University of Hertfordshire

DATA MANAGEMENT SYSTEM VALIDATION

Clinical Trials Support Network (CTSN)

Standard Operating Procedure for the validation of data management systems

SOP Number: gSOP-42-02	**Effective Date:** 28th July 2022
Version Number: 2.0	**Review Date:** 3 years (or as required)

1. BACKGROUND

This is a University of Hertfordshire (UH) standard operating procedure.

2. PURPOSE

This standard operating procedure applies to software used for UH sponsored/co-sponsored clinical trials that require validation and verification to evidence that it is fit for its intended purpose.

3. APPLICABLE TO

Data managers, statisticians and anyone wishing to provide assurance that a system is operating to its specification and requirements and that it is fit for its intended purpose.

4. RESPONSIBILITIES

The statistician and data management team are responsible for the validation of the systems used for clinical trial data.

The Chief Investigator (CI) has overall responsibility for ensuring the database meets all requirements.

5. PROCEDURE

There are three key features of computer system validation:

1. It demonstrates that the system was developed and implemented and is operated and maintained in a controlled manner throughout its lifetime up to and including decommissioning.

2. Results in a high degree of assurance that the system performs reliably and consistently and is therefore suitable for its intended purpose.
3. Documentation is available to support the application of the controls.

5.1 Computer system validation

All computer systems, both hardware and software, used for the collection and analysis of clinical trial data for clinical trials of investigational medicinal products (CTIMPs) must have undergone full validation checks. The results of which should be filed as evidence in the Trial Master File.

Whether the system to be used is a bespoke or commercial off-the-shelf (COTS) product in clinical trial activities the following should occur to demonstrate that it is fit for purpose:

- Validation of the development or installation of the computer system.
- Validation of any trial specific builds, applications, programming undertaken using the validated system.

Computerised laboratory information systems which capture test results conducted during a clinical trial is also part of the data management for CTIMPs and medical device trials. The CI/Principal Investigator (PI) should ensure the accreditation status of the laboratory computerised system is suitable and that evidence of this is filed in the trial master file (TMF).

5.1.1 Risk- Assessed Validation

The level of validation required must be determined by making a risk-based assessment of the nature of the system. This assessment will include:

- Identification of all risks posed to the system validity.
- Measures taken to mitigate those risks.
- What evidence is required to demonstrate risk mitigation.

This assessment should be carried out by the CI (or delegated other) and agreed with the sponsor during study set up.

5.2 Functional Specification

For bespoke system development a Functional Specification (FS) should be produced in addition to a User Requirements Specification. The Functional Specification provides details about the operations and activities that the system must be able to perform. It covers many aspects of the system that need to be documented. It should be used to verify that the implementation of the system performs according to the specification.

5.3 Change control

Any change to the system must be controlled and documented. The following information should be included:

- Person requesting changes
- Reason for changes
- Risk assessment
- Assessment of the changes
- What actions are required

- Approval of the changes
- Testing
- Validation report
- Release documentation.

5.4 System Backup

- Arrangements should be in place to ensure that data can be retrieved if there is a computer system failure.
- Computer systems should be located within an infrastructure which provides for routine backups and disaster recovery to protect against accidental loss.
- Confirmation of this should be documented within the data management plan (DMP), or on a global level if more appropriate.
- Local copies of different versions of data sets/databases should be retained if there is no audit software in place. These will be subject to organisational backups.

6. RELATED DOCUMENTS

- gSOP-40 Data Management Overview
- Data Validation Plan Report Template/ CTSN TP- Data Validation Checklist

8. APPENDICES

- Appendix 1 – Definitions

9. VERSION HISTORY/REVISIONS

Version Number	Effective Date	Reason for Change

10. AUTHORSHIP & APPROVAL

Author

Signature  **Date 20th July 2022**

Megan Smith

Pro-Vice Chancellor (Research & Enterprise) Approval

Signature  **Date 16 June 2022**

Professor J M Senior

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

Please detach and retain within <u>your training files</u>

I have read and understood the contents and requirements of this SOP (ref gSOP-042-02) 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 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 Products (IMP) - means 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 purposes of the trial -

(a) used or assembled (formulated or packaged) in a way different from the form of the product authorised under the authorisation,

(b) used for an indication not included in the summary of product characteristics under the authorisation for that product, or

(c) used to gain further information about the form of that product as authorised under the authorisation

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

The Medicines & Healthcare products Regulatory Agency (MHRA) - UK Competent Authority responsible for regulation of clinical trials.

The Regulations - Medicines for Human Use (Clinical Trial) Regulations 2004 transposed the EU Clinical Trials Directive into UK legislation, as Statutory Instrument 2004 no 1031. This became effective on the 1st May 2004. An amendment to implement Directive 2005/28/EC was made to the Regulations as Statutory Instrument 2006 no 1928.

Validation
The assurance that a system meets the needs of the customer and other identified stakeholders

Verification
The evaluation of whether a system complies with the requirements and specification of the system

Software Requirements
The business needs for the system are defined in terms of the user, system and interface needs of the system.

Functional Specification
A functional specification documents the operations and activities that a system must be able to perform.

Installation Qualification
Installation Qualification verifies the proper installation and configuration of a system

Operational Qualification
Operational Qualification verifies the proper functioning of a system

Performance Qualification
Performance Qualification validates that a system performs according to the user requirements of the system and is therefore fit for purpose