University of Hertfordshire

TRIAL DATA MANAGEMENT SYSTEM MAINTENANCE AND SUPPORT

Clinical Trials Support Network (CTSN)

Standard Operating Procedure for Maintenance and Support of Clinical Trial Data Management Systems in University of Hertfordshire Sponsored/Co-Sponsored Clinical Trials

SOP Number: gSOP-43-02	**Effective Date**: 10/08/22
Version Number: 2	**Review Date:** 3 years (or as required)

1. BACKGROUND

This is a University of Hertfordshire standard operating procedure.

This Standard Operating Procedure (SOP) describes procedures for the process Maintenance and support of Trial Data Management Systems (TDMS) in University of Hertfordshire Sponsored/co-sponsored clinical trials. Where there are potential conflicts between different collaborating organisations' SOPs, project level working instructions should be developed, to determine precedence.

2. PURPOSE

Once a Trial Data Management System has 'gone live' there is a requirement for a structure within which issues arising can be dealt with, covering:

- Reporting problems
- Initial response
- A framework for solution of problems

This SOP describes the processes of managing bug reports and enhancement requests for TDMS that have been deployed into the Live environment for UH Sponsored/co-sponsored clinical trials.

3. APPLICABLE TO

Any UH employee involved with the management of data for clinical research including but not limited to Chief Investigators (CI), Principal Investigators (PI), Consultants, Clinical Trial Pharmacists, Trial Managers, Monitors, Statisticians, Statistical programmers, Research Assistants & Data Managers.

"ICH GCP guidelines state that only appropriately qualified individuals should supervise trial data handling, verify the data and conduct the statistical analyses (ICH 5.5)".

4. RESPONSIBILITIES

The data manager working with the database programmer is responsible for maintaining and supporting the TDMS.

5. PROCEDURE

5.1. Reporting Bugs in the System

- Bugs are instances of the system failing to work to the current agreed Functional Specification.
- The system user can report bugs to the data manager by whatever means is convenient, but this will usually be by phone or email.
- On receipt of a bug report, the data manager will attempt to reproduce the problem either in the Development environment or the Test environment.
- If the problem is reproduced, then the data manager will record the details onto an error log.
- If not reproduced, the data manager will inform the system user and further discussion will determine if the issue can be dropped or requires further investigation.
- The data manager should prioritise the problem according to the following rules as far as possible:
    - Critical bug –where entry of all or part of the study data is halted, corrupted or subject to serious delay.
    - High priority bug –where there is significant breakage or loss of functionality, but work can continue until a fix is available.
    - Low priority bug –where there is no significant loss of integrity or performance.

The data manager should then inform the system user that the problem has been identified and set a timeline for its resolution.

5.2 Requesting Enhancement to the System

- Enhancements are items of data or functionality that were not in the agreed system specification.
- Requests should be made to the data manager by the trial manager.
- On receipt of a request for an enhancement, the data manager will log the issue.
- The data manager should prioritise the problem according to the following rules as far as possible:
    - Substantial enhancement-needs to be treated as a project and will require costing.
    - Small enhancement-can be treated in a similar way to a high priority bug.
- The distinction between small and substantial is a subjective judgement and must be agreed between the data manager and the trial manager.

5.3 Bug Fixing

- The database programmer will fix the bug and test it in the Development environment.
- If appropriate, the Functional Specification and/or the associated Test Plan (see gSOP-40 Data Management Overview) should be updated to incorporate the change.
- The database programmer will prepare a Release Note giving details of the change, test instructions and any special deployment instructions.
- The database programmer will install the updated software in the Test environment and run the appropriate tests. Any failures will need re-fixing, re-deployment, and re-testing.
- While the updated software is still only on the Test system, the database programmer may, if required, ask the trial manager who reported the problem to check details of the fix, particularly where the update is complex or hard to reproduce.
- When the Test environment has been satisfactorily updated, the data manager will update the Live system and send a notification to the trial manager who reported the problem. This will usually be by email with an attached copy of the Release Note.
- The trial manager should check the fix in the Live system and if OK, sign the acceptance form provided with the Release note, returning it to the data manager who will file it in the Data Management System file.
- If a fix requires a change to the data structures, the user interface or special functionality then the trial data management system Data Dictionary should be updated to incorporate the change.

5.4 Implementing Enhancements

Small enhancements will be treated in the same way as bugs and documented with a Release Note.

- Substantial enhancements will need to go through a specification, development, test, and deployment process.
- Any changes to the data structures, the user interface or special functionality should be incorporated into an updated Functional Specification and Data Dictionary.
- Any small enhancements made between large enhancements should be included in the revised Functional Specification and Data Dictionary.

5.5 Availability of Support

- The data manager will ensure that cover is available for standard office hours (09 AM till 05 PM).
- The Trial Risk Assessment will determine whether out-of-hours support is required for any functions of the Data Management System.

6. RELATED DOCUMENTS

gSOP-40 Data management Overview

7. APPENDICES

- Appendix 1- Definition

8. VERSION HISTORY/REVISIONS

Revision Chronology:		
Version Number	**Effective Date**	**Reason for Change**
02	**10/08/22**	**Scheduled review**

9. AUTHORISATION

Author

Signature  **Date 23/07/2022**

Pro Vice-Chancellor (Research & Enterprise) Approval
Professor J M Senior

Signature  **Date 08/08/22**

10. AGREEMENT (MOVE ON TO SEPARATE SHEET BEFORE PRINTING)

Please detach and retain within your training files

I have read and understood the contents and requirements of this SOP (ref gSOP-040-02) and accept to follow University policies implementing it.

Recipient
Signature: ……Date: ……..
Name & Position: ……

Appendix 1: Definitions

Chief Investigator (CI)
A Registered Physician, Dentist, Pharmacist or Registered Nurse who has overall responsibility for the conduct of the trial.

Clinical Trial
A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or control) to evaluate the effects of those interventions on health outcomes.

Clinical Trial Authorisation (CTA)
Regulatory approval issued by a Competent Authority to conduct a clinical trial within a Member State.

Clinical Trial of Investigational Medicinal Product (CTIMP)
A study that looks at the safety or efficacy of a medicine/food stuff/placebo in humans as defined by the Medicines for Human Use Regulations (2004).

Investigational Medicinal Product (IMP)
A pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial. This includes a medicinal product which has a marketing authorisation but is, for the purpose of the trial –

- Used or assembled (formulated or packaged) in a way different from the form of the product authorised under the authorisation,
- Used for an indication not included in the summary of product characteristics under the authorisation for that product,
- Used to gain further information about the form of that product as authorised under the authorisation

Non-Substantial Amendment
Minor changes to the original REC application, to the protocol, or any other supporting documentation that will NOT affect to a significant degree.

- The safety or physical or mental integrity of the subjects of the study.
- The scientific value of the study.
- The conduct or management of the study.
- The quality or safety of any investigational medicinal product used in the trial

Principal Investigator (PI)
A Registered Physician, Dentist, Pharmacist or Registered Nurse who has responsibility for the conduct of the trial at a host site.

Substantial Amendment
Amendments to the original REC application, to the protocol, or any other supporting documentation that is likely to affect to a significant degree:

- The safety or physical or mental integrity of the subjects of the study.
- The scientific value of the study.
- The conduct or management of the study.
- The quality or safety of any investigational medicinal product used in the trial

The Medicines & Healthcare products Regulatory Agency (MHRA)

UK Competent Authority responsible for regulation of clinical trials.