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 UH Bristol

ISSUE Data must be collected, stored and analysed using systems which are compliant with the applicable regulations, laws and Good Clinical Practice (GCP).

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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
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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. 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 UH Bristol
Out of Scope: Computer systems used in non-CTIMP studies sponsored by UH Bristol or studies hosted and not sponsored by UHBristol

4. Responsibilities

All research staff setting up and managing UH Bristol 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 maintain 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

6. Procedure

6.1 Validation

- All computer systems, used to manage and record study data for UH Bristol 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) and agreed with the sponsor during study set up.

6.1.2 Examples of systems and levels of validation required

- **Off the shelf:** Microsoft Excel for data management and simple analysis:
    - Cell 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, 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, in accordance with *SOP_012 Study Data*. These will 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 UHBristol Sponsored CTIMP data on EDGE