to development, testing and rolling out of the desired change. This SOP is only intended for managing changes on the software involved in the PB SAM Data Management Environment. Data changes are out of scope.

The following is the responsibility matrix for change management in the study.

Role	Responsibility	Scope
Site Staff (field, data entry, lab or clinical)	Identify and raise issues (bugs, feature enhancements) to site data manager.	Site
Site Data Manager	Compile list of issues from site staff and send to Network Data Management coordinators. Informs site co-ordinator and or site PI on status of issues.	Site
Network Data Manager	Receive and updates sites data managers on status of issues and solve them. Advance issues to other network coordinators. For ALEA, advance bugs/feature requests to development team.	Network
Network Co-ordinators (Clinical, Lab, Communication, etc)	Provide subject matter expertise advice and direction on change management. Accept and approve change requests	Network

3.0 DEFINITIONS /ABBREVIATIONS:

3.1 Change: Any desired outcome expected to happen to an existing item.

3.2 Issue: Anything causing undesired consequences. Issues can be categorized as: -

3.3 Bug: An anomaly on a computer system causing it to malfunction on the affected functionality.

3.4 Feature request: A desired addition/enhancement that would improve the functionality of the part of the system.

3.5 Data Management Environment: ALEA, KIDMS, & Reports Dashboard systems.

3.6 UAT: User Acceptance Testing – A form of software feature testing that is geared to fit for purpose of the feature under testing.

3.7 Production or production environment: The version of the system being used for real work/data entry.

4.0 MATERIALS

5.0 METHODOLOGY:

5.1 Change Management at Site

5.1.1   Site staff identify the need for a change on a part of a system/software on the data management environment. They raise this request to their site data manager.

5.1.2   Site data manager discusses the issue with the staff to see if the matter can be resolved locally. If not, he/she takes note and forwards it to the Network Data Manager.

5.1.3   Site data manager updates site co-ordinator and or site PI of the status of issues raised from the site.

5.1.4   Site data manager follows up with network data co-ordinators for resolution of issues. Conducts User Acceptance Testing (UAT) and participates in approving changes (especially those raised by them).

5.1.5   Site data manager receives updates (on completion of changes at production) from central coordination team and communicates to site staff.

5.1.6   Site data manager and site coordinator co-ordinates any training required to effectively implement the change.

5.2 Change Management at Central Co-ordination

5.2.1   Data coordination team receives issues from site data managers and channels them to appropriate central co-ordination team members.

5.2.2   Proposed changes from sites are discussed by subject matter Network Coordinator and an evaluation made as to whether these affect all sites. If this is the case, the subject matter coordinator (clinical, lab, communication e.t.c.) should discuss these with site PI/coordinator but also evaluating if updates are needed in the main system for all sites.

5.2.3   If changes target all sites. Network coordinator responsible makes changes to paper CRFs and circulates a draft version. E.g. if production Enrolment CRF is v1.1, then he/she releases v1.1.1 or 1.1.2 (second decimal version). The paper CRF is circulated among Co-ordination and Leadership members through specific calls/meetings to discuss where necessary. In the event of minor changes, an email vote can be provided. This step may be omitted if the requested change does not need a paper crf change.

5.2.4   Once, voted, the sub-version is implemented (by co-ordination data management team) on our UAT server http://uat.chainnetwork.org or on ALEA acceptance server. A link is shared again to the same group that approved the paper change. If okay, it is advanced for testing at the site that raised the issue. If the issue came from the coordination team, then a candidate testing site is selected.

5.2.5   Once UAT is successful, success criteria being the expected documented changes according to the paper CRF sub-version released (which ideally will include any skip patterns and plausible ranges), a communication is sent to the people that voted for the change (could be coordination or leadership teams). Final approval will be given by the subject matter coordinator. E.g. if Lab issue then Caroline or Clinical then Johnstone etc.

5.2.6   If changes are production ready and necessary approvals have been provided, then data team will update CRF versioning document, depending on the change, this could be a major release or minor release. In the event of a major release, then a full version count is increment. Otherwise the sub-version number is implemented. i.e. if enrolment is at v1.1, and we have changes on UAT at v1.1.2, then a minor release will be v1.2 and a major release will be v2.00.

Note: Production versions run on one decimal system, UAT versions run on second decimal system.

5.2.7   Data team or subject matter coordination team sends communication out to the network. Training sessions are held for the changes to be introduced and once ready the change is deployed.

6.0 APPENDICES:

None

7.0 REFERENCES:

None

8.0 DOCUMENT CHANGE HISTORY

Version Table:

Version 1.0: Title: **Change Management**	Dated: **21st October 2021**	SSP No.: **DM05**	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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