

Standard Operating Procedure

VALIDATION AND BACKUP OF COMPUTER SYSTEMS USED IN RESEARCH

SETTING	Trustwide
AUDIENCE	Chief Investigators and associated Research Staff setting up and managing Clinical Trials of Investigational Medicinal Products sponsored by UHBW
ISSUE	Data must be collected, stored and analysed using systems which are compliant with the applicable regulations, laws and Good Clinical Practice (GCP).
QUERIES	Contact R&I department : Ext 20233 or research@uhbw.nhs.uk

Document History

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-	1.0	27/OCT/15	03/NOV/15	Diana Benton	Diana Benton
November 2016	1.1	23/JUN/17	03/JUL/17	Genna Nicodemi, Jess Bisset & Debbie McPhee	Diana Benton
07/DEC/2017	1.2	19/FEB/18	21/FEB/18	Trusha Rajgor	Jess Bisset
27/AUG/2020	1.3	07/SEP/20	07/SEP/20	Katharine Wale & Debbie McPhee	Jess Bisset

Version Number	Reason for change
Original V1.0	n/a –original
1.1	Annual review – addition of CTIMP verification appendix and minor updates and clarifications
1.2	Annual review and applied new SOP template
1.3	Biennial review with minor updates (including change of Trust name to UHBW)

1. Introduction

Clinical Trials of Investigational Medicinal Products (CTIMPs) are subject to the Medicines for Human Use (Clinical Trials) Regulations and any amendments. Data therefore must be collected, stored and analysed using systems which support compliance with the law and Good Clinical Practice (GCP).

2. Purpose

The purpose of this SOP is to describe how to test and document that a computer system in use within a Clinical Trial of an Investigational Medicinal Product (CTIMP) is fit for purpose and supports sponsor compliance with applicable legislation and Good Clinical Practice (GCP). Please note whilst this SOP is specifically for CTIMPs the principles of validation also apply to non CTIMPs and therefore should be considered and applied to those studies in a risk proportionate way.

3. Scope

In Scope: Computer systems, both hardware and software, that are used in CTIMPs sponsored by UHBW

Out of Scope: Computer systems used in non-CTIMP studies sponsored by UHBW or studies hosted and not sponsored by UHBW

4. Responsibilities

All research staff setting up and managing UHBW sponsored CTIMPs are responsible for ensuring that the computer systems in use are fit for purpose through adequate and continuous validation. They must also ensure any validation carried out is appropriately documented.

The R&I department (as sponsor representative) is responsible for ensuring research staff are aware of their responsibilities and for maintaining sponsor oversight of validation. The R&I department must also validate any applicable systems in use within R&I (e.g. EDGE). For systems developed in R&I it is the responsibility of the Information Officer to carry out appropriate validation.

5. Abbreviations and Definitions

Abbreviations	
GCP	Good Clinical Practice
CTIMP	Clinical Trial of Investigational Medicinal Product
CSV	Computer systems validation
DMS	Document management system
UHBW	University Hospitals Bristol and Weston NHS Foundation Trust

6. Procedure

6.1 Validation

- All computer systems, used to manage and record study data for UHBW sponsored CTIMPs must be validated. This applies to systems procured from an external supplier, or developed within the trust.
- Validation for all types of systems should include robust controls throughout the system's use, demonstrable evidence that a computer system in use is fit for purpose and any supporting documentation (e.g. a Data Management Plan (DMP)). Please refer to *SOP_012 Study Data* and *TMPL_041 Data Management Plan* for further information on a DMP.
- For activities within the scope of this SOP that are carried out by a third party (e.g. a clinical trials unit), evidence of validation of relevant systems must be provided prior to their use.

- The CI will document the computer systems that (s)he intends to use to collect and manage data for the CTIMP in the DMP (or agreed alternative). The DMP and subsequent amendments must be agreed with the trial sponsor prior to implementation in accordance with *SOP_012 Study Data*.

6.1.1 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), agreed with the sponsor during study set up and documented in the DMP.

6.1.2 Examples of systems and levels of validation required

- **Off the shelf:** e.g. Microsoft Excel for simple data management and analysis (not recommended for CTIMP trials):
 - Field formatting and formulae should be checked to ensure the required specification is met, and the checks made should be documented.
 - For example, confirm that columns intended to receive a date are appropriately formatted; confirm the required number of decimal places is captured; confirm that values calculated from a number of cells use the correct formulae.
- **Trial specific:** Adaptation of a commercially available off the shelf package (e.g. randomisation systems, eCRFs):
 - Document the agreed and approved specification, how the system will be tested (both by the users and the developers), that any issues with the system identified through testing have been resolved and the specification is met (validation report), instructions for use and how users will be trained, training records, how the final system will be released.
- **Bespoke system:** Purpose built system solely for the trial:
 - Document the process by which the decision to use a bespoke system was made and the risk assessment conducted as part of that decision making process, the agreed and approved specification (functional and user requirements), validation plan, code-testing documentation, that any issues with the system identified through testing have been resolved and the specification is met (validation report), instructions for use and how users will be trained, training records, how the final system will be released.

6.2 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.

6.3 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 in order to protect against accidental loss.
- Confirmation of this should be documented within the DMP.
- Local copies of different versions of data sets/databases should be retained if there is no audit software in place, in accordance with *SOP_012 Study Data*. These should be subject to organisational backups.

7. Dissemination and training in the SOP

This SOP will be disseminated to applicable research staff (including R&I) and will be available on the R&I website.

All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP. The personal training log of the individual (and the Investigator Site File/Trial Master File if required) should be completed to document that the content of this SOP has been read and understood as described in *SOP_007 Research Training*.

8. Related documents

SOP_003 Developing and Designing your Study

SOP_007 Research Training

SOP_008 Investigator Oversight of Research

SOP_010 Monitoring and Oversight of Research Activity

SOP_012 Study Data

SOP_016 Research Contracts and Vendor Selection

TMPL_041 Data Management Plan

WI_004 R&I Work Instruction for verification of UHBW Sponsored CTIMP data on EDGE